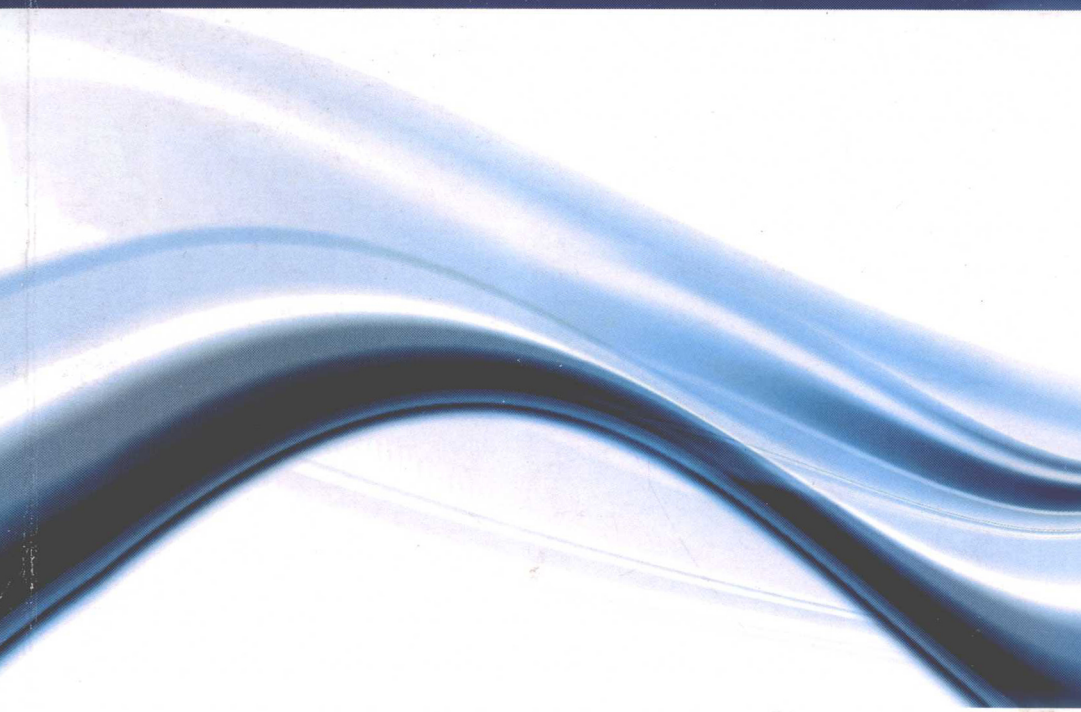

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Impressum/Imprint (nur für Deutschland/ only for Germany)
Bibliografische Information der Deutschen Nationalbibliothek: Die Deutsche Nationalbibliothek verzeichnet diese Publikation in der Deutschen Nationalbibliografie; detaillierte bibliografische Daten sind im Internet über http://dnb.d-nb.de abrufbar.

Coverbild: www.ingimage.com

Verlag: LAP LAMBERT Academic Publishing GmbH & Co. KG
Dudweiler Landstr. 99, 66123 Saarbrücken, Deutschland
Telefon +49 681 3720-310, Telefax +49 681 3720-3109
Email: info@lap-publishing.com

Herstellung in Deutschland:
Schaltungsdienst Lange o.H.G., Berlin
Books on Demand GmbH, Norderstedt
Reha GmbH, Saarbrücken
Amazon Distribution GmbH, Leipzig
ISBN: 978-3-8443-9171-8

Imprint (only for USA, GB)
Bibliographic information published by the Deutsche Nationalbibliothek: The Deutsche Nationalbibliothek lists this publication in the Deutsche Nationalbibliografie; detailed bibliographic data are available in the Internet at http://dnb.d-nb.de.

Cover image: www.ingimage.com

Publisher: LAP LAMBERT Academic Publishing GmbH & Co. KG
Dudweiler Landstr. 99, 66123 Saarbrücken, Germany
Phone +49 681 3720-310, Fax +49 681 3720-3109
Email: info@lap-publishing.com

Printed in the U.S.A.
Printed in the U.K. by (see last page)
ISBN: 978-3-8443-9171-8

1. A HUMAN RIGHTS APPROACH TO TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS (TRIPS)

The World Trade Organisation (WTO) was conceived as and continues to be an international body whose main agenda is to facilitate the growth of international trade. As part of this agenda, intellectual property rights in the form of "the Agreement on Trade Related Aspects of Intellectual Property Rights" (TRIPs) were also brought within the ambit of WTO. While the organisation continues to be mainly devoted to trade issues, controversies have arisen on issues like "trade and environment" and "trade and health" Since solutions to such issues were never clearly contemplated in the texts, the institution has found it difficult to resolve them to the full satisfaction of all the parties involved. One such issue has been accessibility to affordable life-saving drugs and the nature of the patent regime for the pharmaceutical industry as required by the TRIPs Agreement. As a result TRIPs has become a battleground between the proponents and the opponents of a globally uniform "one-shoe-fits-all" intellectual property regime. This article assesses how far the WTO regime has accommodated human rights concerns while briefly looking at three recent developments in international intellectual property law: the Doha Declaration in 2001, Council for TRIPs Decision in August 2003 and the amendment to the Canadian Patent Act in May 2004.

As TRIPs became a part of the WTO regime the member countries became bound to provide intellectual property protection as per TRIPs provision and were forced to amend their laws in tune with TRIPs. WTO's dispute settlement mechanism made sure that those countries which failed to amend their laws forced to do so. For example, on a complaint by the US, the WTO appellate body held that India's patent law violated (*i*) Article 70.8(*a*) of TRIPs by failing to provide a means for the filing of patent applications for pharmaceuticals and agricultural chemical

products, and (*ii*) Article 70.9 of TRIPs by not providing exclusive marketing rights (EMRs) to pharmaceutical and agricultural products. As a result, India was forced to amend the patent law in 1999 with effect from 1995. The binding nature of the TRIPs Agreement is likely to have immense impact once all the member countries become bound to implement an across-the-board product patent regime.

Before the Agreement came into force many developing countries, including India, allowed patents only for pharmaceutical processes and not for pharmaceutical products. Some countries like Brazil, Thailand and Korea simply did not include medicines within the patent laws. Due to a weak patent regime generic versions of patented medicines could be produced locally and therefore, the local prices of a formulation were much lower compared to that in the developed world. However, a product patent results in a complete monopoly in favour of a patentee and he becomes free to manipulate the market price of the product. Arguably, patent rights for pharmaceutical products result in higher prices making the drugs inaccessible for the poor. There, thus, seems to be an apparent conflict between the TRIPs regime and human rights values.

TRIPs and human rights

The provisions of TRIPs are clear on the rights to be granted and modes of enforcement of those rights. TRIPs mandates that, without discrimination, there should be patent protection for inventions in all fields of technology, if an invention is (*a*) new, (*b*) involves an inventive step, and (*c*) is capable of industrial application. Article 33 states that the term of patent protection shall be 20 years counted from the filing date. Articles 41 to 50 deal with the "enforcement of intellectual property rights" and provide for injunctions, damages and other remedies. According to these commands no distinction ought to be made between (*i*) a process patent and a product patent, and (*ii*) between the industries.

However, in direct contrast to the above cited articles, are general provisions couched in vague language such as Article 7 (objectives of the Agreement), Article 8 (principles of the Agreement), Article 6 (exhaustion of intellectual property rights), Article 30 (exceptions to patent rights conferred) and Article 31 (dealing with other compulsory licences). These provisions encourage the member countries to:

(*i*) promote technological innovation, transfer and dissemination of technology in a manner conducive to social and economic welfare;

(*ii*) adopt measures necessary to protect public health and nutrition;

(*iii*) promote the public interest in sectors of vital importance to their socio-economic and technological development;

(*iv*) prevent the abuse of intellectual property rights;

(*v*) restrict practices which unreasonably restrain trade or adversely affect the international transfer of technology; and

(*vi*) take action against anti-competitive practices.

Article 27.3 of TRIPs also allows the countries to provide exceptions for:

(*i*) the commercial exploitation to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, and

(*ii*) diagnostic, therapeutic and surgical methods for the treatment of humans or animal.

These are provisions that, arguably are conducive to the promotion and protection of human rights and seek to maintain the balance sought under

the Universal Declaration of Human Rights[22] (Article 27) and the International Covenant on Economic, Social and Cultural Rights (ICESCR) (Article 15). These two covenants encourage States to design intellectual property systems in a way that strikes a balance between promoting general public interests in accessing new knowledge as easily as possible and in protecting the interests of the authors and inventors in such knowledge.

However, TRIPs or other WTO documents do not provide any guidance on interpretation and implementation of these general provisions. Furthermore, this balancing has to work efficiently in the backdrop of some fundamental differences between TRIPs and human rights philosophy: (*a*) The overall thrust of TRIPs is the promotion of innovation through the provision of commercial incentives. The various links with the subject-matter of human rights—the promotion of public health, nutrition, environment and development—are generally expressed in terms of exceptions to the rule rather than the guiding principles themselves, and are made subject to the provisions of the Agreement. (*b*) While the Agreement identifies the need to balance rights with obligations, it gives no guidance on how to achieve this balance. The Agreement only alludes to the *responsibilities* of patent-holders that should balance those rights in accordance with its own objectives. (*c*) Like any international treaty, TRIPs takes away a degree of autonomy from States. Prior to TRIPs, States were free to decide the level of protection they would give to cover a technology they saw as relevant to their development and public needs. (*d*) The protection contained in the TRIPs Agreement focuses on the forms of protection that have developed in industrialised countries. For example, in case of patents, protection in the Agreement is most relevant to the protection of modern forms of technology, such as biotechnology, and to innovators situated in a selected number of industrialised countries.

Because of ambiguity on some fundamental issues, numerous controversies have arisen in the past. For example, when the South African Government sought to allow compulsory licences and parallel imports of HIV/AIDS drugs, it met with stiff resistance from the multinational pharmaceutical companies with the backing of the US and the EU. From 2001 onwards, however, there have been a few positive developments on this issue which indicate a trend to approach intellectual property from human rights perspective.

The Doha Declaration

The "Declaration on TRIPs and Public Health", adopted at the Fourth WTO Ministerial Conference in 2001 at Doha, openly acknowledged that the public health problems in many countries were in part a result of the intellectual property regime under the TRIPs Agreement. The Declaration was significant because it intended to dispel the notion that the intellectual property regime under TRIPs solely concentrates on a trade-motivated agenda and has no place for human rights concerns.

The Declaration proposed a balancing approach to the interpretation of the TRIPs Agreement. In the first four paragraphs of the Declaration it was agreed that the TRIPs Agreement had to be a part of a wider national and international action to address the grave public health problems afflicting many developing and least developed countries, especially the problems resulting from HIV/AIDS, tuberculosis, malaria and other epidemics. Paras 3 and 4 stated that the intellectual property protection is important for the development of new medicines and reiterates the commitment to TRIPs. On the other hand the paragraphs also acknowledge the effect of intellectual property protection on drug prices and state that TRIPs should not prevent members from taking measures to protect public health.

However, the Declaration failed to provide any substantive guidelines to the Governments on measures that could be taken to overcome the intellectual property barrier while making available cheap medicines. The Declaration left open all the possibilities that already existed under the TRIPs Agreement in the all important para 5. Read in the context of the TRIPs Agreement, the paragraph reiterates that member States can have provisions relating to parallel importing, or use the Article 30 exception, or use the option of compulsory licensing. In relation to compulsory licence the member States given a right to determine what constitutes a "national emergency". According to Article 31(*b*) of TRIPs, in case of a "national emergency" there is no prerequirement for a proposed user of the compulsory licence to make efforts from the patent-holder to obtain authorisation on reasonable commercial terms and conditions. Thus, if there exists a "national emergency", grant of a compulsory licence should be relatively easy. But the Doha Declaration did not define any parameters for declaration of a national emergency and merely provided that "public health crisis, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics can represent a national emergency or other circumstances of extreme urgency".

The Declaration acknowledged that the compulsory-licence approach fails where a country has insufficient or no manufacturing capacities in the pharmaceutical sector. For such types of cases, it was left to the TRIPs Council in para 6 of the Declaration to find "expeditious solution to this problem and to report to the General Council before the end of 2002". But a solution was reached by the TRIPs Council only on 30-8-2003, just a few days before the Cancun Ministerial Conference, where the US feared a backlash from a strong and determined developing world. Prior to that, the US was the only country that wanted to restrict the scope of diseases covered under para 6 of the Declaration and was not willing to agree to the proposals that wanted a specific reference to the public health

problems afflicting many developing and least developing countries, especially resulting from HIV/AIDS, tuberculosis and malaria.

Decision of the TRIPs Council

The Council for TRIPs Decision on the "implementation of para 6 of the Doha Declaration on the TRIPs Agreement and public health", waives the obligations set out in paras (*f*) and (*h*) of Article 31 if certain exceptional circumstances exist. A developing country can import the drugs, after notification to the Council for TRIPs, only in limited circumstances such as a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In the notification, the developing country, apart from other things, would need to confirm that the member has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for that product. In case the imported product is already under a patent, the developing country would also need to confirm that a compulsory licence has already been granted. The importing country is also under an obligation to take reasonable measures to prevent re-exportation of the products that have actually been imported into their territory and to ensure that the imported products are used for public health purposes only. The importing country is not obliged to pay "adequate remuneration" as set out in Article 31(*h*) of TRIPs if the exporting country has already done so.

The Council for TRIPs Decision on the "implementation of para 6 of the Doha Declaration on the TRIPs Agreement and public health", waives the obligations set out in paras (1) and (2) of Article 31 if certain exceptional circumstances exist. A developing country can import the drugs, after notification to the Council for TRIPs, only in limited circumstances such as a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In the notification, the developing country, apart from other things, would need to confirm that the member has established that it has insufficient or no manufacturing capacities in

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On the other hand, the compulsory licence granted by the exporting member has to include the condition that the product to be exported under compulsory licence should be clearly identified through specific labelling or marking. Such identification could be through special packaging or special colouring or shaping of the products, provided it does not impact the price significantly. The exporting country is also obliged to pay adequate remuneration to the patent-holder taking into account the economic value to the importing country. The Decision also alludes to the general responsibility of all member countries: (*a*) ensuring effective legal means to prevent importation and sale of the products using the waiver, and (*b*) promoting transfer of technology and capacity building in the pharmaceutical sector to overcome the problem identified in para 6 of the Doha Declaration.

The Decision of the TRIPs Council signified the three approaches proposed by the Doha Declaration. The international community agreed for compulsory licensing. The Decision also highlighted the great apprehension within the developed countries that drugs allowed for export could be diverted to other countries for commercial purpose and could harm the commercial prospects of the patent-holder. As a result of this concern, there was a specific provision for labelling or marking either

through special packaging or special colouring or shape of the drugs. The Decision also allowed WTO to second-guess the granting of individual compulsory licences to the generic industry.

Canadian Patent Act amendment

In May 2004, Canada became the first country to amend its patent law to allow for the use of patents for international humanitarian purposes. The amendment would allow the Canadian generic pharmaceutical companies to obtain compulsory licences to manufacture generic medicines and export them. The new law specifies the criteria under which the countries are eligible for importing the generic medicines. [43] The countries are listed in Schedules 2, 3, and 4 on the basis of their belongings to the categories of least developed country, a WTO member, a non-WTO member or a country listed for official development assistance by OECD. The amendment incorporates provisions on how a country could be included in or excluded from the list. There is also a list in the form of Schedule 1 containing 56 drugs that are permitted for exports from Canada.

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Schedule 1 containing 56 drugs that are permitted for exports from Canada.

The amendment seeks to follow up on the decision of the TRIPs Council. The amendment serves a timely reminder to the international community that the Doha Declaration and the Decision of the TRIPs Council should not become a dead letter law and steps need to be taken immediately for their effective implementation. However, the provisions of the Bill if taken collectively have the ability to hamper the move to export the drugs and address effectively a public health crisis elsewhere.

Firstly, the Schedules limit the number of drugs that could be exported out of Canada and also the countries that would be eligible for importing the drugs. Schedule 1 is limited mostly to drugs for the treatment of HIV/AIDS, malaria and tuberculosis, even though there are no restrictions in the Decision of the TRIPs Council on drugs for the treatment of these three diseases. Similarly, only the listed countries would be allowed to import the drugs. Furthermore, the process of including a new country in the Schedules could be quite cumbersome and might have to face bureaucratic roadblocks considering the fact that recommendation from three different Ministries would be required.

Secondly, an applicant for a licence would have to give an undertaking that within 30 days prior to filing the application he sought a licence from the patentee to manufacture and sell the drug on reasonable terms and conditions and that such efforts were unsuccessful. Such a requirement not only runs counter to the objectives of the TRIPs Council Decision but is entirely unnecessary in view of Article 31(*b*) of the TRIPs Agreement.

Thirdly, the issue of royalty and non-commercialisation of the exported drugs could turn out to be most legally troublesome. The amendment gives the Governor-in-Council the authority to determine the royalty,

taking into consideration the humanitarian and non-commercial reasons for the licence. However, the Federal Court has been given the power to enhance the royalty earlier fixed on an application from the patentee. The Federal Court would take into account (*a*) the humanitarian and non-commercial reasons, and (*b*) the economic value of the use of the invention in the importing country. Moreover, the Federal Court has been authorised to terminate the licence if among other things, the authorisation-holder fails to pay, within the required time, "any" royalty required to be paid or the product gets exported to a country other than authorised to import the drug. It is important to note that this last condition does not have any requirement of knowledge on the authorisation-holder's part and any deviation of the goods, other than in the normal course of transit, would allow a patentee to approach the Federal Court for termination of the licence. Finally, determination of whether a contract entered into by a generic manufacturer is commercial in nature or not could also invite vexatious litigation. The average price of the drug cannot be equal to or greater than 25% of the average price in Canada. If this is true, then the agreement would be termed as a commercial agreement and could lead to either termination or payment of additional compensation over and above the royalty amount. However, if an audit proves that the average price of the product is less than the total of the cost of the direct supply of the product and 15 per cent of that direct supply cost, no order of termination or payment of additional compensation could be made.

Conclusion

The journey from the Doha Declaration to the latest amendment to the Canadian patent law highlights that the international community accepts that intellectual property rights have a significant bearing on issues relating to human rights and corrective steps are required on that front.

There seems to be an increasing willingness to accommodate human rights concerns in the intellectual property law. However, certain shortcomings, as seen from an analysis of the three documents, still remain. It is too early to predict if the system as contemplated under the TRIPs Council Decision and the Canadian amendment would be successful, and if it would be able to provide a sound legal framework under which life-saving drugs at affordable prices could be provided to the poor.

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The concern over divergence of the drugs to third world countries or using them for commercial purposes reflected in the TRIPs Council Declaration and the Canadian amendment also highlight the underlying tension between intellectual property law and human rights i.e. how to have a system in place that guarantees adequate protection to a patent-right holder while keeping in view the public welfare. It is imperative that for a stable solution the debate focuses on the justifications for intellectual property rights—a statutorily granted right and human rights—rights that are inherent in every human being, and the interplay between

these two rights. Patents may be of vital importance for specific industries, like pharmaceuticals, and may go a long way in encouraging research and development in new drugs, but the effectiveness of the current system needs to be thoroughly assessed from a human rights perspective.

From an Indian point of view, it is equally important that the national patent law also reflect a social commitment. The Patent Act of 1970 was highly instrumental in keeping the drug prices under control and promoting the Indian pharmaceutical industry, which in recent years has emerged as a strong contender to the western pharmaceutical industry. More importantly, Article 21 of our Constitution casts a total and absolute obligation on the State to preserve life. The Supreme Court has time and again categorically emphasised that Article 21 also includes within its ambit the right to health. Article 47 in the directive principles of the Constitution also stresses on the improvement of public health and the Government has an obligation to regulate the prices of drugs and medicines so that they are made available to the citizens at affordable prices. Thus, before a further amendment is carried out to the patent law, the Indian policy-makers need to realise the importance of the recent international developments and our constitutional obligation to "right to health".

2. CHILD LABOUR: THE ERITREAN SCENARIO

The child's place is the home and second home is the school. It is the prophecy in some sacred books "child is the incarnation of God" and such child should not be put to work at such age. It is the age of learning and not earning. This paper is concerning child labour in Eritrea which highlights a few causes of child labour and an attempt is made to highlight certain issues with their remedies which would be a beginning or first step to stir up issues involved regarding such evil.

In Eritrea generally those persons who are under the age of 18 years are divided into two categories. Under the first category fall those who are under the age of 14 and under the second category fall those who are between the ages of 14 to 18 years. The first category is generally what we call children and according to Proclamation No. 8/91 (an amended Labour Code under Eritrean Labour Proclamation No. 118/2001 has been enacted on 15-11-2001 repealing Labour Proclamation No. 8/1991), the employment of these children is prohibited. The second category is called the "young persons" who according to the proclamation can be engaged in light works that are not dangerous to their health.

There are many causes of child labour — problems like poverty (root cause of child labour), a big family, drop out of school, social attitude, structure of labour market, divorce etc. In divorce, the children deprived of parental love and affection which affects them morally, leave their home and quit school and try to earn themselves. Such child can be abused as well as harassed by the employer either in the formal sector or the informal sector. When we speak of culture, we see especially in rural areas, a boy of six or seven years is herding cattle and in case of a girl, she is a maid for her family or she may be employed in houses for doing domestic work. In the capital of Eritrea, in most places it is observed that the boys are engaged in boot/shoe polishing and girl children are working