CHAPTER –VI

HUMAN RIGHTS AND CONSTITUTIONAL
DIMENSIONS OF INTELLECTUAL
PROPERTY RIGHTS
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6.1 Introduction

In the present day, world human rights norms have become the rule of the day to measure the sustainability of cultures, religions, ideologies, and the practices of states, international organizations, and even corporations. The moral significance of and practical respect for human rights has grown so much that human rights are now described as a global religion. They have established a new standard for civilization. Just as raw materials and labour were key resources in the first industrial revolution, intellectual property is a central asset in information or knowledge-based economy. The manner in which creative works, cultural heritage, and scientific knowledge are turned into property has significant human-rights implications.\(^1\) Recently there is an emergence of discontentment, which is termed as the human rights paradox in intellectual property. “The allocation of rights over intellectual property has significant economic, social and cultural consequences that can affect the enjoyment of human rights”\(^2\). As a concept, knowledge covers vast ground and has multiple meanings. In the present day, the term ‘knowledge economy,’ is used to refer to the importance of knowledge as a contemporary commodity. We are living in a world in which the moral legitimacy of cultures, religions, ideologies, and the practices of states, international organizations, and even corporations

\(^1\) Audrey R. Chapman, “Approaching intellectual property as a human right: obligations related to Article 15 (1) (c)”, Copyright bulletin, UNESCO PUBLISHING, Vol. XXXV (July–September 2001), digital version available @http://unesdoc.unesco.org/images/0012/001255/125505e.pdf

is being measured against human rights norms.\textsuperscript{3} Intellectual property regimes have moved to the centre stage of trade regulation and global markets. The old capitalism was a capitalism of goods, factories and labour. But now factories and labour, even skilled labours are in abundant supply. The new capitalism is at its core about the control of information and knowledge. It is for this reason that issues concerning the design of intellectual property rights have become so important and pressing.\textsuperscript{4}

Since the establishment of the World Trade Organization and the entering into effect of the Agreement on Trade-Related Aspects of Intellectual Property Rights, government officials, international bureaucrats, intergovernmental and nongovernmental organizations, courts, and scholars have focused more attention on the interplay of human rights and intellectual property rights. The International Covenant on Economic, Social and Cultural Rights is in many ways the most crucial legal instrument through which the relationship between the two fields can be examined.\textsuperscript{5} First, it recognises, for instance, the rights to health and food, which are some of the rights whose realisation can be affected in developing countries that adopt or strengthen intellectual property rights frameworks; based on the commitments they take under the TRIPS Agreement or other intellectual property rights treaties. Secondly, it recognises the need to reward individuals and groups that make specific intellectual contributions that benefit society\textsuperscript{6}. It must be noted at the outset that the rewards, which are recognised under the Covenant, are not related to existing intellectual property rights regimes. There may be cases where the

\textsuperscript{5} International Covenant on Economic, Social and Cultural Rights, Adopted and opened for signature, ratification and accession by General Assembly resolution 2200A (XXI) of 16 December 1966  
\textsuperscript{6} \textit{Ibid}, Article 15(1) c
realisation of this right may be effected through existing intellectual property rights but overall, there is no necessary correspondence between the rights recognised in the Covenant at Article 15 and existing intellectual property rights.

**Article 15 of the Covenant reads as under**-

1. The States Parties to the present Covenant recognize the right of everyone:
   
   (a) To take part in cultural life;
   
   (b) To enjoy the benefits of scientific progress and its applications;
   
   (c) To benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.

2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for the conservation, the development and the diffusion of science and culture.

3. The States Parties to the present Covenant undertake to respect the freedom indispensable for scientific research and creative activity.

4. The States Parties to the present Covenant recognize the benefits to be derived from the encouragement and development of international contacts and co-operation in the scientific and cultural fields.

   It is noteworthy that the Covenant provides a basis for the recognition of all intellectual contributions and they need not fit into the existing intellectual property rights paradigm. In other words, Article 15(1) c of Covenant is broad enough to accommodate the claims of traditional knowledge holders for instance.

   The Committee on Economic, Social and Cultural Rights, which oversees the implementation of the Covenant, decided to examine in more detail the relationship
between contributions to knowledge and human rights several years ago. The Committee started by focusing on the impacts of existing intellectual property rights on the realization of human rights. This culminated in the adoption of a Statement issued in 2001.\(^7\) Subsequently the Committee undertook the preparation of a politically and legally more significant document in the form of a General Comment. It is adopted at the next session of the Committee in November 2004. This General Comment constitutes an authoritative interpretation of Article 15(1) c of the Covenant. Unlike the 2001 Statement, the General Comment focuses mostly on the rights of individual contributors to knowledge and gives little space to questions concerning the impacts of intellectual property rights on human rights.

### 6.2 Human Rights, Contributions to Knowledge and Intellectual Property Rights

There are at least two ways in which links between human rights contributions to knowledge and existing intellectual property rights can be analysed. First, existing intellectual property rights can have impacts on the realisation of human rights recognised in the Covenant such as the right to food or the right to health. These can be positive or negative impacts depending on the specific legal regime, which is introduced. In the context of the introduction and strengthening of intellectual property rights standards brought about through the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) in developing countries, intellectual property rights raise a number of concern with regard to their impacts on the realization of human rights in general and the right to health and to food in particular. Secondly, the Covenant includes at Article 15

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a number of rights, which are related to culture and science. Article 15(1) is particularly important and reads as follows:

The States Parties to the present Covenant recognize the right of everyone:

a) to take part in cultural life;

b) to enjoy the benefits of scientific progress and its applications;

c) to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.

The relationship between human rights and intellectual contributions was a topic of debate during the drafting of the Covenant. However, it came into the limelight because of problems faced by developing countries in the context of their implementation of the TRIPS Agreement. In the past decade, there has been increasing interest for these questions and different bodies have addressed certain aspects of the issue. The Sub-Commission on Human Rights has, for instance, come to the conclusion that—Since the implementation of the TRIPS Agreement does not adequately reflect the fundamental nature and indivisibility 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 intellectual property rights regime embodied in the TRIPS Agreement, on the one hand, and international human rights law, on the other.

Following what became a highly public controversy concerning access to drugs, medical patents and the right to health in the context of the price of HIV/AIDS drugs in sub-Saharan African countries most affected by the epidemics, the ESCR Committee

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decided to first adopt a statement on intellectual property rights and human rights in 2001 as a first step towards the adoption of a General Comment. The 2001 Statement was adopted in the wake of the collapse of the case filed by pharmaceutical companies against the South African government for attempting to limit their patent rights and the Doha Health Declaration adopted by the 2001 Ministerial Conference of the WTO.\(^9\) In this Statement, the ESCR Committee specifically argued that the protection of the moral and material interests of authors must be balanced with the right to take part in cultural life also introduced at Article 15. It argued that intellectual property protection must serve the objective of human well-being, which is primarily given legal expression through human rights.\(^10\) In other words, intellectual property regimes should promote and protect all human rights.\(^11\) More specifically, the Committee stated that any intellectual property rights regime that would make it more difficult for a state to comply with its core obligations in relation to the right to health and food would be inconsistent with the legally binding obligations of the concerned state.\(^12\) Thus, the Statement was concerned with the impacts of intellectual property rights over the enjoyment of human rights.

The proposed General Comment was meant to build on the Statement and to provide a more elaborate interpretation of the relationship between human rights and intellectual property rights. The first general characteristic of the draft General Comment is that it adopts a much narrower focus than the Statement. First, it focuses only on questions related to the recognition of intellectual contributions as human rights and only


\(^{10}\) Supra note 7, Paragraph 4

\(^{11}\) Ibid., Paragraph 5

\(^{12}\) Ibid., Paragraph 12
makes passing comments on the impacts of existing intellectual property rights on the realisation of human rights in general. Secondly, even within the context of this narrow framework, the draft General Comment carves itself an even narrower niche by focusing exclusively on sub-paragraph (c) of Article 15(1) which provides that the benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author are to be recognised. In other words, it focuses on the interests and rights of the individual author and inventor and leaves aside the other parts of Article 15(1) which focus on everyone’s right to benefit from the development of science and to enjoy their own culture.

The rest of this chapter examines in more detail some of the main issues that arise from the existing draft General Comment. It first analyses some issues related to the recognition of intellectual property rights as human rights and then examines questions concerning the impact of existing intellectual property rights regimes on the realisation of human rights. Finally, it also examines some ways in which an intellectual property rights approach to human rights could be made more relevant in today’s world

6.3 Intellectual Contributions in a Human Rights Context.

The notion that IPRs promote development remained uncontested for a long time. International policymaking and norm setting in the field of intellectual property focused almost entirely on ensuring that national intellectual property regimes provided strong protection for right holders, with the presumption that benefits would then accrue for developing countries\(^\text{13}\). However, in the past several years, the impact of intellectual property rights on basic human rights has come under increased scrutiny. Motivating this

are highly publicized cases where IPRs appear to threaten access to particular medicines and diagnostics. As IPRs become globalized, so does the controversy. Principally, the current global trade markets have denied developing countries the opportunity to protect the right to access essential medicines appropriately, where they have felt it necessary to sacrifice public health in order to promote economic development in other ways. Developed countries have sustained significant leverage over the less developed by maintaining a highly unequal trade system, which has induced lower income nations to resort to desperate measures to remedy their exclusion.14

The starting point of an enquiry into the place of individual or collective intellectual contributions in a human rights context is Article 15 of the Covenant, which generally talks about science and culture. In general, it seeks to ensure that states provide an environment within which the development of science and culture is undertaken for the greater good of society while recognising the need to provide specific incentives for this to happen. Article 15(1) is more specifically concerned with the balance between the individual and collective rights of all individuals to take part in culture and enjoy the fruits of specific development, and the rights of individuals and groups making specific contributions to the development of science or culture.15 Overall, Article 15(1) is to be seen as a provision, which focuses on society’s interest in culture and the development of science and provides for the recognition of the rights of specific individual or collective contributions to the development of science, arts or culture. Article 15 in general is a provision, which devotes significant attention to culture and science and it recognises the importance of contributors. But this article does not indicate

15 Article 15 (1) (c) of the International Covenant on Economic, Social and Cultural Rights
how the balance between incentives and enjoyment has to be achieved. Further, sub-
section (c) which deals with the reward for individual contributions do not indicate with
any specifically the type of contributions, which are covered here. This has led a number
of people to conclude that Article 15(1) refers to existing intellectual property rights.

Intellectual property rights as currently recognized and enforced in most legal
systems around the world are based on the premise that there must be a balance between
the rights granted to the property rights holder and society’s interest in having access to
novel developments in the arts, science and technology. While intellectual property rights
frameworks introduce rights for individual contributors, they only balance it with what
can be generally seen as recognition of the broader public interest of society in generally
benefiting from artistic or technological advances. Intellectual property rights
frameworks do not recognise everyone’s right to enjoy the ‘benefits of specific progress
and its applications’ as an individual and/or collective right. While the plain reading of
Article 15(1)c may be tempted to make an association with categories of rights
recognised in intellectual property rights frameworks, nothing indicates that Article
15(1)c talks only about existing categories of intellectual property rights. In fact, Article
15(1) c recognise intellectual contributions in general without making any special
reference to one or the other category of existing intellectual property rights. In this
context, it is noteworthy that the draft General Comment takes a position which is largely
based on existing intellectual property rights regimes by referring to everyone’s right to
benefit from the progress of science as an element to be ‘given due consideration’ in
striking the balance with the interests of authors. However, it is unclear whether it refers
to this balance in terms of a right of equivalent standing.
6.3.1 Intellectual Property as Human Right

The Committee interprets ‘scientific production’ as including scientific inventions. This implies that Article 15(1)c is meant to include not only authors who get protection through copyright but also ‘inventors’ who are protected under existing intellectual property rights by patent rights. This interpretation is debatable but the more important point is whether considering ‘inventors’ as ‘authors’ implies that Article 15(1)c must only be analysed with regard to existing categories of intellectual property rights. First, it is instructive that the draft General Comment specifically indicates that certain types of intellectual property rights such as trademarks, which bear no personal link to a creator, are excluded from the protection under Article 15(1) c. Secondly, debates preceding the adoption of Article 15(1) c provide interesting pointers. On the one side, some countries, which are today the greatest defenders of intellectual property rights, were completely opposed to associating intellectual property rights and human rights as a matter of principle. However, most of the states have conceived the issue mostly from the point of view of authors or written work. This indicates that the inclusion of inventors under Article 15(1) c was not an obvious interpretation at the time of the adoption of the Covenant. This also confirms that there is no congruence between the rights recognised at Article 15(1) c and rights recognised in intellectual property rights frameworks. There are no doubt overlaps in certain situations but the content of Article 15(1) c is not circumscribed by existing intellectual property rights frameworks. This article is a very broad provision which covers the IPRs incidentally. Thus, human rights cannot be reduced to single privileges or claims, powers

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or immunities. Rather, they encompass and transcend all these incidences in a way that led Hannah Arendt to characterize them as the “right to have rights.”

6.3.2 Distinction between IPRs and Human Rights

It is apparent that the drafters understand the tension between the analysis they put forward and the underlying human rights framework, which serves as a reference point. On the one hand, the draft brings in inventors within the scope of Article 15(1) c. On the other hand, the draft is at pains to attempt a distinction between the rights recognised under the Covenant and existing intellectual property rights. The draft seeks to emphasize the distinction between human rights and intellectual property rights regimes. Human rights are deemed fundamental, inalienable, universal entitlements while intellectual property rights are statutory rights granted by the state which are temporary, can be traded, and whose enjoyment can be curtailed. The draft General Comment further indicates that while intellectual property rights also protect business interests, human rights do necessarily protect business interests.

However, the draft does not set any boundaries between the rights of the individual author and the rights that may accrue to businesses under intellectual property rights. In the context of innovations protected by patents, for instance, it is becoming increasingly difficult to dissociate ‘individual’ inventors from institutions with which they are associated. The draft General Comment does not seem to take into account the fact that today, there are few, if any, patented inventions which are commercially exploited by the individuals which can be identified as ‘inventors’ from the point of view of patent laws. The Draft’s response is to provide that it is only the ‘basic material

\footnote{17 Hannah Arendt, \textit{The Origins of Totalitarianism}, 2\textsuperscript{nd} edn, (Cleveland: Meridian, 1958), pp.296–297.}
interests’ of authors and inventors that are protected under the Covenant. This constitutes an attempt to distinguish the monopoly rights provided through intellectual property rights from the protection available under the Covenant. This is not a sufficient analytical response because in practice it is difficult to distinguish the material benefits of individuals having contributed to an innovation from those of a company exploiting the innovation. The distinction between IPRs and human rights is better understood by making a parallel comparison with property rights in general. It is shown in the following table.

<table>
<thead>
<tr>
<th>Point of Distinction</th>
<th>IPR</th>
<th>Property Rights in general</th>
<th>Human Rights</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nature and form of right</td>
<td>Privilege or claims</td>
<td>Claims, immunities, and powers are associated.</td>
<td>Every forms of right</td>
</tr>
<tr>
<td>Subject matter</td>
<td>Inventions, expressions, etc.</td>
<td>Created or discovered.</td>
<td>Humanity and human dignity</td>
</tr>
<tr>
<td>Right holders</td>
<td>Corporations and individuals</td>
<td>Individuals and Corporations</td>
<td>Individuals, communities and even groups</td>
</tr>
<tr>
<td>Duty holders</td>
<td>The world at large or all those who do not have this right.</td>
<td>The world at large or all those who do not have this right.</td>
<td>States, governments and even corporations.</td>
</tr>
<tr>
<td>Duration</td>
<td>Limited</td>
<td>Unlimited</td>
<td>Unlimited</td>
</tr>
<tr>
<td>Mode of assertion</td>
<td>Acquired, enjoyed and exercised</td>
<td>Enjoyed exercised</td>
<td>Recognised, Exercised and enforced.</td>
</tr>
</tbody>
</table>

Table 1: *Relationship between IPR and Human Right* 

From this table it can thus be stated that IPR should not be implemented so as to violate and infringe upon human rights. IPR should be subsumed to human rights, national interests and the preservation of genetic resources. In fact, intellectual products

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are basically social products. This should not be forgotten when granting certain 'rights' to innovators. Therefore, Intellectual Property Rights cannot be considered as 'rights' as in the case of immutable human rights. In this sense, Intellectual Property Rights are only certain 'privileges' conferred on individuals or corporate innovators. Overall, a human rights perspective to intellectual contributions will be meaningful if it completely dissociates itself from existing intellectual property rights regimes and examines all intellectual contributions by individuals and groups as falling within the scope of Article 15(1).

6.4 Impacts of Intellectual Property Rights on the Realisation of Human Rights

As noted in the previous section, Article 15(1) c should not be read as referring to existing intellectual property rights but should be seen as being much broader in scope. Existing intellectual property rights are nevertheless of immediate relevance in this field because of the impact they can have on the realisation of human rights. This is at least as important as questions concerning the rewards granted to authors and inventors and should constitute one of the core aspects of a general comment addressing all the main challenges in this area.

The draft General Comment does not completely ignore questions related to the impacts of intellectual property rights on the realisation of human rights and seeks, for instance, to confirm that there is a need to strike an adequate balance between the protection of intellectual property rights and human rights to food, health and education. These kinds of international instruments must be understood and interpreted as providing that there should be a balance between the human rights claims of authors/inventors and the social function of intellectual property rights. In recent years, social issues have
increasingly been integrated into bilateral and regional trade agreements. In other words, the balance is not a question of the relative importance of the human rights to health, food and education on the one hand and intellectual property rights on the other hand. The balance is only the same basic ‘social’ balance, which intellectual property rights regimes seek to achieve. This is of considerable importance because it downgrades fundamental human rights such as the rights to food and health.

The draft General Comment also provides that the parties should therefore ensure that their intellectual property regimes constitute no impediment of their ability to comply with their core obligations in relation to the right to health, food, education, or any other right set out in the Covenant’. This is much closer to the concerns that had been highlighted in the 2001 Statement and to concerns, which have by now been largely recognised as constituting some of the main challenges that all actors involved in the realisation of the rights to health and food must take into account. The Draft recognises that the current expansion of intellectual property rights protection raises significant challenges from a human rights perspective. Thus, it acknowledges ethical issues linked to the patenting of parts of the human body. From the point of view of the realisation of social and economic rights, it is limited in scope as it focuses only on some narrow concerns. From the point of view of the realisation of the human rights to food, health and education, the main implication, which is considered, is that ‘unreasonably high license fees or royalties’ should not undermine their realisation. But, there is no specific acknowledgment that the scope of protection under existing intellectual property rights may be an issue, which needs to be addressed from the perspective of human rights. The

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introduction of product patents in the health sector is, for instance, an important concern in many developing countries. In countries like India, having specific restrictions on product, patents in this field may be construed to be retrogressive step in the realisation of the human right to health unless it is counter-balanced by measures to ensure that people affected by the higher prices of patented drugs do not lose access to these drugs. The most important challenge that the human rights need to address in the days to come is that some of the changes in intellectual property rights frameworks have the capacity to affect the realisation of human rights.

6.5 Additional Links between Human Rights and Intellectual Contributions

To ensure that the WTO treatment of environmental measures permits governments to pursue optimum economic and environmental policies, including international cooperation to address transboundary issues and the protection of the global commons, the following principles should guide the application of WTO rules and, in particular, Article XX.

a) Prices for tradable goods should reflect true social costs. In particular, prices should include the costs of environmental externalities.

b) The values societies assign to environmental externalities are affected by geography, culture and income levels. For domestic problems, national governments are the most competent to assign values to externalities.

c) For environmental problems having a transnational dimension, international agreements among governments are the best means to assign values. Measures to implement and enforce these agreements should be the least trade-restrictive necessary to accomplish their objectives.
d) International environmental problems are identified by consensus among affected parties about the nature of the problem and the goals to be accomplished – for example, sea turtles are an endangered species and should be protected.

Thus the social costs, environmental externalities, transnational environmental problems, and issues pertaining to lives in seas are covered by these rules.

Even in the field of intellectual property rights, the balance between the rights of the author/inventor and the interests of society are recognised. In any case, Article 15(1) goes much further since it puts all the rights including IPRs on the same level and can in fact probably be read as putting everyone’s right to benefit from the development of science as being more important than the interests and rights of authors/inventors.

The limitations of a General Comment focusing only on one sub-section of Article 15(1) are readily apparent. What is less immediately visible and more significant is the fact that the draft General Comment misses out an opportunity to adopt a more comprehensive view of what constitutes intellectual contributions and an opportunity to use the possibly unfortunate inclusion of Article 15(1)c in the Covenant to use it to the benefit of those who are most disadvantaged within the existing legal framework and do not get recognition for their intellectual contributions through the existing intellectual property rights system.

Article 15(1) c should not be narrowly interpreted to include and justify the present IPRs alone. It covers the intellectual contributions made by different individuals or communities to knowledge. This is neither new nor controversial. In the past ten years, significant developments have taken place around the introduction of so-called *sui generis* forms of intellectual property rights to ensure that actors who cannot be rewarded
under existing intellectual property rights are provided some form of legal protection. Two main issues have been considered. First, in the context of Article 27(3) b of the TRIPS Agreement, the question of plant variety protection has given rise to proposals for the protection of farmers’ rights besides the rights granted to patent holders and commercial plant breeders. While an international definition of farmers’ rights remains elusive at the international level, several developing countries have already attempted to operationalise the concept of farmers’ rights in their legislation. Secondly, in recent years, there has been an increasing focus on the development of legal forms of protection for traditional knowledge. At the international level, debates have not proceeded beyond the stage where traditional knowledge is considered as an issue, which must be addressed. However some countries have passed legislations on the protection of Traditional Knowledge.

The inclusion of farmers and traditional knowledge holders in the scope of Article 15(1) c is an indication that this law can also be relevant to today’s challenges. As long as intellectual contributions are equated with existing intellectual property rights, Article 15(1) c can only serve to justify the existence of intellectual property rights and to limit debates concerning the impacts of intellectual property rights on the realisation of human rights. Generally, human rights bodies need not concern themselves with existing intellectual property rights. For instance, patent holders are today more than adequately rewarded by existing intellectual property rights regimes in almost all countries. This is not the case for informal innovators such as farmers and traditional knowledge holders who are not rewarded in existing legal frameworks. In keeping with the recognition that

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20 India’s Protection of Plant Varieties and Farmers’ Rights Act of 2001 is the most far-reaching legislation with regard to establishing rights for farmers to save, use, exchange and sell farm-saved seed.
the implementation of human rights must be judged according to its impacts on the weakest and most disadvantaged sections of society, Article 15(1) c should be construed as providing one of the few avenues through which a comprehensive perspective on intellectual contributions can be taken. In other words, there are inventors and innovators, such as individuals and communities who constantly update and improve traditional knowledge that do not benefit from existing intellectual property rights regimes but deserve as much as other creators to benefit from the protection of the moral and material interests attached to their intellectual contributions. At this level, the existing Draft takes into account some of the specific problems faced by indigenous peoples but it needs to go much further to consider all traditional knowledge innovators and the need to find new ways to protect their innovations and intellectual contributions besides the existing intellectual property rights system. Ideally, there has to be a solid integration between the IP and human rights regimes. The two regimes have a great deal to learn from each other. Viewing intellectual property through the prism of human rights discourse will encourage us to think about ways in which the property mechanism might be reshaped to include interests and needs that it currently does not.

Intellectual property experts can bring to the aspiration of human rights discourse regulatory specificity. In other words the IP experts can supply the specific regulatory mechanisms to be adopted within the human rights regime.

It is conceivable that solutions that are acceptable to the majority of political participants in the international community can be reached even where the two regimes—

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human rights and free trade—clash. In this way, it can be argued that the relationship between human rights and intellectual property is not, and should not be viewed as total contradiction.

6.6 Human Rights Realization in the Intellectual Property Regime; the Indian Experience

India and some developing countries are trying to combine their respective constitutional socialism with the free market ideology at different points of time and in different ways. India began this nexus in 1991 when the government adopted the New Economic Policy (NEP) of privatisation, liberalisation, disinvestment and deregulation. Ultimately the Supreme Court settled the issue by upholding constitutional validity of privatisation and disinvestment in specific instances.

Human rights philosophy provides a critical base through which human needs are transformed into legal entitlements. The spiritual value of human rights demands action from state institutions and agents. Human rights therefore not only hold the potential to alter the behavioral incentives currently driving the system but, as law intimately linked to social design, may provide a mechanism capable of reforming the system itself. Access to essential medicines is a fundamental human rights claim under the rights to health and life. In State of Punjab v. Devans Modern Breweries Ltd., Indian Supreme Court has gone to the extent of observed, “Socialism might have been a catchword from our history.

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24 Delhi Science Forum v. Union of India, AIR 1996 SC 1356; Balco Employees Union v. Union of India, AIR 2001 SC 350
It may be present in the Preamble of our Constitution. However, due to the liberalisation policy adopted by the Central Government from the early nineties, this view that the Indian society is essentially wedded to socialism is definitely withering away.”\footnote{State of Punjab v. Devans Modern Breweries Ltd., (2004) 11 SCC 26, 148 (emphasis added). (In this case, the Court also pushed for an economic interpretation of the Constitution; an interpretation which is suitable in the changed economic environment both at the national as well as international levels).}

Despite this development, it is fair to say that the Indian government is aware of growing economic disparity and has not totally forgotten its social welfare commitments under the Constitution. This goes to show that the marriage between a socialist constitution and the free market ideology is riddled with some tensions.

**NOVARTIS: Case Comment**

A Switzerland based pharmaceutical company; Novartis AG filed a patent application in the Chennai (Madras) Patent Controller’s office for the beta-crystalline of *imatinib mesylate*, brand name *Glivec (Gleevec)*.\footnote{Application No. 1602/MAS/1998, dated July 17\textsuperscript{th} 1998.} The claim was based on the ground that it invented the beta crystalline salt form (*imatinib desolate*) of the free base, *imatinib* to produce leukemia drug. This application was kept in the mailbox and not opened until 2005 as the TRIPS Agreement permitted developing countries such as India not to provide product patent protection to pharmaceuticals and agrochemicals until 1 January 2005.

In the meantime, Novartis had obtained Exclusive Marketing Rights (EMR) for marketing *Gleevec* in India. On the basis of this, it obtained orders preventing some of the generic manufacturers from manufacturing and selling generic versions of the medicine. At that time, Novartis was selling *Gleevec* at USD 2666 per patient per month.
Generic companies were selling their generic versions at USD 177 to 266 per patient per month.

In 2005, India went for patent law amendment to comply with its obligations under the TRIPS Agreement. By virtue of this process and product patent protection in all fields of technology, including pharmaceuticals and agrochemicals has been introduced. A significant and important provision to prevent ever greening and granting of frivolous patents is introduced thereby. Consequent to this some of the generic companies filed pre-grant oppositions against Novartis’ patent application for *imatinib mesylate*, claiming, among other things, that Novartis’ alleged “invention” lacked novelty, was obvious to a person skilled in the art, and that it was merely a “new form” of a “known substance” that did not enhance the substance’s efficacy, and was thus not patentable under section 3(d). It was contended that the patent issued in 1993 effectively disclosed both the free base, *imatinib*, and the acid-addition salt, *imatinib mesylate*. Further, CPAA and generic companies argued that different crystalline forms of *imatinib mesylate* did not differ in properties with respect to efficacy, and thus the various forms of *imatinib mesylate* must be considered the “same substance” under section 3(d).

**Novartis’ patent application rejected by Patent Controller [January 2006]**

The Patent Controller refused to grant Novartis a patent, by holding that invention lacked novelty and was obvious, and hence was not patentable under section 3(d). Generic companies could manufacture and market their generic versions of the drug, both

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28 See Sec.3 (d) of the Patents Act.
29 The opposition was based on the fact that Novartis had already been granted a patent in 1993 in the United States and other jurisdictions for the active molecule, *imatinib*, and that the present application only concerned a specific crystalline form of the salt form of that compound.
30 US Patent Application No. 08/042,322). This application was abandoned and another continuation-in-part application was then filed on April 28, 1994 (US Patent Application No. 5,521,184).
in India and abroad, and make available the generic *imatinib mesylate* priced at less than one-tenth of Novartis’ price after this decision.

In June 2006, Novartis AG and its Indian subsidiary, Novartis India, filed a series of writ petitions against the Government of India, CPAA, and four Indian generic manufacturers (Natco, Cipla, Hetero and Ranbaxy), before the Madras High Court. The decision of the Patent Controller to refuse Novartis a patent for the beta-crystalline form of its anticancer drug, *imatinib mesylate*, as well as the validity of section 3(d) that provided one of several grounds for rejecting its patent application as challenged in these litigations.

For the purpose of judicial convenience, the writ petitions challenging the decision of the Patent Controller were converted into statutory appeals. In April 2007, the Government of India notified that the IPAB got jurisdiction to hear appeals relating to patents.\(^{31}\) Consequently, Novartis’ appeals were transferred to the IPAB, a specialist tribunal on matters relating to intellectual property.

**Constitutional validity of section 3(d) upheld by Madras High Court [August 2007]**

Meanwhile, in August 2007, the Madras High Court rejected Novartis’ writ petition\(^{32}\) challenging the validity of section 3(d). The Madras High Court refused to examine whether section 3(d) was in compliance with the TRIPS Agreement.

The Court held that section 3(d) was not vague or arbitrary and therefore did not violate the Indian Constitution. It held that the term “efficacy” was known in the pharmaceutical field to mean “therapeutic efficacy”.

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\(^{31}\) Government of India Notification No.12/15/2006-IPR-III

\(^{32}\) W.P. No.24759 of 2006
The court observed: “We have borne in mind the object which the Amending Act wanted to achieve namely, to prevent evergreening; to provide easy access to the citizens of this country to life saving drugs and to discharge their Constitutional obligation of providing good health care to its citizens.”

**The litigation before the IPAB**

After a series of litigation in which Novartis contested the constitution of the IPAB, Novartis’ appeal challenging the Patent Controller’s order was finally heard by a specially constituted Bench of the IPAB, comprising Justice Negi (Chairperson) and Dr PC Chakraborty (Technical Member) in November and December 2008.

The IPAB overturned the Patent Controller’s findings on novelty and inventive step, held that the beta-crystalline form of *imatinib mesylate* was new, and involved an inventive step. However, the IPAB held that Novartis’ alleged invention did not satisfy the test of section 3(d) in as much as Novartis did not provide data to show that the beta-crystalline form of *imatinib mesylate* exhibited significantly enhanced therapeutic efficacy over *imatinib mesylate*, the known substance. Hence, the appeal was rejected and the beta-crystalline form of *imitanib mesylate* was again rejected.

**Proceedings before the Supreme Court**

Novartis approached the Supreme Court directly by filing a special leave petition challenging the IPAB’s interpretation and application of section 3(d) to its patent application. Subsequently, CPAA and Natco filed cross-petitions challenging the IPAB’s findings on other issues including novelty and inventive step. The Supreme Court of India on April 1, 2013 rejected Novartis’ appeal for patent protection for its blood-cancer.

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33 CIVIL APPEAL No. 2728 OF 2013
treatment drug “Glivec”, which was held an “incremental innovation” not liable for protection.

The Supreme Court confirmed that the beta crystalline form of imatinib mesylate failed the test of Section 3(d). The Court clarified that efficacy as contemplated under Section 3(d) is therapeutic efficacy. The judgment has received severe criticism from a number of originator pharmaceutical companies, including Novartis, and from the US Chamber of Commerce.

The case involves a many complex technical issues. They are discussed as under:

1) The Patents Act as amended in 2005 is reflected in this considered Parliament sought to limit practices that might result in the grant of patents for insubstantial technological contributions. Section 3(d) along with it explanation require that patents for new forms of known substances should only be granted on the showing of a significant enhancement in known efficacy.

2) The WTO TRIPs Agreement, provide sufficient leeway or flexibility in the adoption of patenting standards to allow the approach adopted by the Indian Parliament.

3) The facts of this case involved certain transitional arrangements between the pre-2005 Indian patent system, which did not allow patents for pharmaceutical products, and the post-2005 regime under which such patents are permitted. For patent applications filed (with priority date) before 1 January 1995, a patent could not be secured in the India for a pharmaceutical product. From 1995 to 2005, pharmaceutical product patent applications could be filed and held in a “mailbox”. A patent could be granted and become effective after 1 January 2005, based on “mailbox application”.
4) The Court considered the fact that Novartis had already secured its patent in US and this makes the invention concerned obvious. This is a warning that Indian law provided for patenting of only genuine inventions and has provisions for discouraging repetitive patenting, generally known as ‘evergreeing’ in the industry.\textsuperscript{34}

5) In 1998, Novartis filed as application in India for this beta crystalline form. The application did not disclose any improvement in efficacy. However, when India adopted section 3(d) in 2005, Novartis undertook some studies to meet the statutory requirement to show enhanced efficacy.

6) The Supreme Court concluded that it was a publically known product. The mesylate salt was the form in which the drug was marketed. To satisfy the requirement of “enhanced efficacy” in section 3(d), comparison of the beta crystalline form had to be made with the already known mesylate salt. In light of this, the Indian Supreme Court found the efficacy studies reported by Novartis very odd. Novartis alleged that the beta crystalline form showed a 30% increase in “bioavailability” (based on tests in rats). But this 30% increase in bioavailability was not in comparison to the known and previously marketed mesylate salt form of the drug, which would ordinarily by soluble, but rather in comparison to the “free base” from of the imatinib drug that was not marketed because it was not soluble. So, Novartis did not compare its “new” from of salt to its “old” marketed form of salt, but rather to what it knew would be a much less bioavailable from. There was no evidence in the record as to how the new salt compared to the old salt even in terms of bioavailability.

\textsuperscript{34} See more at: http://www.witnesslive.in/in-depth/65-the-conclusion-of-novartis-saga#sthash.QruaAQie.dpuf
7) The term “efficacy” in Section 3(d) requires that the new form of a drug must demonstrate an improvement in its therapeutic effect or curative property as compared to the old form in order to secure a patent. The Court held that these properties may be important from storage point of view, but would not be relevant to showing “enhanced therapeutic efficacy”.

8) As previously noted in this chapter, Novartis also presented evidence regarding increased “bioavailability”. The Court observed that “bioavailability” measures the level at which the drug is made available in the human body. The level of bioavailability may or may not have an influence on the therapeutic or curative effect of the drug.

9) At the very end of the decisions, in requiring Novartis to pay the costs of the challengers, the Court said that it appeared that Novartis was in fact marketing an older form of the drug and not the beta crystalline version, and that it appeared that Novartis may have been trying to use a patent in India to cover a drug that it was not actually selling.

The Novartis threatened to withdraw its investment from India. But such threats or actions cannot make big impact. Such threats have been scoffed at as the R&D expenditure of Novartis India in 2012 constituted roughly 0.03 percent of its entire expenditure in India.\(^\text{35}\)

Novartis itself has said that it will now “cautiously” invest in India. The common accusation is that the Indian Judiciary takes an activist approach when it comes to pharma patents. But this accusation is baseless as the Supreme Court as the custodian of law of

land stands for rule of law. Hon’ble Supreme Court has applied the law to the facts of the case and decided it on merits. The judgment seems to be the consequence of a judicial process, and not an arbitrary executive action. India, a developing country, has a substantial portion of its population below the poverty line, their per capita income not being sufficient to attain the basic amenities of food, clothing, shelter and medication. The patents in India, under the Act, are granted for genuine and innovative drugs only. The Act provides for a high standard of an inventive step, especially with reference to newer and updated version of already known products. Thus, evergreening and repetitive patenting is prohibited and is not encouraged under the provisions of the Indian law pertaining to patents. Therefore, in so far as this case is concerned, the rule of law has been certainly adhered to. Consequently, the judgment certainly cannot be the basis for any unwarranted generalization that India does not respect the Intellectual Property Rights of foreign investors.

6.7 Conclusion

Traditionally, intellectual property regimes sought to balance the rights of creators with the interests of the public to have access to artistic works and the very existence of intellectual property rights was originally justified on the grounds that incentives and rewards to artists and inventors result in benefits to society. However, current developments tend to weaken these balances and to skew the system in favour of a much narrower range of interests. Commercialization has changed intellectual property from a means to provide incentives to researchers and inventors to a mechanism intended to encourage investment and protect the resources of investors. The privatization of the public domain reflects this transformation. Preserving the public domain is important
because it serves as a resource for future creators and as raw material for the market place of ideas. Human rights and Intellectual Property rights, especially patent right regime, are two branches of law that have overcome their initial shyness of each other and are now becoming increasingly intertwined by the day. These two disciplines have developed in virtual isolation from each other for several decades. However, during the past few years, there have been a plethora of international standard setting activities, which have begun to explore the common objectives of patent law on the one hand and human rights law on the other. IPRs have now spread throughout the world by virtue of an intrinsic network of bilateral, regional and multilateral treaties as already discussed in this work. Extensive use of such rights has resulted in varying impacts on human rights. The aim of a ‘human rights approach’ to patents is a desire to obtain an inherent balance between the moral and economic rights of inventors and the interests of the society. An integral component of intellectual property, patents assumed the global importance only during the 20\textsuperscript{th} century. The IPRs consist of the whole array of contrasting rights. Many of them are statutory and they are protected for varying periods. Human rights, on the other hand, mean those basic rights and freedoms to which all humans are entitled, like the right to life and liberty, freedom of thought and expression, and equality before the law, those basic standards without which people cannot live in dignity.

Rules protecting the IPRs are usually highly specific and have very effective enforcement machinery. On the other hand, the human rights set out in international treaties seem vague, indeterminate, non-specific and unenforceable. It would be difficult to use Human Rights treaties to counter rights set out in TRIPS and other IP treaties.