Compulsory Licences Imbroglio: Provisions Under TRIPS and Their Interpretations

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One of the most crucial components of the TRIPS Agreement is related to the provision for the grant of compulsory licences, which is not in fact a new phenomenon introduced under the TRIPS Agreement. Practically all countries including US, Canada and those in Western Europe had provisions for grant of compulsory licences in their Patent Acts and have used them on several occasions in the past. A proper understanding and a judicious interpretation of the available provisions for compulsory licences under the TRIPS Agreement could go a long way in ensuring a proper balance between the rights of the patent holder and the public health needs of the people in developing countries. The paper discusses in detail about the compulsory licence and the need for granting it. Amendments to the Indian Patents Act 1970 on compulsory licence issues are also discussed briefly.

Keywords: TRIPS Agreement, compulsory licence, anti-competitive practices, public health issues, non-commercial use, dependent patents, Doha Declaration

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is one of the important components of the General Agreement on Tariffs and Trade (GATT), which was unanimously endorsed and signed by all founding members including India in Marrakesh in April 19941. Currently, 147 countries are members of the World Trade Organization (WTO), which administers and implements the various provisions, obligations and responsibilities related to all aspects of GATT. Of the over 70 Articles of this Agreement covering a wide range of issues for the implementation of the minimum requirements to be met by the Members, some of the most contentious, complex and somewhat controversial ones are those connected with the exceptions under TRIPS provisions for the grant of compulsory licences under certain specified, but rather ill-defined conditions. At the same time, these are the provisions, which have in some ways maximum impact on developing countries, which constitute over 80% of the membership of WTO. The specific provisions for compulsory licences are spelt out under Article 31 of TRIPS according to which, the following have to be respected:

(a) authorization of such use shall be considered on its individual merits;
(b) such use may only be permitted if, prior to such use, the proposed user has made
efforts to obtain authorization from the rights holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use;

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized;

(d) such use shall be non-exclusive;

(e) such use shall be non-assignable;

(f) any such use shall be authorized predominantly for the supply of the domestic market;

(g) authorization of such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized;

(h) the rights holder shall be paid adequate remuneration;

(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review;

(j) any decision related to the remuneration provided in respect of such use shall be subject to judicial review;

(k) Members are not obliged to apply conditions set forth in sub paragraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive; and

(l) where such use is authorized to permit the exploitation of a patent (second patent) which cannot be exploited without infringing another patent (the first patent).

To those who believe that Article 31 strikes at the very roots of the concept of exclusivity granted as a reward system for innovation and creativity through the instruments of grant of patents, it should be mentioned that the TRIPS Agreement through Articles 7&8 defining the objectives and principles specify that the system is meant to work to the “mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare and a balance of rights and obligations (Art 7) and may adopt measures 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 the Agreement (Art 8.1).” Further, Members are free to adopt measures, which will prevent abuse of intellectual property rights (IPR) by rights holders, which unreasonably restrain trade or adversely affect international transfer of technology (Art 8.2). Finally, under Art 73(b), “nothing in this Agreement shall be construed to prevent a Member from taking any action which it considers necessary for the protection of its essential security interests.” In essence, therefore, it is obvious that Articles 7, 8 and 73 would be deemed to be sufficient to ensure equity between the interests of the patent holder and the user and Art 31 is merely the provision of an instrument enforceable by the Government to ensure such equity.

What is a Compulsory Licence and Why is it Granted?

A compulsory licence is a licence granted by the Government to a third party to use
patents and other forms of intellectual property to limit patent and other rights in order to correct distortions in the exploitation of the patent by the holder and avoid the negative impact of such action on the consumer. Governments are authorized to issue compulsory licences to broaden access to products and technologies, and to achieve certain public good when it is threatened by the monopoly granted by the patent rights. The Paris Convention already had a provision which states that each country has the right to take legislative measures for the grant of compulsory licences to prevent the abuses which might result from the exclusive rights conferred by the patent e.g., failure to work the patent3,4.

Apart from Para 31 of TRIPS, multilateral Agreements under NAFTA, the European Union and other trade blocks also have provisions to issue compulsory licences through national legislations for broad biotechnology tools of research, dependent patents, unreasonable prices, anti-competitive practices and for non-commercial use e.g. in research.

Even the US, the most patent-savvy country in the world, has provisions for compulsory licences under 28 USC 1498 for Government use, under which the US Government does not have to seek a licence or negotiate for use of a patent. Examples of Government use include use by NASA, National Institute of Health (NIH) and various other bodies of various inventions, which have strategic relevance to the space programme, defense or health. For example, the NIH may use and manufacture any patented product, whether or not developed by Federal funds without a licence, subject to liability for paying reasonable compensation. Most of the disputes leading to litigation in the area of compulsory licences have been on the matter of adequacy of the compensation package, which have ranged from 0 % to 10% of sales. Even infringement suits filed by patent holders have been dismissed when products under patents have been produced for supply to the Government5.

Grounds for Grant of Compulsory Licences

Under the Paris Convention as well as TRIPS Agreement, the grounds for grant of compulsory licences are determined by the national laws. The various grounds under which compulsory licences6 could be granted are:

Refusal to Deal

In the US, UK and many developed countries, this condition is used for grant of compulsory licences primarily when patents result in anti-competitive practices or when the patent holder refuses to work the patent to beat competition in the market place. Most countries have legislation for grant of compulsory licences when the demand for the product, say a drug, is not met by the patent holder or when the patent holder has refused licence to third parties on reasonable terms. Until 1999, Canada had a law, which granted compulsory licences even for import of a patented product when lower prices justified such imports. Both Brazil and South Africa have invoked the compulsory licence clause for importing anti AIDS/HIV drugs needed by their poor populations who could ill-afford to access them at the patent holders’ prices. Even though the US companies initiated legal
In the US, compulsory licences have been issued when violations of anti-trust laws have taken place. In fact, over 100 such licences have been issued over time using patented innovations of leading companies such as IBM, Kodak, GE, Dupont, Xerox and many others. The interesting aspect of some of these licences is that some of them were licensed at zero royalty payment to the patent holder. The European Community under Art 86 of the European Treaty has also ordered issue of compulsory licences in cases of refusal to deal, particularly in the case of certain drugs. UK and Canada have been even more liberal in the interpretation against monopolies and anti-competitive practices. Between 1953 and 1971, as many as 20 compulsory licences were issued covering some of the blockbuster drugs of that time such as Librium and Valium. Canada allowed parallel manufacturing of patented drugs based on applications from local producers claiming lower cost of production when manufactured indigenously. Where economies of scale were not favourable for domestic production, compulsory licences were also issued for importation of drugs (similar to the case made for parallel imports today). However, under increasing pressures from the US pharmaceutical lobby, Canada amended many of these provisions in 1992 and provided more sanctity for IP protection.

Public Interest and Anti-Competitive Practices

While TRIPS emphasizes that public interest could be a legitimate reason for grant of compulsory licences, the interpretation of what exactly would constitute public interest has varied a great deal. For example, in USA, insufficient working, high prices and constraints on use of dependent patents are hardly considered detrimental to public interest for grant of compulsory licences. Certain public interest legislations such as Atomic Energy Act (USCA 2183) and the Clean Air Act can be invoked as public interest and compulsory licences could be granted for related inventions.

Several other countries including Germany had tried to interpret public interest to include access to life saving medicines and in fact got a ruling by the German patent court in 1991 in favour of grant of compulsory licences for a drug Polyferon of a German biotechnology company, Bioferon, for arthritis. However, the ruling was reversed by the Federal Supreme Court on the reasoning that since alternatives were available for treatment of that condition, there was little justification for the grant of a compulsory licence.

Public Health Issues

At the 4th Inter-Ministerial Conference held in Doha in 2001, Para 6 of the Doha Declaration reiterated the fundamental tenet that Public Health issues in Member countries will supersede private interests reflected through exclusivity granted through the patent system. It endorsed the rights of members to interpret and implement through appropriate measures, protection of public health and promotion of access to medicines subject to respective Articles 3&4 referring to the Most Favoured
Nation (MFN) treatment to nationals and non-nationals. The rights of Members were also extended to determine the grounds for compulsory licences, define national emergencies and implement exhaustion rights. Provisions were also introduced to transfer to the Least Developed Countries (LDCs) under Art 66.2 to extend the implementation schedule under Art. 5&7 of Part II of the TRIPS Agreement till January 2016.

While the methodology to assist countries with no technological strengths to implement compulsory licences was to be worked out by the TRIPS Council before the end of 2002, that deadline could not be met. However, in August 2003, just prior to the Cancun Conference, the TRIPS Council finalized the implementation modalities for Para 6 of the Doha Declaration making it possible for the LDCs with no technological capability to exploit their compulsory licences through import of the products under their licence from another Member with adequate technological capability. The terms had to be mutually agreeable and very strict conditions were to be imposed to ensure that the licences are not abused by using such production for markets other than the country for which the drugs are produced. It is also mandatory to get the TRIPS Council’s approval prior to transferring of such licences to third parties in every case and to have separate production and marketing lines for the specific products for which the licence is issued. These conditions are so onerous that in terms of their practical utility in achieving the objectives of the Doha Declaration, there are grave doubts that an equitable and time-bound implementation is possible. In that case, the LDCs which need the drugs, but have little or no technological capability to produce them under the compulsory licences issued to them, will continue to be the losers and countries such as India and Brazil which have the production capabilities also lose an opportunity to export these essential drugs acutely needed to meet the challenges of serious epidemics including HIV/AIDS.

Non-Commercial Use

The most important case of public non-commercial use is the use of patented products and processes for R & D purposes. There is little dispute on this issue and in fact the Bolar provisions whereby developmental work on patented products could be carried out during the life time of a valid patent is an example of the endorsement of this principle. Bolar provisions, of course, are meant to assist filing of ANDAs with the US FDA. However, if R&D efforts using a patented invention lead to a patentable commercial product, there could be claims of royalty from the commercialized product, which could not have been discovered or developed without using the prior patented invention. The classical examples of these would be patents on genes and DNA sequences, which, while may be available free from industry R&D groups, ultimately if products are developed for commercial use, the original supplier of data could claim royalty on sales of those products.

Government Use

Apart from issues related to public interest and public health as reasons for
grant of compulsory licences, most countries have provisions in the Patents Act for grant of such licences for products to be used by their Governments. Right from 1883, UK had used the “Crown Clause” in its Patent Act for grant of compulsory licences not only for production of the concerned article, but also even for imports from any source outside the country. The US, under 28 US Code, Section 1498 uses patented inventions of third parties without any liability for infringements, but are liable for payment of adequate compensation for such use.

Use of Dependent Patents

There are several instances where a valid patent cannot be exploited since they are dependent on an earlier product patent of another inventor. Most countries have appreciated that there has to be a provision for grant of compulsory licences in such cases to enable the second patent holder to work his invention not only for his benefit but also for the society in general. The provision for grant of compulsory licences in such cases where the original patent holder refuses permission to allow the subsequent patentee practice his invention, also often leads to a negotiated settlement outside the compulsory licence system to cross license the invention to the mutual benefit of both parties.

Compulsory Licences for Medicines and Doha Declaration

Under Art 27.1 of TRIPS, there is no provision to discriminate any technology segment from the patentability criteria for granting of patent rights to inventors. Prior to the GATT, several countries such as India, Canada, Italy and many Latin American countries had differential provisions for medicines in their Patent Acts, primarily by not allowing the grant of product patents for inventions related to them. Apart from grant of compulsory licences, in India, these products were eligible for automatic licences of right and reduced periods of protection according to Indian Patents Act 1970. Continued pressures from the developing countries which were concerned about the impact of TRIPS and a globally harmonized patent system on access to affordable drugs led to what is now termed as Doha Declaration agreed upon at the 4th Inter-Ministerial Conference. In reality, the Doha Declaration is only a further endorsement of the objectives and principles enunciated under Art 7 & 8 of TRIPS. The fundamental tenet under the Declaration is that TRIPS needs to address public health problems affecting the developing and the least developed countries especially concerned with diseases such as malaria, TB and HIV/AIDS. While respecting the importance of IPR protection for innovation of new medicines, the unaffordable high prices of patented drugs is also a matter of concern and hence the Declaration was an attempt to reconcile these seemingly divergent interests. Considering the fact that health security interests ultimately are paramount for Member States, the Declaration took the view that when public health issues are threatened by the patent system, the former should take precedence over the latter. The Doha Declaration also endorsed the view that under Para 5 of the Declaration, the Members have the right to determine the grounds under which compulsory licences
could be granted to face the challenges of the diseases, ravaging the developing countries.

While the final methodology for the implementation of the Doha Declaration was supposed to have been finalized by the TRIPS Council by end 2002, largely due to the intransigence of the US lobby, this deadline was not met and it was only in August 2003 that the TRIPS Council announced the formula for its implementation. As already discussed, the methodology proposed for the implementation of Para 6 of the Doha Declaration is far from satisfactory from the LDCs’ perspective for meeting the objectives spelt out in the Declaration.

The economics of compulsory drug patent licensing has been discussed by Scherer et al. who discuss the conditions under which pharmaceutical products might be subjected to compulsory licences under TRIPS with special emphasis on the situation in developing countries.

Amendments to Indian Patents Act 1970 on Compulsory Licence Issues

India being a developing country and in view of the fact that the Indian Patents Act has no provisions for grant of product patents for pharmaceuticals, food and agricultural products, the transition period for implementation of a fully TRIPS compliant patent system ends on 31 December 2004. India opted to ensure this through three amendments, the first in 1999, the second in 2002 and the third presumably in 2004 (the draft 2003 Amendment placed in the Lok Sabha has since lapsed due to the dissolution of the Lok Sabha). The finer nuances for the grant of compulsory licences and all issues connected with the same have been incorporated in the Third Amendment.

The clauses enabling the grant of compulsory licences are contained in Sections 84 to 92 of the parent Act, the Indian Patents Act 1970. These sections deal with the conditions under which compulsory licences can be applied for and granted. These conditions include non-working of the patent, hindrance to a second patentee to practice his invention, circumstances of national emergency, extreme urgency or non-commercial use. Under Chapter XVII, Sections 99 and 100 specify the power of the Central Government or its assignee to use or acquire the patented invention for Government use. In Section 49 of the Draft Third Amendment to Indian Patents Act, 1970, Section 92 of the parent Act is proposed to be amended by the insertion of the following clauses.

92A (1) Compulsory licence shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided a compulsory licence has been granted by such country.

(2) The Controller shall, on receipt of an application in the prescribed manner, grant a compulsory licence solely for manufacture and export of the concerned pharmaceutical product to
such country under such terms and conditions as may be specified and published by him.

(3) The provisions of sub-sections (1) and (2) shall be without prejudice to the extent to which pharmaceutical products produced under a compulsory licence can be exported under any other provision of this Act.

These amendments have been proposed in view of the Doha Declaration which has the twin objectives of granting compulsory licences to countries which need them to tackle their public health problems and to ensure that such licences are usable by themselves or can be transferred to other countries which have the technological capability to produce the needed drugs and export them to the licencee.

As far as the institutional issues in IP policymaking, administration and enforcement aspects are concerned, the Indian scene has been analysed in a report of the commission on intellectual property rights.

Conclusions

Grant of compulsory licences for patented inventions has been an established practice in practically all countries of the world. There have been minor variations in the national laws with respect to conditions under which such licences are granted. More importantly there have been relatively major differences in the matter of interpretation of what constitutes legitimate conditions within the prescribed definitions of public interest, public health, national emergency, extreme urgency, etc. The basic considerations, which led to the Doha Declaration on TRIPS and Public Health, remain valid. The questions that arise are related to what diseases to be included while considering the need for compulsory licences to alleviate problems of non-accessibility and non-affordability of drugs. The Doha Declaration mentions malaria, TB and HIV/AIDS as illustrative examples. The US stand that the provision should be restricted to just these three diseases has not found favour with the other Members.

It should be obvious from the provisions under the Paris Convention of which India is a Member as well as the various Articles under TRIPS that the ultimate authority to finally establish the terms of reference and determine the qualifying considerations for grant of compulsory licences rest with India. As of now, there are sufficient grounds and precedents to take judicious decisions on these matters and bring in appropriate legislations and guidelines, based on the country’s interests. A careful analysis of the various provisions under TRIPS and its various subsequent modifications will show that there is sufficient room to interpret them to the advantage of the country. That indeed should be the top-most priority for the Government and its policy planners.

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