Patent System: Implications for Health Care and Pharma Industry*

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The paper discusses the merits and demerits of the TRIPS Agreement and its implications for healthcare and pharma industry. Implications of this Agreement would have an adverse effect on the accessability and affordability of medicines. The existing pricing profile of developed countries if applied to developing countries would become a serious problem for the poor people. The UN commission on human rights has thus stated that TRIPS Agreement constitutes contravention of international human rights law. At the end, the author lists some critical issues, which need special attention while amending our Patents Act, 1970.

The Uruguay Round of GATT negotiations concluded in December 1993 and the World Trade Organization (WTO) was established on 1 January 1995. The setting up of the WTO, with a new comprehensive mandate contained in 29 legal texts (Agreements), has brought up a totally new environment for policy and law making at the national and international levels. In particular, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is the most contentious and comprehensive international instrument on all types of intellectual property rights (IPR). Tough standards practised in technologically advanced countries, have been laid down in TRIPS Agreement in order to obtain worldwide protection for the inventions/innovations generated in those countries by the transnational corporations. According to the World Health Organization, "the TRIPS standards derived from those of industrialized countries are not necessarily appropriate for all countries' level of development". The important fea-

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ture of the various new IPR regimes is for strengthening the rights of the owners of IPR whereas their obligations have been significantly dilut ed. The member countries of WTO are under obligation to enact or amend their domestic legislations for various IPR to conform to the provisions of the TRIPS Agreement. Through the proposed patent system, the developed countries will be able to secure control over markets through technologies as well as by preventing the use of their technologies without authorization and economic compensation. The important issue considering the various new factors here is that while the WTO was set up to ensure free trade, the issues covered in the TRIPS Agreement, never earlier part of the international trade regulations framework, may make for the strengthening of monopolies and dilution of competition resulting in strong barriers to free trade.

**Patent (Second Amendment) Bill 1999**

The Patents (Amendment) Act, 1999 in March 1999 was supposed to fulfill two obligations, viz. establishing ‘mail box’ facility from 1 January 1995 for accepting product patent applications for pharmaceuticals and agrochemicals. The other obligation related to providing exclusive marketing rights (EMR) to such applicants. The haste with which this law has been enacted provides for certain controversial provisions which have compromised our national interest to a considerable extent.

A similar haste should not be shown for enacting the Patents (Second Amendment) Bill, 1999. The government has no doubt referred the Bill to the Joint Committee of both Houses of Parliament but it is aiming at getting the Bill passed as early as possible. Any haste would mean that the country is being pushed into a situation, which has serious implications for our people and for the domestic industry. It would be pertinent to point out that the Parliament took almost 15 years to produce appropriate patent laws in 1970 to suit our country’s needs and interests.

There is no doubt that the government is committed by a certain date to conform our patent laws to the TRIPS Agreement. The matter should not end at this, as it will be a too simplistic view. There are many important issues of interpretation involved here. If we are serious about defending the interest of our people, our objective should be to assert our position and use every legal latitude that exists for doing so, rather than to submit ourselves obediently to certain particular interpretation of legal rectitude that we have received from the developed countries. It exposes us to acts of future subjugation both within the WTO and in all subsequent agreements that it would spawn. We would be in serious problem, in other words, to being at the receiving end one *fait accompli* after another, each more prejudicial to our own people’s interest than the preceding one.

**Prima Facie Impact on Health Sector**

The accessability and affordability of medicines is certainly going to be adversely affected after the patent laws are changed to bring in line with TRIPS Agreement. The examples are:

**Accessability**

(i) The dependence upon imports of pharmaceuticals increased in Mexico, Brazil, Chile, Canada, Spain and even Italy after the patent laws were changed by these countries.
(ii) Pfizer, Parke-Davis, Squib, Bayer and Schering AG closed their manufacturing plants in Chile and Brazil and started importing pharmaceuticals.

The above situation affected the accessability of medicines from indigenous sources after the above quoted countries made changes in their national patent laws.

**Affordability**

There is every likelihood of steep rise in prices of medicines after monopolies over products get established in favour of the patent-holders. The high prices will have no relationship with the buying capacity of the consumers in poor countries. Table 1 gives the comparative position of prices, and a similar pricing scenario will be established in India also.

The pricing data have the direct relationship with the monopolistic situation prevailing due to the patent system being practised in these quoted countries.

There is yet another price comparison (Table 2) which is also an alarming data to be taken note of by our Parliament in dealing with amendments to the Patents Act, 1970.

We have to be extremely cautious in concluding any comprehensive legislation to change our Patents Act, 1970, which was enacted after long deliberations in Joint Select Committees and in-depth debate in both the Houses of Parliament preceded by recommendations of two high-powered commissions headed by Justice, Bakshi Tek Chand and Justice, Gopalaswami Iyengar. Our Patents Act of 1970 was considered as a model law for the developing countries by the UNCTAD. We should ensure that again we produce another model in our amended patent laws so that other developing countries may be able to go along with us. Such a model could ensure around the unity of the developing countries. This cannot be

**Table 1—Differences in prices of medicines (prices in Indian Rupees)**

(Wide difference in prices due to monopolization factor)*

<table>
<thead>
<tr>
<th>Drugs/Brands</th>
<th>Company</th>
<th>India</th>
<th>Pakistan</th>
<th>Indonesia</th>
<th>UK</th>
<th>USA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ranitidine</td>
<td>Glaxo</td>
<td>7.16</td>
<td>195.50</td>
<td>178.35</td>
<td>316.20</td>
<td>739.60</td>
</tr>
<tr>
<td>(Zantac)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>150 mg x 10s</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>times costlier</td>
<td></td>
<td>27.30</td>
<td>24.90</td>
<td>44.16</td>
<td>103.30</td>
<td></td>
</tr>
<tr>
<td>Diclofenic</td>
<td>Ciba Geigy</td>
<td>5.64</td>
<td>106.74</td>
<td>59.95</td>
<td>123.76</td>
<td>505.68</td>
</tr>
<tr>
<td>(Voltaren)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>50 mg x 10s</td>
<td></td>
<td>18.93</td>
<td>10.63</td>
<td>21.94</td>
<td></td>
<td>89.66</td>
</tr>
<tr>
<td>times costlier</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Retail prices in India and wholesale prices in other countries considered.

Conversion Rate: One US $ = Rs 43.00; One GB pound = Rs 68.00 One Pak = Re 2.00 One Indonesia RP = Re 9.005 Sources: USA (Red Book 1998); UK (mims June 1998); Pakistan (Pharmagnuide March 1998); Indonesia (IIMS No. 1, 1998); India (Drug index, May-June 1999)
Table 2—Comparison of retail price (US$) of drugs commonly used by elderly people in USA

<table>
<thead>
<tr>
<th>Product (dose, no of pills)</th>
<th>Used to treat</th>
<th>US</th>
<th>Canada</th>
<th>Mexico</th>
<th>India*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zocor (5 mg, 60)</td>
<td>Cholesterol</td>
<td>106.84</td>
<td>43.97</td>
<td>47.29</td>
<td>6.45</td>
</tr>
<tr>
<td>Ticlid (250 mg, 60)</td>
<td>Stroke</td>
<td>112.92</td>
<td>52.35</td>
<td>39.61</td>
<td>10.35</td>
</tr>
<tr>
<td>Prilosec (20 mg, 30)</td>
<td>Ulcer</td>
<td>105.50</td>
<td>53.51</td>
<td>29.46</td>
<td>2.45</td>
</tr>
<tr>
<td>Relafen (500mg, 100)</td>
<td>Arthritis</td>
<td>110.90</td>
<td>59.55</td>
<td>49.26</td>
<td>17.20</td>
</tr>
<tr>
<td>Procardia XL(30 mg, 100)</td>
<td>Hypertension</td>
<td>110.90</td>
<td>72.82</td>
<td>87.88</td>
<td>6.38</td>
</tr>
<tr>
<td>Zoloft (50 gm, 100)</td>
<td>Depression</td>
<td>195.07</td>
<td>124.41</td>
<td>155.52</td>
<td>5.40</td>
</tr>
<tr>
<td>Vasotec (10 mg, 100)</td>
<td>Hypertension</td>
<td>94.31</td>
<td>73.42</td>
<td>57.03</td>
<td>8.30</td>
</tr>
<tr>
<td>Norvasc (5mg, 90)</td>
<td>Hypertension</td>
<td>109.24</td>
<td>87.71</td>
<td>88.08</td>
<td>3.40</td>
</tr>
<tr>
<td>Fosamax (10 mg, 100)</td>
<td>Osteoporosis</td>
<td>169.73</td>
<td>45.01</td>
<td>51.33</td>
<td>11.00</td>
</tr>
<tr>
<td>Cardizem (240 mg, 90)</td>
<td>Hypertension</td>
<td>162.22</td>
<td>142.70</td>
<td>88.14</td>
<td>17.50</td>
</tr>
</tbody>
</table>

*Indian prices added in the statement for comparison.
Source: National Council for Senior Citizens/Reuters

achieved in haste. There should be adequate consultations and in-depth consideration in giving an amended look to our Patents Act, 1970.

**Patents Act 1970 and Our People**

The Patents Act, 1970 which was enacted after in-depth consideration provides for the following provisions:

- process patent for pharmaceuticals and other chemical based products;
- a short term of 5/7 years for process patents and 14 years term for product patents;
- strong safeguard provisions through licensing of right system.
- Section 83 laying down general principles of our patent laws:

> "that patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent and not to enable patentees to enjoy a monopoly for the importation."

These are some of the major provisions that helped the country in establishing a formidable pharmaceutical industry having a strong competitive environment in providing pharmaceuticals of various therapeutic groups to its people at prices, which are the lowest in the world. This situation to a large extent suited the environment of our poor country where over 35% of the population is still below poverty level and then the overall position being that 70% of the population is unable to afford medicines.

**Constitutional Rights – Government’s Obligations**

The Constitution of India guarantees ‘right to life’ as a fundamental right to its citizens. The present situation in the country about the availability of drugs and pharmaceuticals
in many ways is conducive to such a constitutional obligation. The question arises whether this constitutional obligation will in any way get vitiated on bringing our patent system compatible with the TRIPS Agreement. There have been many studies in the country and also there have been statements by the government functionaries that with the implementations of the TRIPS Agreement, the prices of drugs will go up. To what extent they will go up is nobody’s guess but surely a situation is likely to be created which would be totally untenable with the interest of the people.

The provisions of the TRIPS Agreement are specifically not sensitive to the needs of the developing economies like India. It is an instrument for the preservation and accentuation of inequalities and sadly our own successive governments during negotiations have been insufficiently concerned with the dangers of being trapped in such an agreement which represents a non-trivial abridgment of our national sovereignty in law-making and a surrender of our people’s collective right to defend themselves according to their own wisdom against the depredations of MNCs.

**International Human Rights Law**

The sub-commission of UN Commission on Human Rights in their session in August 2000, categorically concluded that the TRIPS Agreement constitutes, contraventions of international human rights law. Some of the most important extracts of the Resolution on IPR and Human Rights are reproduced as follows:

- Noting that Human Development Reports 1999 and 2000, which identify circumstances attributable to the implementation of the TRIPS Agreement that constitute contraventions of international human rights law.
- Noting further that actual or potential exist between the implementation of the TRIPS Agreement and the realization of economic, social and cultural rights....
- Declares, however, that since the implementation of the TRIPS Agreement does not adequately reflect the fundamental nature and divisibility of all human rights, including the right of everyone to enjoy the benefits of scientific progress and its applications, the right to health, the right to food, and the right to self-determination, there are apparent conflicts between the IPR regime embodied in the TRIPS Agreement, on the one hand, and international human rights law on the other;
- Requests all government and national, regional and international economic policy fora to take international human rights obligations and principles fully into account in international economic policy formulation;
- Requests the World Trade Organization, and the Council on TRIPS during its on going review of the TRIPS Agreement, in particular, to fully take into account the existing State obligations under international human rights instruments;
- Requests the United National High Commissioner for Human Rights to undertake an analysis of the human rights impacts of the TRIPS Agreement;

National governments and parliamentary institutions have a solemn obligations towards their people to protect the fundamental rights and other obligations enshrined in the...
national constitutional (Constitution of India) and international human rights obligations must at all cost prevail upon any commitment concluded at the Uruguay Round of negotiations. The author has also discussed later as to how USA has protected their laws in case of any conflict with the Uruguay Round obligations.

**Consumer's Choice and Medicines**

The drug industry's products have a peculiarity, which must be understood, namely, there is no consumer choice in pharmaceuticals. People buy medicines prescribed by doctors; they do not make their own independent choices between drugs depending on their relative prices. While high monopoly prices in other commodities may give rise to a degree of consumer resistance, the same cannot be said of pharmaceuticals. Monopoly, therefore, does enable charging of exorbitant prices as long as the medical professionals prescribe the medicines. Pharmaceutical price control would be difficult to exercise *vis-à-vis* a firm that holds monopolistic rights and that too on products imported by it.

The consumer's concerns from the TRIPS Agreement basically arise from:

- the introduction of product patent system;
- treating of imports at par with the domestic production from the patent right's angle;
- providing long patent term of 20 years;
- inadequate compulsory licensing for which all kinds of interpretations are being advanced to confuse issues; and R&D activity by other enterprises on the patented products during patent term.

**Basic Approach for Changes**

The basic approach for amending our patent laws should be to subserve public interest on the above important issues. However, if a pragmatic and judicious approach is applied in implementing TRIPS Agreement, there are certain windows available in TRIPS that can help in safeguarding our national interest. These windows are available in Article 7&8, and preamble of TRIPS.

**Article 7: Objectives**

"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".

(i) The above objectives of the TRIPS Agreement lay special emphasis that IPR should contribute to:

- the promotion of technological innovation; and
- the transfer and dissemination of technology.

The question of transfer and dissemination of technology is extremely important in the context of working of patents by the licencees after the grant of compulsory licence which may be for any contingency. Some of the contingencies are extremely important for undertaking the production of patented product by others without any loss of time. Even though the objectives are clear about the transfer and dissemination of technology, there is no provision proposed in the amendments to the Patents Act, 1970 providing for an obligation on the patent holder to transfer the technology and help in its dissemination after the grant of compulsory licence. In a situation where a domestic enterprise may seek a compulsory licence and
he may succeed in getting the compulsory licence, he may not be able to produce the technology for that product. If the patent holder is not agreeable to transfer his technology, then the law should contain an obligatory provision for the patent holder to transfer the technology and if within a reasonable period of time (say 6 months) he does not do so, then the Controller should consider revoking the patent or shortening the remaining term of the patent after giving the patent holder an appropriate notice.

(ii) The other objectives in Article 7 also lay emphasis that the contribution of IPR should be conducive to socio-economic welfare. This article also mentions about the need of balancing of rights and obligations. Keeping these aspects in view, an attempt has to be made to contain the long term of the patent right and provide appropriate sections to ensure compulsory licensing ensuring balancing of rights and obligations for the patent holder. Working of patents, compulsory licences, licences of rights and revocation of patents are thus compatible with the provisions of the TRIPS Agreement and we should fully make use of these provisions in Article 7.

(iii) The entire Article 7 “Objectives” could also be reproduced as sub-section (c) of Section 83 in amending our laws. This will strengthen the philosophy of our Patents Act, 1970.

Article 8: Principle

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 measure are consistent with the provisions of this Agreement.

2 Appropriate measures, provided that they are consistent with provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by the right holders or resort to practices which unreasonably restraint trade or adversely affect the international transfer of technology.

(i) The principles stated in Article 8 are in the nature of direction to the member countries that in formulating or amending their laws and regulations, necessary provision should be made to protect public health and nutrition and to promote the public interest in sectors of vital importance to the socio-economic and technological development. These are laudable principles, which should be effectively made operative for both the product and process patent regimes particularly because the rights of the patent holders have been vastly strengthened. Domestic enterprises’ role has to be strengthened by allowing them compulsory licences in a liberal manner and also that the provision relating to the licensing of rights has to be effectively used so that in the vital area of public health and nutrition, there are no compromises.

(ii) Sub-article (2) of Article 8 also provides to ensure that there are no constraints for trade or international transfer of technology. Our law has to adequately provide for
these principles. Compulsory licences should also be available both for parallel imports and exports of patented products apart from producing for domestic demand. Compulsory licences and licences of rights must accompany with the obligation on the part of the right holder to transfer technology.

Preamble of TRIPS

"Recognizing the underlying public policy objectives of national systems for the protection of intellectual property, including development and technological objectives".

(i) The public policy objective of our national system in relation to the rights of our people have been clearly laid down in our Constitution. Indian citizens have been guaranteed fundamental rights on numerous aspects of public welfare. One of the important fundamental rights relates to 'right to life' which incorporates 'right to health'. While amending our patent laws, care has to be taken that there are no constraints in accessibility and affordability of medicines for all kind of ailments.

(ii) While for accessibility, the role of domestic enterprises has to be strengthened, there has also to be effective price control system to ensure that there is no exploitation and profiteering from life or death through medical discoveries.

The constitutional rights have to be kept in mind while formulating our patent system. The government has greater obligation to uphold the constitution rather than obligation to conform its patent laws to the TRIPS Agreement if some aspects thereof are not in line with the provisions of our constitution. Price control of patented products should be strictly enforced to ensure affordability by the poor people of our country.

In fact, the public health laws, national drug policy and the patent system, which are intensely interrelated, have to subserve the constitutional obligations in an unambiguous manner.

(iii) In connection with the above issues attention is invited to US Act cited, the "Uruguay Round Agreement Act" which was enacted immediately after the conclusion of the Uruguay Round of GATT negotiations providing for specific provisions stating that if there are inconsistencies between the provisions of WTO multilateral trade system and the US laws, the latter will prevail. The relevant sections are reproduced as follows:

Sections 102 (a)

"(a) Relationship of Agreements to United States Law

(1) United States Law to Prevail in Conflict- No provision of any of the Uruguay Round Agreement, or the application of any such provision to any person or circumstance, that is inconsistent with any law of the United States shall have effect.

(2) Construction- Nothing in this Act shall be constructed-

(A) to amend or modify any law of the United States, including any law relating to

(i) the protection of human, animal, or plant life or health.

(ii) The protection of the environment,
(iii) Worker safety, or
(B) to limit any authority conferred under any law of the United States, including section 301 of the Trade Act of 1974; unless specifically provided for in this Act”.

Section 102 (b) (2) (A):
“(2) Legal Change-
In General – No State law, or the application of such a State law, may be declared invalid as to any person or circumstance on the ground that the provision or application is inconsistent with any of the Uruguay Round Agreements, except in an action brought by the United States for the purpose of declaring such law or application invalid”.

By Section 313, the following provision is added in connection with enquiry and report by USTR.

Section 182 (4)
“(4) A foreign country may be determined to deny adequate and effective protection of intellectual property rights, notwithstanding the fact that the foreign country may be in compliance with the specific obligations of the Agreement of Trade-Related Aspects of Intellectual Property Rights referred to in Section 101 (d) (15) of the Uruguay Round Agreement Act”.

If US laws have to prevail even when they are inconsistent with the Uruguay Round Agreements, why not then the laws of other countries should also prevail similarly? Our sovereign rights are in no way inferior to the sovereign rights of USA. We have to assert that at least there has to be no inconsistency with the constitutional provisions while implementing the agreements under the Uruguay Round and particularly the TRIPS Agreement with which we are dealing here-with.

Critical Issues for Special Attention
In the background of above analysis while amending our Patents Act, 1970 a special care has to be taken in dealing with the following issues:

(i) TRIPS provides that imported products and locally produced products under patent would enjoy the same patent rights without discrimination. There is a need to contain the patent rights on imports for a large country like India. Our dependence upon imports would not be in our national interest and hence this right should be conceded only for a shorter period.

(ii) Imports in implementing TRIPS should not be treated as ‘working of the patent’ as argued by certain experts. The working of the patent should rightly be related to transfer and dissemination of technology as provided in Article 7 of TRIPS.

(iii) There should also be a clear provision regarding parallel imports under the doctrine of exhaustion. The footnote under Article 28 and the provision of Article 6 in TRIPS do allow the facility of parallel imports under certain conditions and these conditions could be the availability at lower prices.

(iv) Article 27.3(b) provides for patenting of microorganisms. This sub-article is under review in WTO since 1999 and no decision has been taken so far. No provision should be made for patenting of microorganisms till the review is completed. Microorganisms occur in nature. They are discoveries and also relate to life form. We should strongly
object to their patenting. We should clearly deal with this aspect in our amendments.

(v) Patents are to be granted for inventions, which are new, involve an inventive step and are capable of industrial application. All these aspects should be properly defined in our national law so that no frivolous claims are entertained in regard to pharmaceuticals, such as, relating to changes in dosage form, new usage and new combinations of off-patent molecules.

(vi) While determining the scope of patentability, traditional system of medicines should be excluded from the patent system and should be categorized as 'discoveries'. Similarly, granting of patent for naturally occurring life forms, gene sequences or cell-components should also be excluded.

(vii) Article 31 of TRIPS provides for grant of compulsory licence by the patent authority if a request made by an enterprise to the patent holder for authorization on commercial terms is either rejected or there is no response within a reasonable period of time. This attempt establishes the legal right to get the compulsory licence and there should be clear-cut provision on this basis.

Compulsory licence should also be provided for non-working of the patent, as it is important that patents are worked in a large country like India.

Compulsory licence should also be granted to prevent the abuse of intellectual property rights by the right holder or when he resorts to practices which unreasonably restrain trade or adversely restrict the transfer of technology.

Compulsory licence should also be granted to remedy the anti-competitive practices, for security reasons to meet needs during national emergency or other circumstances of extreme urgency or in case of public non-commercial use.

Compulsory licence should also cover authorization for meeting export commitments. This is possible within the scope of Article 31 in sub-para (i)

(viii) Reasonable commercial terms should also be defined and royalty payment restricted within 4-8% of ex-factory sales. Similarly, reasonable period of time for response by the patent holder should also be prescribed as 100/150 days. An appropriate authority could recommend the quantum of royalty, which the Controller can prescribe at the time of sealing of the patent.

(ix) The provision of reversal of burden of proof should be provided in such a manner that patent holder is not able to misuse it to perpetuate monopoly. Certain conditions must be satisfied by the complainant before the defendant is asked to prove that he was not guilty.

(x) The examination of all applications already received in the mailbox should be started after the new amending Bill is passed and not kept pending till 31.12.2004. In fact examination could start even now as we are not changing our provisions relating to examination of patent applications in our Patent Acts, 1970.

(xi) While amending our patent laws, the Preamble of WTO, the Preamble of TRIPS Agreement, Article 7 ‘Objectives’ and Article 8 ‘Principles’ of TRIPS Agreement and resolution of
Human Rights Commission, etc. should be totally kept in view.

Conclusions and Flagging of Issues for TRIPS Review

The Patent laws should neither become laws for exploitation nor laws for monopolization. National patent laws should only be framed or amended to accord with the TRIPS Agreement in a manner to subservire social and economic welfare and to balance the rights and obligations of IPR holders as envisaged in Article 7 of TRIPS. It is apparent that the TRIPS patent system in the present form is a charter of rights for the patent holders. No direct obligation as such has been cast on them in the substantive sections on patents in the TRIPS Agreement. When rights are being strengthened, correspondingly the obligations should also be strengthened. The stakes of national governments in the health care of their people are quite high. In developed countries, the general public, to a considerable extent, are able to take care of their health problems through the general insurance system whereas similar facility is not available in most developing and the least developed countries including India.

In order to ensure public interest for achieving the laudable objectives of 'Health for All' and to provide for a pragmatic approach to health care programmes, it is necessary that the domestic pharmaceutical industry in developing countries and the least developed countries are facilitated to play their role in the health care sector. For achieving this objective, which is totally in consonance with Article 7 and 8 of the TRIPS Agreement, the developing and least developed countries will have to ensure an unrestricted role of the domestic industry in patented products/processes. Though there is enough clarity that member countries can suitable provide for the objectives and principles laid down in Article 7 and 8 of the TRIPS Agreement in their national patent laws, it would, however, be better as a long-term approach that the spirit of these two articles is also unambiguously operationalized in Section 5 of the TRIPS Agreement. This aspect could be flagged for TRIPS review and suitable elaboration of Article 31 could be sought for smooth transfer and dissemination of technologies. Similarly, the long patent term and exclusive rights to imports should also be flagged for review.

Finally, the governments in large developing countries, like India, must strengthen the basic R&D activity in their countries through direct funding or through strengthening of their tax concessions so that the industry is able to gear itself to meet the global challenges of uniform patent system of the TRIPS Agreement.

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