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AND CANCUN – A PERSPECTIVE**

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INTELLECTUAL PROPERTY RIGHTS AND CUNCUN — A PERSPECTIVE

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Unprecedented advances in Science and Technology, positive growth in World Trade and formulation and implementation of Rule-based Multilateral Trading Framework marked the second millennium, which left us about two years ago. In a dynamically changing environment, the human race is constantly trying to innovate and create an array of options for achieving what is commonly known as "sustainable development". The key driver of the future is "knowledge" and the thrust is towards converting ideas into innovations with value creation and exploitation.

In the interests of creativity, formal processes for innovations, value creation and sharing of knowledge within communities for the society's benefit have been established. For instance, formal frameworks have been set up to grant recognition to the creator/innovator by protecting his creation/innovation through the instruments of Intellectual Property Rights (IPRs). While so affording protection, rules for the legal use of the innovation have been grounded in terms of statutory underpinnings. IPRs are expected to posit a conducive and transparent legal system to protect the interests of the innovator on the one hand and to protect the interests of the consumer and the society at large on the other.

GATT, WTO AND TRIPS

To foster a reduction in tariffs and quotas to arrive at ground rules for an effective trade liberalising agreement, the General Agreement on Tariffs and Trade (GATT) was nucleated in 1944. GATT came into effect in 1948. In the 1970s, this graduated to include in its scope and ambit, matters like technical standards and regulations, subsidies, antidumping and government procurement. Following the Uruguay Round of discussions culminating in the establishment of the World Trade Organisation (WTO), many GATT obligations were confirmed and the ambit was extended to service industries like banking, securities, telecommunications and insurance. A notable consequence of

This monograph addresses issues relating to and arising from TRIPS that need focus and consideration at the next WTO Ministerial meet at Cancun.

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Uruguay Round was the coming into being of the Multi-lateral Agreement called TRADE RELATED INTELLECTUAL PROPERTY RIGHTS (TRIPS).

The subject Intellectual Property Rights (IPRs) has been a much debated issue in the post-GATT Uruguay round scenario. According to one view, by placing IPRs under the WTO, the developed countries would benefit, as they would have control on future innovations. The other view is that it would safeguard results of technology development and at the same time engender, nourish and sustain creative endeavours of nations. These conflicting views are partly due to lack of proper understanding of the impact of IPRs on development and their importance and relevance in nurturing creativity. Their increasing role and importance on international trade, investment and economic growth can no longer be overlooked.

INTELLECTUAL PROPERTY

Intellectual Property can be regarded as a single generic term that protects applications of ideas and information that are of commercial value. In terms of the Final Act embodying the results of the Uruguay Round of multilateral trade negotiations, agreed upon at Marrakesh on 15th April 1994, Intellectual Property includes:

- 1) Copyright and Related Rights
- 2) Trade Marks
- 3) Geographical Indications
- 4) Industrial Designs
- 5) Patents
- 6) Layout - designs (Topographies) of the Integrated Circuits
- 7) Protection of Undisclosed Information.

Thus, Intellectual Property, as a title may sound rather grandiloquent. But, at its more serious, this is a branch of the law, which protects some of the finer manifestations of human achievement. The objects of Intellectual Property are the creations of the human mind and the human intellect, thus, the designation "Intellectual Property".

Intellectual Property, as a subject, is growing in importance in the advanced industrial countries in particular, as the numerous exploitable ideas are becoming more sophisticated and as their hopes for a successful economic future are becoming increasingly dependent upon their superior corpus of new knowledge. There has been, recently, a tremendous upsurge in the political and legal activity designed to assert and strengthen the various types of protection for ideas. Also in motion are the campaigns for new rights. For instance, new plant varieties are now protected in a number of countries. The circuit of a silicon chip has been afforded its own regime.

Intellectual Property Rights help to sustain the lead and investment of those with technical know-how and with successful marketing schemes and are generally seen to foster immense commercial returns. Bearing testimony to this are the increasing numbers of patents granted and trade marks registered, particularly in the industrial countries and the explosion in the areas of publishing, record-producing, film-making and broadcasting.

CHALLENGES TO INTELLECTUAL PROPERTY

On the one hand, there is a demand for increased protection of the Intellectual Property Rights and on the other, there is considerable suspicion and criticism of the protection. Two dimensions are worth noting.

First, the developing countries often find themselves with an inheritance of protectionist laws from colonial days. They have yet to exploit Intellectual Property of their own. The protectionist laws, as inherited, enable the foreign industry, technical and cultural, to cream off scarce resources in royalty payments. But the developing countries, in order to forge ahead in economic advancement, have the need to acquire technology from the advanced nations and there is often a popular demand for products bearing the allure of western prosperity. In order to attract foreign enterprises, the developing countries tend to maintain the relic of the colonial past in the form of patent, copyright and trade mark laws as they originally existed. Of late, however, the developing countries are seeking to at least modify the operation of the protectionist laws by bringing about curbs on the manner in which royalties may be paid, compulsory licensing requirements and close examination of the terms on which foreign right owners establish their local operations. These constitute derogations from, what we may call unfettered rights of Intellectual Property. The rationale for the derogations is the need of such countries for freer access to technical and educational materials and for self-sufficiency and independent initiatives for national business concerns. These derogations, of course, are met with resistance on the part of the developed countries, who are demanding that the developing countries should tighten their laws, provide the infrastructure for their enforcement and cease to harbour Intellectual Property pirates (Cornish, 1993).

The second dimension is the tendency among the developed countries to limit the monopolistic tendency of successful enterprises through their competition law agencies. The reason for this is that powerful anticompetitive collaborations result from the protection given to Intellectual Property Rights. Such collaborations exclude competitors and therefore, have been regarded as accretions of market power. A direct resultant of this' premise has led to imposition of restrictions upon at least the most visible excessive arrangements like patent pools, copyright collecting societies, international or regional divisions of marketing territories achieved by the splitting of rights and the suppression of the initiative and independence of licensees.

IMPLICATIONS OF IPRs FOR TRADE

It is axiomatic that any unauthorised use of Intellectual Property constitutes an infringement of the right of the owner. Until about two decades ago, such infringements had implications largely for domestic trade. They were further considered to pose problems mainly at the national level, which - apart from affecting the interests of the owners of rights - impinged on scientific progress and cultural life.

There has been increasing realisation of late, that the standards adopted by the countries to protect their IPRs as well as the effectiveness with which they are enforced have implications for the development of international trade. Many reasons can be attributed for this, but the important ones merit mention.

Industrial production in most advanced countries is increasingly becoming research and technology intensive. This leads to the consequence that their export products, not merely the traditional ones like fertilisers, pharmaceuticals and chemicals but also the newer products like computers, telecommunication equipment, videos etc. now contain more patented high technology and creative inputs. This, therefore, drives manufacturers to ensure that wherever they market their products, there is adequate protection for their rights to enable them to recoup their research and development expenditure.

The technological improvements in products entering the international trade market are matched by technological advances that have made reproduction and imitation inexpensive and even very simple. In countries, where IPR governing statutes are not strictly enforced, this has resulted in the increased production of counterfeit and pirated goods, which are not only marketed in the domestic sector but also in the export sector (Shahid Ali Khan, 1998). Furthermore, some countries have only protection of process patents and not product patents in respect of some items, which can lead to practices like reverse engineering.

Yet another reason is that a large number of developing countries have ushered in liberalisation and removal of restrictions on foreign investment. Thus, new opportunities are emerging for the manufacture in these countries of patented products under licence or through the route of joint ventures. The industries in the advanced countries are more than willing to enter into such arrangements and make their technology available but at the same time are concerned about the IPR system in the host country whether their property rights will be protected and not usurped by local partners making use of reverse engineering.

INTELLECTUAL PROPERTY, COMPETITION LAW AND MONOPOLY

All forms of Intellectual Property have the potential to raise competition law problems. Presently, competition laws are generally viewed in the context of economic theories about the way in which various forms of business practices, broadly leveled "anti-competitive" interfere with and distort the free market. As normally understood, Intellectual Property provides exclusive rights to the holders to perform a productive or commercial activity, but this does not automatically include the right to exert restrictive or monopoly power in a market or society. The Intellectual Property, often, may not be able to generate market power. In a few really successful cases, the potential pejorative character of power may be unjustifiably great because of the public policies like the encouragement of inventions, but on the other hand if investment of resources to produce ideas or conveying information is left unprotected, the competitors may take advantage and benefit by not being obliged to pay anything for what they take. This may result in lack of incentives to invest in ideas or information and the consumer may be correspondingly the poorer. What is called for is a balance between unjustified monopolies and protection of the property holders' investment.

The relationship between competition law control and Intellectual Property Rights is inherently contradictory as there is a potential conflict between the two, in that the existence and the exercise of Intellectual property Rights may often produce anti-competitive effects through the monopoly power granted to the holder of the rights.

Merkin suggests that the conflict is not as severe, as it first appears, as the powerful public policy justification for maintaining the rights can be harmonised with protecting competition and consumer interest in the market (Merkin, 1985). Such harmonisation has been attempted by the European Court of Justice (ECJ) developing a workable formula for disposing of the conflict. The said European Court in the context of EEC Law, saw its task as bringing the exercise of Intellectual Property Rights under control without offending the protective provisions of the Treaty of Rome (The Treaty deals with controls on restrictive trading agreements and with monopoly controls). As a first stage, the ECJ confirmed that the anti-competitive aspects of the exercise, or of the licensing of such rights, might be controlled by the Treaty. ECJ made a distinction between the existence of Intellectual Property Rights and their exercise. Within this dichotomy, all aspects of a right which relate to its existence will be undisturbed by the Treaty of Rome, but those aspects which relate to its exercise may be capable of regulation if they are anti-competitive (Frazer, 1988).

By way of illustration, the mere possession of a patent or other right will not be regarded as giving rise automatically to a dominant position in the market. If there are effective alternates for the patented product, the holder of the right will not be able to exercise monopoly power. If there are no effective alternates, the possession of Intellectual Property Rights may give rise to considerable market power and the possibility of abuse.

TRIPS

One of the main legal instruments that now form the Uruguay Round legal system is the set of Multi-lateral Agreements. Within the broad group of Multi-lateral Agreements is the Agreement on Trade Related Aspects of Intellectual Property Rights, briefly called TRIPS, to which reference has been made earlier. TRIPS Agreement lays down minimum standards for the protection of the Intellectual Property Rights as well as the procedures and remedies for their enforcement. It establishes a mechanism for consultations and surveillance at the international level to ensure compliance with these standards by Member countries at the national level.

TRIPS Agreement builds on the main international conventions on Intellectual Property Rights by incorporating most of their provisions. It provides that countries may in pursuance of the conventions, guarantee higher protection than is required by the TRIPS Agreement, as long as it does not contravene its provisions. The main provisions of TRIPS Agreement are:

- (a) Basic principles and general obligations
- (b) Minimum standards of protection, including the duration of protection and the control of anti-competition practices in contractual licences
- (c) Restricted business practices
- (d) Enforcement of Intellectual Property Rights (Court orders, customs actions etc.)
- (e) Transitional arrangements for the implementation of the rules at the national level.

TRIPS Agreement is binding on all members of the WTO including India (Alec Sugden, 1998). As noted earlier, the Agreement covers 7 categories of Intellectual Property

Rights.

TRIPS AND ANTI-COMPETITIVE PRACTICES

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) thus provides a Multi-lateral framework for the protection and enforcement of Intellectual Property Rights (IPRs) by Members. Therein are included provisions relating to abuse of IPRs and anticompetitive practices that may accompany the rights.

Article 8.2 of the TRIPS Agreement, entitled "Principles", provides as follows:

"Appropriate measures, provided that they are consistent with the 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."

Further to this general provision, Article 40 of Section 8 of Part II of the Agreement deals with the control of anti-competitive practices in contractual licences.

In the area of patents, TRIPS Agreement allows Governments to grant compulsory licences, under certain conditions in order to remedy abuses. The conditions for the grant of compulsory licences are set out in Article 31 of TRIPS Agreement and also in the last sentence of Article 27.1 thereof. Article 31 is entitled "Other Use without Authorization of the Right Holder" and stipulates conditions, aimed at safeguarding the legitimate interests of the right holder, on the grant of compulsory licences and also on Government use (use by the Government or by third parties on behalf of the Government without the authorisation of the right holder). Article 37.2 of TRIPS allows compulsory licensing of layout-designs of integrated circuits or of their use by or for the Government without the authorisation of the right holder.

Subparagraph (k) of Article 31 provides that, in situations where a practice has been determined after judicial or administrative process to be anti-competitive, certain of the conditions are not applicable. In such cases, the applicant for a compulsory licence need not seek first a voluntary licence on reasonable commercial terms and the compulsory licence need not be limited to use predominantly for the supply of the domestic market of the Member granting the licence. Moreover, the need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases and the competent authorities shall have the authority to refuse termination of the compulsory licence, if and when, the conditions that led to its grant are likely to recur.

There is a basic complementarity between intellectual property law and competition law. Intellectual property laws provide for intellectual property to be valued and exchanged and competition laws ensure that the market assigns a fair and efficient value to this property.

ABUSE AND ANTI-COMPETITIVE PRACTICES

Provisions of TRIPS Agreement that are considered to relate to the treatment of anti-

competitive practices, are in particular Articles 6,8,31 and 40. Compatibility between competition law and Intellectual Property Right depends on the former being properly applied to the exercise of the latter. A proper application of competition law should avoid two extremes. Too stringent an application could lessen innovation. An ineffective or insufficient application could result in an over-extended grant of market power. Both outcomes would have an adverse effect on output as well as an inhibiting effect on trade. TRIPS Agreement reflects the thinking that regimes for the protection of intellectual property should be balanced by safeguards intended to restrain anticompetitive practices involving the use of intellectual property rights. TRIPS provisions do not clarify the practices that need to be treated as abuse and say little about the remedies that Members of the WTO can avail of.

Cancun needs to address the question as to what constitutes abuse and what remedies should be spelt out for the Members to invoke. Furthermore, future negotiations in the area of intellectual property rights should give equal weight to recognising the risks of both under-protection and over-protection of intellectual property rights.

PARALLEL IMPORTS

In considering the relationship between intellectual property rights and competition policy, it is important to address the issue as to the extent to which remedies for abuse of such rights could and should be sought within the competition policy and as to what extent the remedies should be found by introducing or strengthening features in laws on intellectual property such as compulsory licensing. Article 6 of TRIPS Agreement is cognisant of the possibility of legally allowing parallel imports, the use or sale of licensed goods outside the territory in which they have been licensed.

Article 6 of TRIPS Agreement provides that:

"For the purpose of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4, nothing in this agreement shall be used to address the issue of exhaustion of intellectual property rights."

This embraces what is known as the principle of "exhaustion of rights", implying thereby that once the right holder has authorised the release of the IPRs, they are considered to have exhausted. Once an intellectual property holder has sold a product to which its IPRs are attached, he cannot prohibit the subsequent sale of that product as his right in that product is said to have been exhausted by the first sale. The right holder has thus no right to control the use or resale of goods that he has put on the market or has allowed the licensee to market. But however, the words "without discrimination" in case of imports used in Article 27 of TRIPS Agreement restricts a country to formulate an export-import policy, which can be used for import restrictions. Parallel imports are consumer welfare oriented in terms of price reduction. India and other like minded countries need to examine the desirability of resorting to the window provided in Article 40 of TRIPS Agreement, which allows members of the WTO to specify, in their legislations, licensing practices or conditions that may have an adverse effect on competition and constitute

abuse of IPR. There is a need to negotiate this issue in the WTO.

Furthermore, the scope and contents of Article 6 of TRIPS Agreement appear unclear. Article 6 provides that exhaustion rules are subject to the provisions of non-discrimination and of national treatment (Article 3) and of most favoured nation (MFN) treatment (Article 4). But doctrines of exhaustion differ in regional and international instruments of agreements. Members may therefore cite such instruments and ban parallel imports. Likewise, Article 28 of TRIPS Agreement does not contain an absolute ban on parallel imports, but relates the matter to Article 6 of TRIPS which allows different doctrines of exhaustion. Thus for a Member State operating under regional or international exhaustion, the right to ban parallel imports is related to distribution rights not only granted domestically but also in the region and worldwide. Some member States may use the ambivalence in Article 6 to ban parallel imports. But Article 6 permits member States to incorporate the principle of international exhaustion of rights in their national legislations.

Cancun needs to confirm this so as to enable Member states to allow parallel imports to protect consumer interest and in particular, to protect public health.

PUBLIC HEALTH

The need to incorporate appropriate provisions in TRIPS Agreement to enable adoption of measures to protect public health and nutrition and promotion of public interest in sectors of vital importance to each country's socio-economic and technological development was stressed by most developing countries in the Doha Ministerial. There has recently been a controversy in South Africa over access to medicines at affordable prices. The issue at stake was the South Africa's Medicines and Related Substances Control Amendment Act, which allows the country to provide medicines at prices that its population can afford by resorting to imports from cheaper sources of supply. This provision was challenged by the pharmaceutical majors in the global market as being violative of the TRIPS Agreement. They contended that the rights enjoyed by the patentees in the patent regime introduced after the implementation of the TRIPS Agreement would be severely curtailed, if the South African law on affordable medicines were used by the Government (Biswajit Dhar, 2001). The question is whether enhancing of the rights of the patent holders (like MNCs and TNCs) in a disproportionate manner could lead to the emergence of oppressive monopolies and this could manifest itself in high prices. Such a situation is difficult to condone in critical sectors like pharmaceuticals, particularly in developing countries like India, where a majority of the poor do not have access to modern medicines. The remedy possibly lies in operationalising the objectives and principles of the TRIPS Agreement provided for in Articles 7 and 8, which refer to several public policy objectives that the agreement should fulfil. Further, it needs to be successfully argued in the WTO, that the use of compulsory licences should not be considered as violation of TRIPS Agreement.

Article 8 of TRIPS Agreement runs as follows:

1. "Members may, in formulating or amending their laws and regulations, adopt

measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

2. Appropriate measures, provided that they are consistent with the 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."

Protection of public health and nutrition is a fundamental principle governing the TRIPS Agreement and is reflected in Article 8. While Members are free to adopt measures necessary to protect public health and nutrition, they need to be consistent with the provisions of TRIPS Agreement. Curiously, the element of exception in Article 8 of TRIPS is sought to be consistent with the Agreement! In other words, if a Member takes measures, which are regarded as inconsistent with the TRIPS Agreement, it would violate Article 8 and would prevent the Member to implement the same to protect public health. Again what constitutes consistency with the TRIPS Agreement may be open to different interpretations. Doha achieved a consensus in this regard on the principle that public health and nutrition should have an over-riding importance over protection of rights of holders thereof.

Cancun needs to confirm that nothing in the TRIPS Agreement will prevent Members from adopting measures to protect public health, as well as pursuing the overarching policies defined in Article 8 thereof.

TRANSFER OF TECHNOLOGY

Article 7 of TRIPS Agreement runs as follows:

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

The protection and enforcement of intellectual property rights do not exist in a vacuum. The society needs to benefit as a whole and mere protection of private rights cannot be an end in itself. The objective of the promotion of technological innovation and the transfer and dissemination of technology places the protection and enforcement of IPRs in the context of the interests of the society.

The said objective is intended and essential for the promotion of health policies, as it encourages the development of domestic production of pharmaceutical products. The provisions of Article 7 of TRIPS Agreement are important in this context for the Members of the WTO. As an illustration, patent rights need to be exercised with the interests of patent holders being protected harmoniously with the interests of consumers of patented medicines. If specific situations arise, where the patent rights over medicines

are not exercised in a manner subserving the objectives of Article 7, Members should be able to take measures to ensure that they are achieved. One such measure is the granting of compulsory licences.

For the poorer strata of the society, pharmaceutical products and medicines are not only required to be accessed in the market but they need to be at affordable prices. Domestic production or local manufacturing of pharmaceutical products assumes importance in this context. Such manufacturing helps sustainable access to medications by insulating the price of patented medicines against currency devaluations. This also supports the development of local expertise. It is in this broad range of objectives, where the patent holder fails to meet the objectives of TRIPS Agreement and of public health policies, Members should be able to take measures to ensure transfer and dissemination of technology to provide access to pharmaceuticals at affordable prices.

Doha Declaration recognizes the fact implicit under Articles 7 and 8 of TRIPS that considerations of public good which includes public health would be the over-riding factor, while offering IPR protection for medicines for specified diseases and epidemics. Doha affirmed that Governments are free to take all necessary measures to protect public health. The Declaration has given primacy to public health over Intellectual Property Rights. But yet, many developing countries have expressed concern as to whether the said Declaration would be interpreted appropriately to serve their interests by some developed countries fuelled by the influence of MNCs and TNCs.

Cancun should enunciate in strong terms the public policy objectives enshrined in Articles 7 and 8 of TRIPS and declare that promotion of IPRs is not an end in itself and that its effectiveness needs to be measured not just in terms of whether or not the rights of the rights-holder have been protected but also in terms of whether or not public policy objectives outlined in Articles 7 and 8 have been adequately met. In other words, there should be a balance of rights and obligations and a balance between private rights and public policy objectives.

COMPULSORY LICENSING

Article 31 of TRIPS Agreement deals with "Other Use Without Authorisation of the Right Holder". This is a long Article and will consume a lot of space if reproduced here. In sum, the said Article allows Members to authorize the use of the subject matter of a patent without the authorization of the right holder. This would include use by the Government or third parties authorized by the Government. Before such use is permitted, the user should have made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions. Such a requirement may be waived by a Member in cases of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. This Article is usually referred to as the compulsory licensing provision.

What is paramount to promote and protect public health is to secure a broad and flexible interpretation of Article 31. The expressions "the proposed user has made efforts to obtain authorization from the right holder", "reasonable commercial terms" and "within a reasonable period of time" occurring in Article 31 are the ones which require flexible and

broad interpretation. As countries have different levels of development and socio-economic goals and aspirations, they should have the right to utilize Article 31 in the ultimate interest of their societies.

In other words, Cancun should take the view that the TRIPS Agreement will in no way stand in the path of public health protection and that it should provide the broadest flexibility for (he use of compulsory licence.

As noted earlier, Article 31 provides for the waiver of certain requirements therein, in cases of national emergencies, extreme urgencies, etc. A health crisis characterized by pandemics and epidemics, major diseases like AIDS, etc. would qualify for an emergency or circumstance of extreme urgency. Here again, each Member, having regard to the spread of certain diseases in its territory, particularly among the vulnerable sections of its society, should have the discretion and power to invoke Article 31 for waiver of the requirements stipulated therein. Similarly, public non-commercial use should cover Governmental health care for the poor.

Cancun needs to declare that Members are free to determine the grounds upon which to issue compulsory licences.

Article 31(f) of TRIPS Agreement stipulates that the use of the subject matter of a patent without the authorization of the right holder shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use. Some of the developing countries, and in particular small economies, have limited industrial capacity and a small domestic market rendering them difficult to manufacture medicines locally and to ensure adequate access to drugs. Nothing in the TRIPS Agreement prevents Members from granting compulsory licences for foreign suppliers to provide medicines in the domestic market. The condition in Article 31(f) that compulsory licences should supply predominantly for domestic markets makes production unviable in small countries with a small domestic market and poor purchasing power. Small countries in such a context would be loathe to set up production facilities for catering exclusively for the domestic market. In order to benefit from the flexibilities available in TRIPS, one option is to licence import from the cheapest source. (Reference to parallel imports has already been made earlier in this article). Another option is to license production, which allows the right mix of domestic use and export, so that economies of scale would be available.

Cancun should confirm with reference to Article 31(f) that nothing in (lie TRIPS Agreement would prevent Members to grant compulsory licences to supply foreign markets.

DIFFERENTIAL PRICING ARRANGEMENT

Another attendant dimension is differential pricing arrangement. Differential pricing arrangement can play a relevant role in providing better access to affordable medicines. Differential pricing is not an intellectual property issue and, therefore, should not be covered by TRIPS. Establishment of price controls, authorization of parallel imports and granting of compulsory licences are all decisions to be taken by Governments of Members in the broader interests of the poorer sections of their societies.

Cancun needs to confirm that differential pricing arrangements would not be prejudicial to the rights of Members to make use of the provisions of the TRIPS Agreement, such as parallel imports and compulsory licences.

BIOLOGICAL AND GENETIC RESOURCES

Article 27.3 of TRIPS Agreement runs as follows:

"Members may exclude from patentability:

- (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
- (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement".

Biological and genetic resources are traditionally found in many countries of the so-called "South" and a number of new drugs and medicines have evolved around them. Patenting of such resources results not only in misappropriation but also in affecting access to medicines based on the said resources. Patent applications should reveal the country of origin of the biological and genetic resource. There should be prior informed consent of the country concerned. Furthermore, there should be equitable benefit sharing.

Article 27.3 would appear to encourage granting of patents on the basis of mere discovery and not invention. It also would appear to promote a tendency not to take into account the knowledge of the traditional communities, which cannot always exist in written form. These concerns impact the accessibility of medicines and drugs at affordable prices.

Cancun needs to address the concerns relating to patenting of biological and genetic resources covered by Article 27.3.

NON-VIOLATION

Article 64.3 of TRIPS Agreement reads as follows:

"During the time period referred to in paragraph 2, the Council for TRIPS shall examine the scope and modalities for complaints of the type provided for under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994 made pursuant to this Agreement, and submit its recommendations to the Ministerial Conference for approval. Any decision of the Ministerial Conference to approve such recommendations or to extend the period in paragraph 2 shall be made only by consensus, and approved recommendations shall be effective for all Members without further formal acceptance process."

The scope of the non-violation complaints is unclear. The application of such complaints could have serious and negative implications on the domestic measures being undertaken by Governments to achieve overarching public policy objectives such as the protection of public health.

Cancun, on the basis of consensus, should declare that non-violation provisions in Article 64.3 would not apply to measures taken by Members for providing access to essential medicines.

GEOGRAPHICAL INDICATIONS

Article 22 of The Trade Related Intellectual Property Rights (TRIPS) Agreement under the WTO auspices requires its members to provide a legal means for interested parties to prevent the use of geographical indications which may mislead the public as to the true place of origin of the goods concerned and to prevent use amounting to unfair competition in the Paris Convention sense (unfair competition is defined in Article 10 of the Paris Convention as any act of competition contrary to honest practices in industrial or commercial matters).

Some countries are well endowed with diverse agricultural products, which are being exported on a regular basis and for a long time. India for instance enjoys the reputation of high quality in products originating from specific regions in the country. Such products are well known in the International market. By way of illustration, Darjeeling Tea, Basmati Rice, Alphonso Mangoes, Malabar Pepper, Alleppey Green, Cardamom and Hyderabad Grapes can be cited.

TRIPS Agreement explicitly provides for protection of geographical indications, such as French Champagne. Even if a sparkling wine almost identical to what is made from Chardonnay Grapes in France can be produced with grapes grown in Goa or Himachal Pradesh, it cannot be labelled Champagne under the WTO provisions. Similar considerations will have to apply to products such as Basmati Rice or Darjeeling Tea, which are products uniquely linked to some particular geographic regions. Before the TRIPS Agreement, geographical indications were not protected in India.

Since then, the enactment of a separate law addressing geographical indications has given the necessary impetus to the effort of Indian exporters to protect the geographical indications attached to the goods in question, thereby creating a domestic base for ensuring that the premium attached to such products is retained both in Indian and foreign markets. The promotion of Intellectual Property Right embodied in geographical indications will also help in preventing the geographical indications of goods becoming generic thereby leading to a loss of distinctiveness and consequently protection.

Cancun should explicitly provide for geographical indications protection for products qualifying for it, as was done for French Champagne.

SUGGESTION

A There is a growing recognition of the fact that a modern and well enforced

- Intellectual Property system is a strong imperative in the process of liberalising economic, industrial and trade policies. Industrial Property system needs to be used as a means for economic and technological development.
- B In order to benefit from the new directions consequent upon the TRIPS Agreement, developing countries need to improve their regulatory framework, laws and service, which will help to increase inventive activity. It is also necessary in this context to enhance basic awareness, upgrade legislation, strengthen infrastructural capabilities and fill in the gaps that remain in these areas.
- C Main provisions of the TRIPS Agreement need to be understood in the context of enlightened national economic self interest by each country. It has to be depoliticised and a national and not a party interest position taken. TRIPS Agreement can open new horizons for a country's industry and can ensure success through competition. IPRs cannot remain static and have to be abreast of the rapidly emerging new technologies and of international developments.
- D TRIPS Agreement has come to stay. The developing countries in general and India in particular should concentrate on using its flexibility to advantage. It cannot be gainsaid that Industrial Property legislation and Administration need to be modernised.
- E There is a great need to study the various Industrial Property Right statutes in depth in order to identify the areas which need to be revised, updated or modified not only to conform to the TRIPS Agreement but also to subserve the national interests without detriment.
- F While making necessary amendments to the IPR statutes, appropriate measures will have to be put in place to prevent the abuse of Intellectual Property Rights by right holders or the resort to practices, which unreasonably restrain trade or the international transfer of technology. Such measures may have to be provided under competition legislation rather than Intellectual Property legislation. The mere use of the protection of Intellectual Property to secure exclusivity in the market place for a new product is in itself not an abuse but Intellectual Property can sometimes be involved in the abuse of a dominant market position or in restrictive trade practices, such as collusion between supposedly competing companies on licence terms and the like. There should be an appropriate competition law to enable suspicious situations to be investigated. It is necessary to keep in view the need to have an effective competition law with an effective enforcement power for the Competition Law Authority to subserve the aforesaid objectives.
- G TRIPS Agreement in Article 40 accepts that some licensing practices and conditions may have adverse rather than beneficial effects on trade and technology transfer. Policy options are open for members to legislate against specific licensing practices or conditions, which may constitute an abuse of Intellectual Property Rights having an adverse effect on competition. Undesirable

practices like exclusive grant back, preventing challenges to validity and coercive package licensing are mentioned in the TRIPS agreement. There could be other undesirable practices like the requirement to purchase basic raw materials from the right owner, the extension of the agreement beyond the expiry or lapse of the patent, requirements to take other unwanted licences,' undue restrictions on the competitive position of the licensee and so on. The legislation therefore should be sufficiently flexible to deal with the issues case by case. Every developing country and in particular India needs to study these possibilities of abuse in detail while taking up amendments to the Intellectual Property statutes.

- H TRIPS Agreement in Article 8 affords some policy options for member countries. It is desirable to protect public health and nutrition and to promote public interest in vitally important socioeconomic and technological sectors, by adopting special measures with the only rider that they have to be consistent with the Agreement itself. For example, there should in general, be no compulsory sequestration or licensing of patent rights without observing the principles of Article 31 of the Agreement. Compulsory licensing and Government use of an invention without the authorisation of the right holder can be built into the national statutes in order to prevent abuse of dominant position or in case of national emergency. Article 31 of the TRIPS agreement indicates conditions, which must be respected before such use can be permitted.
- I TRIPS Agreement in Article 22 requires the member signatories to provide a legal means for interested parties to prevent the use of geographical indications which will mislead the public as to the true place of origin of the goods concerned and to prevent use amounting to unfair competition. Unfair competition is an act contrary to honest practices in industrial or commercial matters. India has already enacted a law dealing with geographical indications. It should be operationalised without delay.
- J The main principle to be kept in view in finalizing the Intellectual Property statutes amendments is that while reinforcing the need for the existence of IPRs, their exercise will have to be under surveillance within the contours of competition law.

NEGOTIATION ISSUES FOR CANCUN

1. **Cancun needs to address the question as to what constitutes abuse and what remedies should be spelt out for the Members to invoke. Furthermore, future negotiations in the area of intellectual property rights should give equal weight to recognising the risks of both under-protection and over-protection of intellectual property rights.**
2. **Cancun needs to confirm that Member can allow parallel imports to protect consumer interest and in particular, to protect public health.**
3. **Cancun needs to confirm that nothing in the TRIPS Agreement will prevent Members from adopting measures to protect public health, as well as pursuing**

the overarching policies defined in Article 8 thereof.

4. Cancun should enunciate in strong terms the public policy objectives enshrined in Articles 7 and 8 of TRIPS and declare that promotion of IPRs is not an end in itself and that its effectiveness needs to be measured not just in terms of whether or not the rights of the rights-holder have been protected but also in terms of whether or not public policy objectives outlined in Articles 7 and 8 have been adequately met. In other words, there should be a balance of rights and obligations and a balance between private rights and public policy objectives.
5. Cancun should take the view that the TRIPS Agreement will in no way stand in the path of public health protection and that it should provide the broadest flexibility for the use of compulsory licence.
6. Cancun needs to declare that Members are free to determine the grounds upon which to issue compulsory licences.
7. Cancun should confirm with reference to Article 31(f) that nothing in the TRIPS Agreement would prevent Members to grant compulsory licences to supply foreign markets.
8. Cancun needs to confirm that differential pricing arrangements would not be prejudicial to the rights of Members to make use of the provisions of the TRIPS Agreement, such as parallel imports and compulsory licences.
9. Cancun needs to address the concerns relating to patenting of biological and genetic resources covered by Article 27.3.
10. Cancun, on the basis of consensus, should declare that non-violation provisions in Article 64.3 would not apply to measures taken by Members for providing access to essential medicines.
11. Cancun should explicitly provide for geographical indications protection for products qualifying for it, as was done for French Champagne.

CONCLUSION

Cancun is a big opportunity for defining flexibility in the TRIPS Agreement in the larger interests of public health and the larger interests of the society, particularly its poorer sections. Developing countries exerted a big influence during the discussions in Doha resulting in the Declaration giving primacy to public health over Intellectual Property Rights. **It is now time to concretise and operationalise the spirit of the Declaration.**

This paper has attempted to list particular provisions of TRIPS Agreement, which would help this endeavour.

There cannot be and should not be any profiteering in the area of health and well

being of the human race.

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