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Access to medicine and the dangers of patent linkage: Lessons from Bayer Corp v Union of India

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In February 2010, the Delhi High Court delivered its decision in Bayer Corp v Union of India in which Bayer had appealed against an August 2009 decision of the same court. Both decisions prevented Bayer from introducing the concept of patent linkage into India’s drug regulatory regime. Bayer appealed to the Indian Supreme Court, the highest court in India, which agreed on 2 March 2010 to hear the appeal. Given that India is regarded as a global pharmaceutical manufacturer of generic medications, how its judiciary and government perceive their international obligations has a significant impact on the global access to medicines regime. In rejecting the application of patent linkage, the case provides an opportunity for India to further acknowledge its international human rights obligations.

INTRODUCTION

On 9 February 2010, the appeal division of the Delhi High Court in India delivered its decision in Bayer Corp v Union of India (unrep, Delhi High Court, Muralidhar J, 9 February 2010),1 rejecting Bayer Corporation’s (Bayer) attempt to introduce a condition into India’s Drug and Cosmetics Act 1940 (IND) which would have required the Drug Controller-General of India (DCGI), in making a decision on whether to grant marketing approval to a new drug, to have regard to whether the drug in question was subject to a patent – a system known as “patent linkage”. Bayer appealed to the Indian Supreme Court, which admitted the appeal in March 2010.

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A case which considers India’s domestic legislative schemes regarding the safety and regulation of drugs may appear to hold little significance for the global access to medicine regime — until one takes into account India’s role in relation to generic medications globally.\(^2\) For example, in 2005 approximately 70% of HIV/AIDS patients in Medecins Sans Frontieres (MSF) programs relied on antiretroviral (ARV) drugs from India, while worldwide, approximately half of those on ARVs in developing countries (350,000 people) depended on Indian generic medications.\(^3\)

Therefore, any developments in India’s domestic legislative and regulatory framework regarding generic production would significantly impact on the public health of many people in developing and least developed countries (LDCs).

The first part of this article sets the legal and regulatory context of this case, discussing India’s domestic legislative and regulatory scheme, and how its international obligations regarding access to medicines have been addressed and implemented. It then considers the background to the case as well as the trial and appeal judgments. This is followed by a discussion of patent linkage which argues that its rejection by the High Court was correct. The article concludes with an argument about the undesirability of the current access to medicines regime where priority is given to the protection of intellectual property (IP). It contends that India has an opportunity to shift this focus.

**THE ACCESS TO MEDICINES REGIME**

In order to understand the Bayer case, it is necessary to discuss the interplay between access to medicines and intellectual property in the international context and India’s domestic implementation of the regime. The three frameworks

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considered are the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS), the Drugs and Cosmetics Act 1940 (IND) and the Patents Act 1970 (IND).

**Agreement on Trade-Related Aspects of Intellectual Property and public health considerations**

Commonly referred to as TRIPS, this agreement is one of 18 agreements annexed to the Agreement establishing the World Trade Organisation (WTO), which came into force in 1995. The Preamble to TRIPS states that its purpose is to “reduce distortions and impediments to international trade” while considering the need to “promote effective and adequate protection of intellectual property rights” and ensuring that such rights do not “become barriers to legitimate trade”. However, TRIPS is better known for providing a minimum set of IP protection standards which WTO member states are obliged to comply with and implement. Although TRIPS only imposed minimum standards, its Articles imposing patent protection over products translated into increasing the domestic standards of intellectual property protection laws of many of its signatory states. One of the states so affected was India which, prior to becoming a WTO member, did not have patents over products (discussed below).

There are various key provisions in TRIPS regarding patent protection over products. Article 27 defines what is “patentable”. Article 28 confers on the patent owner exclusive rights by preventing third parties from “making, using, offering for sale, selling or importing for these purposes” the patented product in question. Article 33 provides for a minimum period of 20 years' protection of the patent, commencing from the patent application filing date.

However, the WTO did recognise that a balance between trade and health interests had to be struck and also acknowledged the primacy of public health. For example,

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Art 8 provided that member states, when incorporating TRIPS obligations into their national laws, were obliged to adopt necessary measures “to protect public health and nutrition”, provided the measures were consistent with TRIPS. Subsequent agreements and declarations relating to TRIPS allowed TRIPS Articles to be interpreted in a way which supported public health and the access to medicine regime, acting as exceptions to the IP protections.

**India’s Drugs and Cosmetics Act 1940 (IND)**

The *Drugs and Cosmetics Act 1940* (IND) and its associated *Drugs and Cosmetic Rules 1945* (IND) are part of India’s drug standard and control system. Under s 5, a Drugs Technical Advisory Board oversees the operation and administration of the *Drugs and Cosmetics Act*. The board consists of a number of members, including the DCGI. The Act and its Regulations provide a framework for drug and cosmetics safety, analysis, manufacturing, sale and distribution in India. For the purposes of analysing the *Bayer* case, s 2, which provides that the provisions of the *Drugs and Cosmetics Act*, “shall be in addition to, and not in derogation of” other laws, is worth noting.

**Patents Act 1970 (IND)**

Prior to the *Patents (Amendment) Act 2005* (the Amending Act), India’s *Patents Act* only bestowed patent protection on *methods or processes* in the manufacture of products and not the actual products.\(^6\) This enabled India to produce generic medications, giving it a leading role in the developing world. Statistics from the MSF dated 2005 stated that an estimated 70% of 25,000 AIDS patients treated by MSF in 27 countries used Indian generics;\(^7\) 2006 statistics stated that 84% of the AIDS drugs used by MSF to treat over 60,000 patients in more than 30 countries were generic medicines from India.\(^8\)

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\(^6\) *Patents Act 1970* (IND), s 5 (now omitted).


Upon becoming a member of the WTO, India was required to comply with the TRIPS Agreement. However, in light of its status as a developing country, India was given until 1 January 2005 to comply, and was also required to allow companies to apply for patents during this 10-year transitional period. Accordingly, transitional arrangements were made in TRIPS in the form of a mailbox system. Specifically, Art 70.8 of TRIPS required parties to “provide as from the date of entry into force of the WTO Agreement a means by which applications for patents” for inventions could be filed; and to apply the criteria for patentability to these applications as if the criteria were being applied on the date of filing. Patent protection would be conferred from the date the patent was granted but the patent term protection of 20 years commenced from the date the application was filed.

As a result, India set up a “mailbox” facility via the Patents (Amendment) Act 1999 (IND). Section 24A was inserted into the Patents Act, allowing applicants wishing to apply for patents in India to file an application with India. The applications would be stored in this mailbox, not to be considered until 31 December 2004, at which time TRIPS would be fully effective in India. If the application was successful, the 20-year term of protection would be counted from the date of the patent application, but protection was effectively only from the date the patent was granted. This therefore offered generic manufacturers a substantial advantage and benefited the access to medicines regime significantly: a particular pharmaceutical product the subject of a patent application could be generically manufactured at least until 31 December 2004 or even further, for while the application remained in the mailbox and a patent had not been granted, no protection existed.

There was a further Patents (Amendment) Act 2002, but the 2005 Amending Act brought India into full compliance with TRIPS intellectual property protection obligations. Significantly, it removed s 5 so that applications for patent protection

10 World Health Organisation, n 7.
11 World Health Organisation, n 7.
over pharmaceutical products received after 1 January 2005 (as well as those awaiting decision in the mailbox) could potentially succeed, provided they satisfied the patent eligibility elements. Therefore, where generic manufacturers wished to produce a pharmaceutical product that had been granted a patent after 1 January 2005, they would be required to seek permission from the patent-holder or obtain a compulsory licence under TRIPS and the Patents Act provisions (discussed below).

THE CASE

It was within this legal framework that both the trial division decision (unrep, Delhi High Court, Ravindra Bhat J, 18 August 2009)\(^\text{12}\) and the appeal for Bayer Corp v Union of India were heard and decided in the High Court of Delhi at New Delhi.

The case revolved around sorafenib tosylate, a drug used to treat kidney and liver cancer.\(^\text{13}\) In March 2008, Bayer Corporation was granted a patent by the Indian Patent Office over this drug, which Bayer marketed under the brand name Nexavar. A month’s worth of treatment (120 tablets) cost 285,000 rupees (US$5,700).\(^\text{14}\)

In July 2008, Bayer became aware of Cipla’s intention to market the generic version of this drug under the name Soranib and contacted the DCGI, requesting that marketing approval not be granted to Cipla on the basis of Bayer holding the patent. In October 2008, Bayer filed a petition to the Delhi High Court for a writ restraining the DCGI from granting the relevant licence.

At both first instance and in the appeal, Bayer argued that the following factors supported its petition to restrain the granting of marketing approval:

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a collective reading of the *Patents Act* and the *Drugs and Cosmetics Act* should be adopted by the courts;

- the effect of this collective reading of the two Acts was that a patent linkage system would apply to the Indian generic medication market; and

- Cipla’s Soranib was, in effect, a “spurious drug” as defined by s 17B of the *Drugs and Cosmetics Act*.\(^{15}\)

Bayer based its argument in support of a collective reading of the two Acts by pointing to ss 48 and 156 of the *Patents Act* and s 2 of the *Drugs and Cosmetics Act*. As the patent in question was granted after the commencement of the Act and was for an article or substance, s 48(2)(a) applied, providing that the patent conferred on Bayer (as patentee) “the exclusive right ... to make, use, exercise, sell or distribute” that article or substance in India. Section 156 provides that the patent “shall have ... like effect against Government as it has against any other person”. Section 2 of the *Drugs and Cosmetics Act* provides that this Act operates in addition to other Indian laws.

Thus, the two Acts should be read together. The effect of a collective reading meant that the patent “has the same effect on the Government as on others”. Since the DCGI oversaw the operation and acted upon the provisions of the *Drugs and Cosmetics Act*, and as “functionaries of the Central Government”, the DCGI was also bound and obliged to respect Bayer’s patent rights. As part of this, the DCGI “needed to ensure that his decision on the grant of marketing approval should not derogate” from other applicable laws. If marketing approval were granted, it would breach s 48 of the *Patents Act* as the patent rights to which Bayer was entitled would no longer be exclusive in nature. Effectively, Bayer attempted to tack an additional condition onto the *Drugs and Cosmetics Act* under which the DCGI, as well as needing to have regard to the provisions of the *Drugs and Cosmetics Act*, would also be required to consider the existence of a patent over the product.

\(^{15}\) As this third issue is not relevant to the question of patent linkage, it is not considered in this article.
Cipla disagreed, arguing that Bayer’s argument was made on the incorrect assumption that any marketing approval granted by the DCGI would, by itself, amount to a patent infringement. The question of whether a patent had been infringed was one to be decided by a court of law having regard to the Patents Act provisions, and was within neither the jurisdiction nor the powers of the DCGI. Cipla then went on to submit that the mere grant of approval was not an act of “making, using, offering for sale, selling or importing” the product and thus would not breach s 48. Cipla also submitted that s 107A (the “Bolar provision” section) clearly exempted from patent infringement acts of making, using or selling a patented product where such actions were required to obtain information for the purposes of obtaining regulatory approval from the DCGI. It was therefore “illogical to argue that when all acts leading up to the stage of drug approval are exempt from patent infringement, the very act of approval itself amounts to an infringement”. In addition, Cipla argued that the imposition of the patent linkage system would be inconsistent with India’s obligations under TRIPS.

Therefore, the question regarding access to medicine and patent linkage in both instances was whether the two Acts should be read together, and if so, whether the DCGI was prevented from granting marketing approval over Soranib to Cipla because Bayer was the patent owner.

**Trial division judgment**

The trial judge, Bhat J, rejected Bayer’s submissions and accepted Cipla’s counter-arguments. After discussing the history of the Patents Act, he made the following points.

First, the function of a patent is not to grant the patentee “the right to use, offer for sale or import” the invention but rather the right to exclude others from doing so. Bhat J also noted that under Indian law patents, unlike other IP rights, are susceptible to a multiple number of challenges, both pre-grant and post-grant and before a number of administrative or judicial bodies.
Secondly, only the Controller of Patents16 and patent officers are experts at judging what is patentable. Such expertise depends upon “adjudging, on an objective basis, whether a product is novel”. Officials operating under the Drugs and Cosmetics Act who were required to test product safety and therapeutic efficiency were not so equipped. The judge accepted Cipla’s argument that to impose the obligation upon the DCGI to determine patent questions was beyond the intention of the Drugs and Cosmetics Act. On a related point, the judge also agreed with Cipla that the question of patent infringement must be established before a court of law – to accept that the DCGI had this obligation would confer jurisdiction upon the drugs agency, denuding the power from the Patents Act bodies.

Thirdly, Bhat J questioned the ability of the judiciary to assume the application of the patent linkage system in India. Noting that, unlike China and the United States, Indian laws did not expressly allow for patent linkage standards, Bhat J doubted that courts should “blaze into an obviously legislative path”. While courts were required sometimes to fill in gaps, in this case, the gap was more of “oceanic proportions”.

Applying this to s 156, it seemed that all s 156 required was that the government and public officials respect the patent and not infringe it. Nothing in the Patents Act or the Drugs and Cosmetics Act indicated a parliamentary intention to “place patent superintendence or policing powers with drug agencies”. To interpret otherwise would result in the judiciary “making a policy choice ... [and] overstepping its obvious interpretive bounds”.

Finally, the court questioned the desirability of introducing patent linkage into India’s domestic legal system. After noting that the European Union had expressly disapproved of the practice, the judge also discussed the negative effects of patent linkage:

- it would blur responsibility between the Patent Office and the Drugs and Cosmetics Act bodies;

16 While the full title of this office is the Controller General of Patents, Designs and Trade Marks, s73(1) of the Patents Act states the office will be referred to as “the Controller of Patents for the purposes of this Act.”
it would transform patents, originally private property rights, into public rights, enforceable by public authorities; and

it would violate India’s public health obligations under TRIPS.

Appellate judgment

The same issues arose for decision before the appeal court. Muralidhar J wrote the leading judgment, essentially agreeing with Bhat J on all points. With regard to the interpretation of s 156, the court classified it as imposing a “negative obligation on the government not to infringe. It creates no positive obligation on the central government or any department thereof to protect.” In addition, there was no mention in the Drugs and Cosmetics Act that marketing approval was to be refused if the product in question was patented; nor did the granting of such an approval result in patent infringement or constitute abetting any infringement. The role of the DCGI was within the framework of the Drugs and Cosmetics Act: “[T]here is no scope for the DCGI to travel beyond the Drugs and Cosmetics Act and ensure the protection of the patent by refusing marketing approval” to a patented product. Finally, the court also agreed that the introduction of a patent linkage system would breach India’s obligations under TRIPS and that the court could not impliedly introduce the system into Indian law.

Analysis

In light of both judgments’ dismissal of Bayer’s attempts at patent linkage, and the court’s recognition of its negative effects, it is unsurprising that many hailed the decision as safeguarding public health and generic medication production. Unfortunately, closer inspection of the decisions would indicate that, while the court was reluctant to implement patent linkage, it did not reject the concept outright. One notable feature throughout the judgments was the reluctance of the court and the Indian Government to acknowledge its international human right obligations, 17

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especially the right to health and medical treatment. The court avoided the issue on the basis that it was a matter for the legislature – a policy question for the government. It would seem therefore that it is theoretically possible that the Supreme Court may decide that it is an area on which the judiciary can decide and rule that Bayer’s submission on a collective reading of the respective Acts is correct.

**PATENT LINKAGE AND PUBLIC HEALTH**

This part of the article examines the system of patent linkage, how its introduction would adversely affect India’s public health obligations, and why the Supreme Court should rule against its operation in India.

“Patent linkage”

Patent linkage is “the practice of linking the granting of ... any regulatory approval for a generic medicinal product to the status of a patent for the originator reference product”.18 As discussed, Bayer’s argument was for patent linkage to occur in India. The European Commission has noted that patent linkage offers a platform for the pharmaceutical industry to prevent sales of the generic product by threatening retailers who sell or stock the generic version with action for breach of patent rights.19

Once the availability of a medication is recognised as being dependent on the existence of a patent, various complications arise, including:

- the adverse impact on the public health exceptions in TRIPS; and
- the enforcement and recognition of patent rights by a body not qualified to do so.

**Impact on public health exceptions**

As discussed, a number of TRIPS Articles were interpreted to operate as an exception to the protection of intellectual property. In regard to public health and

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19 European Commission, n 18, pp 338-339.
access to medication, the two common exceptions are the Bolar provisions and compulsory licensing.

Bolar provisions allow generic manufacturers to prepare production and regulatory procedures before patents expire so that products can be ready for sale as soon as the patent ends, rather than having to go through the lengthy preparatory process only after the patent period is over.  

Article 30 allows members to provide "limited exceptions to the exclusive rights conferred by a patent" provided the exceptions do not unreasonably conflict with the patent-holder’s rights or legitimate interests. In a 2000 dispute between the European Commission and Canada, a WTO Panel considered the legality of two provisions of the Canadian Patent Act 1985 which allowed third parties to "construct, use or sell" a patented invention solely for uses related to the “development and submission of information” required by relevant domestic laws and to stockpile the patented product intended for sale after patent expiration. The Panel held that the Bolar provisions were one of the “limited exceptions” modifying the exclusive rights, as allowed by Art 30.

Section 107A of India’s Patents Act implements Art 30 so that “any act of making, constructing, using, selling or importing a patented invention solely for the uses reasonably relating to the development and submission of information required by law” shall not be considered as infringement.

Compulsory licensing occurs where a third party obtains authorisation to perform acts that would legally require the patent-holder’s permission. In the context of generic medicines, the third party would be the generic manufacturer obtaining authorisation to produce pharmaceutical products the subject of patent protection. Article 31 of TRIPS provides that where the law of a WTO member “allows for other use of the subject matter of a patent without the authorisation” of the patent owner

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22 Panel Report, n 21, p 40.
(ie, pharmaceutical companies), certain procedural requirements must be respected. Therefore, although not expressly using the term, Art 31(b) acknowledged the possibility of compulsory licensing, provided that the government issuing the licence has made attempts to obtain permission from the patent-holder (except for a case of national or extreme emergency) and that use was predominantly for that country’s domestic market (Art 31(f)).

The last requirement was uncontroversial until it was realised that countries most in need of medicines usually had little (or no) manufacturing, production or research and development capability.\(^2\)\(^4\) This realisation led to the 2001 WTO meeting in Doha, Qatar, and resulted in the Declaration on the TRIPS Agreement and Public Health (the Doha Declaration). Paragraphs 1 to 3 recognised the “gravity of public health problems” and how IP protection can impact upon this issue. Paragraph 4 confirmed that TRIPS must be “interpreted and implemented in a manner supporting [members’] right to ... promote access to medicines for all”. Paragraph 5 then confirmed the right of member states to use compulsory licensing under TRIPS, Art 31 (the term was expressly used) in cases of national or extreme emergency. More importantly, however, the paragraph also provided a non-exhaustive list of such emergencies including HIV/AIDS, tuberculosis, malaria and other epidemics. Such references recognised that an emergency could be a long-term problem.\(^2\)\(^5\) However, paragraph 6 triggered the solution to the conundrum posed by Art 31(f). Recognising that some countries had “insufficient or no manufacturing capabilities in the pharmaceutical sector”, it instructed the TRIPS General Council to find an expeditious solution to the problem. On 30 August 2003, the General Council adopted the Decision of the WTO General Council on the Implementation of Paragraph 6 of the Doha Declaration of the TRIPS Agreement and Public Health (the Decision). Article 2 of this Decision allowed a country which issued the compulsory licence to export products to an “eligible importing country”.

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\(^2\) Correa, n 24, p 17.
Article 1(b) of the Decision defines such a country as a LDC. On 6 December 2005, the General Council amended TRIPS by inserting Art 2 of the Decision into TRIPS where it became known as Art 31bis.26

Sections 84, 92 and 92A of the Patents Act address compulsory licensing circumstances in India. Section 84 provides that a licence may be granted by the Controller of Patents if the applicant can establish that “reasonable requirements of the public with respect to the patented invention have not been satisfied”, or “the patented invention is not available to the public at a reasonably affordable price”, or “the patented invention is not worked in the territory of India”. However, in circumstances of “national emergency ... extreme urgency or public non-commercial use”, where the Indian Central Government is satisfied that it is necessary for a compulsory licence to be granted, s 92 allows the government to make a declaration to that effect, so that an applicant for the compulsory licence is granted that licence on such terms as the Controller of Patents sees fit. “Public health crisis” is referred to in s 92 as an example of the three circumstances. Section 92A allows the export of products manufactured under a compulsory licence, where the receiving country is one “having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems”. These provisions recognising the existence of exceptional circumstances reflect the operation of TRIPS Arts 31(f) and 31bis.

Should patent linkage be allowed, the operation of patent linkage would render the above exceptions useless and result in delayed access to the generic products. Bolar provisions would be of no effect as the existence of a patent over the pharmaceutical product would halt any granting by the relevant drug authority of marketing approval for that product. The applicant would be required to wait until the patent expires or is deemed invalid before applying for marketing approval. Not only would the availability of the generic product be significantly delayed, but the

patent-holder would enjoy additional market exclusivity while the generic product was awaiting marketing approval.\textsuperscript{27} With regard to compulsory licensing, patent linkage does not affect the government’s ability to override patent-holders’ exclusive rights by allowing compulsory licensing in certain situations. However, for a generic product to be eligible to be produced and available under a compulsory licence, the \textit{Drugs and Cosmetics Act} and its Rules require the generic product to have the requisite marketing approval. The impact upon compulsory licensing therefore would be an extension of the problems arising from patent linkage under the Bolar provisions. Unless the patent-holder gives permission for the product to be produced under a compulsory licence, the inability to grant the generic product the requisite marketing approval prevents the product from being utilised by compulsory licensing and thus renders the exception useless.\textsuperscript{28}

\textbf{Enforcement and recognition of patent rights}

One reason for the rejection of Bayer’s argument was that the intricacies involved in patent linkage exceeded the scope of the DCGI’s duties under the \textit{Drugs and Cosmetics Act}. A drug regulatory authority’s ability to determine patent infringement and enforce patent rights has been commonly cited as reasons against patent linkage. Imposing patent linkage would result in the drug regulatory body enforcing a company’s private patent monopoly rights, despite the fact that the body would not have the power to decide the validity of the patent.\textsuperscript{29} Galantucci notes that the burden would be on the generic manufacturer, as the applicant, to prove that the patent is invalid or ineffective.\textsuperscript{30} In addition, it would distract the drug regulatory


\textsuperscript{29} Medecins Sans Frontieres, n 28.

\textsuperscript{30} Galantucci, n 27.
body from its duty to deliver the “green light” for medicines to enter the market by ensuring their safety, quality and effectiveness.31

THE RIGHT TO HEALTH

As well as breaching public health obligations, patent linkage is also inconsistent with the general right to health. Under international law, the right to health has been recognised in numerous documents.32 Article 25 of the Universal Declaration of Human Rights provides that “everyone has the right to a standard of living adequate for the health and well-being of himself and of his family including ... medical care”. In addition, Art 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) requires state parties to “recognise the right of everyone to the enjoyment of the highest attainable standard of physical and mental health”.

As part of this obligation, state parties must take steps necessary for “the prevention, treatment and control of” diseases and the “creation of conditions which would assure to all medical service and medical attention in the event of sickness”. The International Covenant on Civil and Political Rights (ICCPR), on the other hand, does not directly provide for the right of public health, but several of its provisions allow the curtailment of other rights “where such restrictions are necessary to protect ... public health”. The World Health Organisation (WHO) Constitution starts with a declaration that “health is a state of complete physical, mental and social well-being” and “the enjoyment of the highest attainable standard of health” is a fundamental human right. Governments are responsible for the health of their peoples and must fulfil this obligation “only by the provision of adequate health and social measures”. These instruments provide the basic principles that “underpin approaches to the issues of and solutions to increasing access to medicines”.33

The next question concerns the specifics of how governments are to satisfy the access to medicine obligation. Resolution 2000/7 from the Sub-Commission on the Promotion and Protection of Human Rights\(^\text{34}\) reminds states of the “primacy of human rights obligations over economic policies and agreements” and expressly refers to TRIPS as an example of the latter. In 2006, the United Nations Secretary-General presented a report to the General Assembly, written by then special rapporteur of the right to health, Paul Hunt.\(^\text{35}\) The report argued that the responsibilities of states included ensuring that medicines are “available, accessible, culturally acceptable and of good quality.”\(^\text{36}\) Availability involved ensuring that existing medicines are “available in sufficient quantities.”\(^\text{37}\) Compulsory licensing was cited as one method of assisting with availability. Accessibility had four dimensions.\(^\text{38}\)

- availability in all parts of a country;
- economically accessible and affordable;
- without discrimination on any prohibited grounds (eg race, sex, ethnicity or socio-economic status); and
- accessibility of knowledge and information about that product.

The report also provided that, as part of this right, the state’s duty to protect (as provided for in General Comment No 14) required a state to "ensure that third parties do not obstruct enjoyment of the right to health."\(^\text{39}\)

As a soft law and recognising that nations differ in economic and social circumstances and status, international law only acts to provide the framework and

\(^{34}\) The Sub-Commission was a subsidiary body of the United Nations Commission on Human Rights, the latter being replaced by the United Nations Human Rights Council in 2006.


\(^{36}\) Hunt, n 35, p 13.


\(^{38}\) Hunt, n 35, p 13.

\(^{39}\) Hunt, n 35, p 15.
guidelines. General Comment 3 of the Committee on Economic, Social and Cultural Rights (CESCR) which monitors implementation of the ICESCR provides that there be a “minimum core obligation to ensure the satisfaction of, at the very least, minimum essential levels of each of the rights” as being incumbent upon every state party. State Parties have “a margin of discretion” in assessing the appropriate measures to implement their responsibilities; however, under Art 2 of the ICESCR, they are obliged to “take steps ... to the maximum of its available resources”. In terms of access to medicines, CESCR’s General Comment No 14 of 2000, which looked at Art 12 of the ICESCR, stated that “medical service” in Art 12 includes the provision of essential drugs as defined by the WHO. In turn, the WHO defines “essential drugs” (termed “essential medicines”) as medicines which “satisfy the priority health care needs of a population ... with due regard to public health relevance, evidence of efficacy and safety, and comparative cost-effectiveness”. The concept of essential medicine is “intended to be flexible and adaptable to many different situations” but what medicines are to be considered essential is a “national responsibility”. The reliance upon social circumstances as determinants to what are essential medicines is reflected in the fact that the WHO essential medicines list has changed 16 times over the past 30 years.

**India**

In India, there is no express right to health. However, in response to India’s obligations under the ICESCR and the ICCPR, India enacted the *Protection of Human Rights Act 1993* (IND). Section 2 defines “human rights” to include the right to life. The Indian *Constitution* also makes frequent reference to the need to protect health. Article 21 acknowledges the right to and protection of life. Article 39(e)
directs state policy towards securing the health and strength of workers. Article 47 requires the state to regard the “raising of the level of nutrition and ... the improvement of public health” as a primary duty.

In turn, the constitutional courts (particularly the Indian Supreme Court) have been quite proactive in acknowledging these references as well as international obligations generally. In *Punjab v Ram Lubhaya Bagga* (1998) 4 SCC 117, the Supreme Court held that Art 21’s reference to the right to live “does not mean mere survival or animal existence, but includes the right to live with human dignity”. The court added:

...Further to secure protection of one’s life is one of the foremost obligation of the State, it is not merely a right enshrined under Article 21 but an obligation cast on the State to provide this both under Article 21 and under Article 47 of the Constitution. The obligation includes improvement of public health as its primary duty.

In *ESC Ltd v Bose* (1992) 1 SCC 441, in considering an industrial dispute and the rights of the worker, the Indian Supreme Court cited the *Universal Declaration of Human Rights* and the ICESCR as recognising that the right to life included the right to physical and mental health. Health was defined as including medical care and health facilities (at [6]). In *Punjab v Chawla* (1997) 2 SCC 83 the court considered a public servant’s right of reimbursement for medical treatment, and noted that it is “settled law that right to health is an integral to right to life. Government has constitutional obligation to provide the health facilities.”

There has also been indirect consideration by the Supreme Court of India’s “minimum core obligations” under General Comment 3 when considering the right to health. In *Paschim Banga Khet Mazdoorsamity v State of West Bengal and Anor* (1996) 4 SCC 37, the court considered the quality of treatment provided to a labourer by various state hospitals. In discussing the level and quality of medical and hospital services, the court acknowledged that financial and other resources were required to provide such facilities, but observed:
At the same time it cannot be ignored that it is the constitutional obligation of the State to provide adequate medical services to the people. Whatever is necessary for this purpose has to be done.

The court further held that the state “cannot avoid its constitutional obligation … on account of financial constraints” in discharging its duty to preserve human life. In this case therefore, the court appeared to consider the right to health as more than a minimal core obligation – maximum resources were to be devoted to it. In Punjab v Ram Lubhaya Bagga (1998) 4 SCC 117 however, the court considered that the state was not breaching its constitutional obligations in having a policy which resulted in an injured worker being unable to claim reimbursement for the provision of certain medical services. While the right to health was regarded as a priority, it was not an absolute right (at 132):

A man is a social animal. He cannot live without the cooperation of large number of persons. Every article one uses is the contribution of many. Hence every individual right has to give way to the right of public at large. This ... applies when there is any constraint on the health budget on account of financial stringencies.

The provision of the “best possible health facility has direct co-relation with finances” and thus the state was entitled to take into account the availability of resources.

While at first glance it seems that the Supreme Court in Bagga took less of a stance on the constitutional right to health than in Mazdoosamity, on closer inspection both judgments in fact regarded this right equally. Both cases acknowledged the primacy of the right to health as a state obligation towards its citizens. The state was required to utilise its resources to the maximum to provide minimal essential services. Maximum utility does not equate to absolute utility or complete medical services. In Bagga, the Supreme Court recognised that the policy provided adequate care and financial support – the state thus had discharged its minimal
core obligations and was justified in considering the availability of resources in
deciding whether it wished to do more.

Therefore, the right to health and treatment has been expressly acknowledged
within India, significantly by the Indian Supreme Court. Although there is no express
constitutional right to medical treatment, the above case law, along with the public
health exceptions allowed in the *Patents Act* reflecting TRIPS, indicates that India is
aware of and has implemented this right. Were the Supreme Court to allow Bayer’s
argument in its appeal for patent linkage, it would be inconsistent with this human
rights-based approach and more importantly, with India’s international obligations.

**CONCLUSION**

Should the Supreme Court allow Bayer’s argument for patent linkage, it would
adversely affect access to medicines, whether they are on the WHO’s essential
medicine list or not. In addition, allowing the appeal would be inconsistent with
previous authority from the Supreme Court upholding the constitutional (and
general) right to health. Granted, past authority only looked at rights to health by
employees and government workers and the provision of health and medical
services; however, this has involved the constitutional courts paying significant
attention to India’s international human rights obligations and being willing to make
concessions in support of these rights, unless there were significant practical
considerations, such as the availability of resources.

The Indian Supreme Court heard Bayer’s appeal in August 2010. Commentators
urge nations involved in free-trade negotiations with countries such as the United
States to “simply say no to efforts to coerce them into accepting patent/registration
linkage”. Likewise, it is possible that the court admitted the appeal as a test case
as well as taking it as an opportunity of saying ‘no’ to Bayer and other future

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potential pressures to impose patent linkage. There have been promising developments which support a positive outcome. For example, despite admitting the appeal in 2010, the Supreme Court refused to stay the Delhi High Court’s appeal judgment, effectively enabling Cipla to launch its generic medication (ironically also in August) at approximately one-tenth of the price of Nexavar. This refusal may indicate that the judiciary is being persuaded to rule against a system where public health is only an incidental part of the focus on intellectual property – a focus that is unhelpful and unhealthy. The Bayer case is only a very recent example of how domestic nations still prioritise intellectual property over human rights. Instead nations should shift their focus to make access to medicines a primary right, and how their obligations under international law can assist in this. India has demonstrated its potential to comply with its international obligations via the various amendments made to its Patents Act as well as its domestic implementation of various rights Conventions. This appeal before the Supreme Court may be the opportunity for it to apply its favourable treatment of human rights in the vital context of the right to medical care and treatment.

POSTSCRIPT: In December 2010, the Supreme Court of India consisting of justices A Alam and R M Lodha dismissed the appeal, noting that Bayer’s simultaneous suit against Cipla for patent infringement, filed at the same time as the marketing approval appeal was still pending before the Delhi High Court. The decision to dismiss the appeal was described as one of a technicality or jurisdictional convenience: “[I]t means that the [Supreme Court] believes that this


case can be dealt with at the [Delhi] high court since the patent infringement case is already ongoing there.”

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