

FEDERATION INTERNATIONALE DES CONSEILS EN  
PROPRIETE INDUSTRIELLE<sup>1</sup>

**BALANCING IP RIGHTS WITH PUBLIC POLICY**

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ABSTRACT: The paper argues that if speaking of public policy one should first identify the 'public'. The public in the South and that in the North is not the same. Nor are the policies underlying IP, insofar as they are discernible, similar. It does not appear that compulsory licences provides an answer. The paper also discusses the South African experience and concludes that without a universally acceptable policy that underpins IP protection we cannot expect acceptance of IP protection across the world on a commonly applicable level.

Imagine a newspaper headline in 2020, reading: IP RIGHTS DEAD.<sup>3</sup> Consider the likely subtitle: SUICIDE or GREED or KILLED IN CROSS-FIRE. Prepare a list of mourners: Politicians? The public? Africans? Or will it be the pharmaceutical industry only, with FICPI sending flowers?

This scenario is the basis of this presentation and for present purposes I intend to focus on four aspects of the debate:

- (1) If we speak of 'public policy' who is the 'public' we have in mind?
- (2) What are the public policy considerations for IP protection?
- (3) the value and importance of compulsory licences in balancing IP rights with public policy.
- (4) The South African experience.

**(1) WHO IS THE PUBLIC?**

IP law has both national and international dimensions.<sup>4</sup> This leads to the assumption that the relevant 'public policy' considerations for the protection of IP rights are universal. They are not.

IP is caught in the crossfire of the wider battle between so-called free market economy forces and the more socially orientated forces.<sup>5</sup> This battle

concerns not only IP but also matters such as agricultural subsidies and open markets. The line can also be drawn between those societies that believe in the supremacy of the individual on the one hand, and those that have a communal approach to life and property on the other. There everything is supposed to belong to everyone (although in reality it may belong to a few). The clash is well illustrated by two statements, one from the Brazilian government and the other from the WTO:<sup>6</sup>

‘Local manufacture of . . . the drugs . . . is not a declaration of war. It is simply a fight for life.’

And

‘Brazilian Aids drug [policy] is a sure path to economic sickness.’

Some 2600 years ago Lao Tzu, the father of Taoism, said that the hidden virtue is ‘to produce without appropriation’ and ‘to create without controlling’.<sup>7</sup> This sentiment, the exact opposite of IP protection, may explain why some of his countrymen (and others) are unwilling to protect IP rights.

Geographically the division is between North and South; otherwise it is between rich and poor; between developed and developing countries (the latter contains a sub-category of least developed countries). These labels are misleading and tragically ironic. The ‘developed world’ is in fact developing; and the ‘developing world’ is stagnating. Not long ago we referred to the first and third worlds (there was no ‘second world’). These terms, now considered to be politically incorrect, were quite appropriate. They remind us that the third world is in its own orbit, light years away from the first world.

No one ever complains about patent protection in relation to a furnace or copyright protection of a painting. The focus of the attack on IP rights is in the field of pharmaceuticals and information technology.<sup>8</sup> In other words, the problem that faces IP is the general belief that IP protection in these areas is overly broad and that IP protection does not serve the public interest. But cancer in one organ can nevertheless be deadly.

## (2) PUBLIC POLICY CONSIDERATIONS

Have we identified the relevant policy considerations underlying IP protection? James Boyle thinks not:<sup>9</sup>

‘Like most property regimes, our intellectual property regime will be contentious . . . It will have effects on market power, economic concentration and social structure. Yet, right now, we have no politics of intellectual property – in the way that we have a politics of the environment or of tax reform. We lack a conceptual map of issues, a rough working model of costs and benefits and a functioning coalition-politics of groups unified by common interest perceived in apparently diverse situations.’

Joseph S Fulda adds:<sup>10</sup>

‘Unlike other property rights, which are usually assumed to be based on natural-rights theory, intellectual property rights are often felt by scholars and the public alike to be ill-founded. No less a source than the US Constitution gives only a utilitarian basis for intellectual property rights.’

Let us concentrate for present purposes on patent law.<sup>11</sup> It is justified on four grounds, namely a contract between the state and the inventor to disclose the invention for the public good; a reward for invention; a means of protecting inventor’s rights; and an incentive to invention and innovation.<sup>12</sup> All this is defensible, but it is no longer true (and has never been universally true), which brings me back to my opening remarks about suicide and over-indulgence. The inbuilt justifications and limitations over the years have been eroded. Are patentees greedy? Is patent law a glutton? Have both bitten off more than they can chew?<sup>13</sup>

The lengthening of the patent protection: the special dispensation for pharmaceutical patents (e.g. supplementary protection certificates); indirect extensions of terms patentees who extend the actual period of their protection beyond that justified – cf. the *Pravigard Pac* debacle/debate,<sup>14</sup> the *AstraZeneca* case in the EU, the unrealistic *Bolar* exception.

The broadening of patent protection: use of other IP rights to extend or bolster patent rights (e.g. by means of copyright, design or trademark protection); criminalizing patent infringement through anti-counterfeiting laws (paradoxically, in Brazil of all places patent infringement is a criminal act);<sup>15</sup> and extending of the field of patent protection (especially in the USA – cf the *Metabolite* case – and through *Trips Plus* bi-lateral trade agreements).<sup>16</sup>

And there are patentees who are prepared to raise the ire even of members of the US Congress by seeking injunctions when damages would probably do (the *BlackBerry* fiasco); and there are patent trolls (stick licensors).<sup>17</sup>

This loss of direction is driven by new policy considerations.<sup>18</sup> They are: Industrial development, investment, research, commercialization, exporting or licensing products – all in or from the North. In other words, it is about national self-interest and, to a lesser extent, personal self-interest. That does not mean that this attitude is blameworthy; it is merely dangerous. Dr Samuel Johnson said some 230 years ago in a related (copyright) context:

‘No man but a blockhead ever wrote,  
except for money.’

How did the wheels not turn? Remember the time when Charles Dickens had no copyright protection in the USA?

Turning to the South: The main policy concerns of the South relate to food, health and education. How does one balance a pharmaceutical patent against public health if some argue that:

Medicine without social justice is unacceptable. Patents are not a gift for drug companies to exercise power without responsibility?<sup>19</sup>

Emotional words but effective words; words that blur the distinction between public policy and public opinion. The latter is erratic but may drive and ultimately determine public policy.<sup>20</sup> As a rule, such patents do not lead to industrial development in the South; commercialization in the South;

investment in the South; scientific research in the South; or exports from the South.

Another irony is that, in an attempt to balance matters, the South wants protection and compensation for non-inventions (i.e., traditional knowledge, which is usually published common knowledge; and indigenous biologic or genetic resources) but wishes to deny protection and compensation for inventions from the North.<sup>21</sup>

### **(3) COMPULSORY LICENCES THE SOLUTION?**

Trips does not prevent countries from granting compulsory licences and they have the freedom to determine the grounds upon which such licences are granted. This freedom has had no practical consequences. The explanation is said to be found in the Trips requirement that a compulsory licence may only be granted if predominantly for the supply of the domestic market (art. 31(f)): developing countries lack the capacity to manufacture.

This requirement was 'waived' at Doha and that the waiver is supposed to become permanent.<sup>22</sup> This means that the rationale for granting compulsory licences is shifting.<sup>23</sup> It is now based on the 'unspoken and illogical assumption' that generic companies are non-profit organisations and that they charge less than what the market can afford.

The countries that can benefit from the waiver are those that have an established generic manufacturing capacity: Canada, Brazil, South Africa, China, Thailand and India.<sup>24</sup>

But, is the argument, developing countries will benefit because they will be able to import generics cheaply. There is some merit in the argument but it must be borne in mind that due to the size of the market (pharmaceutical or otherwise) and the lack of proper enforcement, global players do not bother to patent in those countries. 'In reality, few antiretroviral drugs have ever been on patent anywhere in Africa . . .'<sup>25</sup> **And, according to Franklin Coedjoe, attacks attack on drug patents calls for more official meddling and distracts**

from the real health problems of the poor: tariffs, bad infrastructure, official interference and poverty.<sup>26</sup>

The Doha Declaration provides that each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.<sup>27</sup>

#### **(4) THE SOUTH AFRICAN EXPERIENCE<sup>28</sup>**

However, the South African government, for reasons that are not easily understood, is not prepared to admit that HIV/AIDS represents a national emergency in spite of the fact that about 10% of the population is affected and that there is a 1:4 probability that a female by the age of 21 will be HIV positive.

Compulsory licences have been available since 1916. Until 1978, compulsory licences were available as of right for, i.a., foods or medicines but were not applied for. During the 'apartheid' years the country was the subject of economic sanctions and there were special provisions making the obtaining of compulsory licences easier and these, too, were not used.<sup>29</sup> And as far as I know, no one has used the Doha waiver. The main manufacturer of anti-retrovirals in the country does so under licence from a number of multi-nationals.<sup>30</sup> It prefers this route, according to its spokesman, 'for sound business reasons'.

Another chapter in the history of generics in South Africa was the legal challenge launched by the pharmaceutical industry against the government. The Medicines and Related Substances Act was amended during 1997. It permitted the Minister of Health to 'prescribe conditions for the supply of more affordable medicines in certain circumstances'. One was to permit the importation of grey medicines, even if contrary to the Patents Act. The industry attacked validity of the legislation. The matter became a public relations fiasco for the industry, and it settled in April 2001. Government

claimed victory. In fact, in terms of the settlement the industry withdrew its application and, importantly, the government undertook to abide by the provisions of Trips and to involve the industry in drafting new regulations.<sup>31</sup>

Government has done so and new regulations have been promulgated in 2003. They permit parallel importation of medicines and define 'parallel importation' as the importation into the Republic of a medicine protected under patent and/or registered in the Republic that has been put onto the market outside the Republic by or with the consent of the patentee in respect of such medicine. Anyone wishing to import a patented medicine must apply for a permit from the Minister of Health. Important are the price of the patentee and the price the importer intends to ask. (There are pricing regulations.) The permit is valid for 24 months. I could not find any publication of a notice that such a permit has to date been granted.

During 2003, the Competition Commission found that two pharmaceutical companies had abused their dominant position in the anti-retroviral field. The complainants were members of the public and not members of the generic industry. The case was that the two had abused their dominant positions by refusing to license their patents to generic manufacturers in return for a reasonable royalty. The Commission could not have been that certain of its case because it did not impose any penalties. The matter was settled before a decision by the Tribunal, and the companies undertook to enter into a fixed number of licence agreements with generic companies at a 5% royalty rate (which is 25% lower than then existing voluntary licence rate). It is not known to what extent this settlement has had an effect on the supply and prices of anti-retrovirals. However, on 25 April 2006, it was reported to an AIDS conference that pharmaceutical companies are not prepared to invest in developing a microbicide gel to combat AIDS because:

'with many governments and NGOs already demanding the free distribution of the earliest available microbicide, funding these projects may not be a good business decision for pharmaceutical companies.'

## CONCLUSION

Mias que voulez-vous?

Je n'ai plus d'idées.

Property calls for boundaries: the question is how and where to draw boundaries relating to holders and subject-matter of rights to the rest of the world.<sup>32</sup>

Without a universally acceptable policy that underpins IP protection we cannot expect acceptance of IP protection across the world on a commonly applicable level.

Sincere words do not sound nice,  
Nice-sounding words are not sincere.<sup>33</sup>

Or, as the Americans would say, the jury is still out on this one.

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<sup>1</sup> Centennial, May 2006, Paris.

<sup>2</sup> Supreme Court of Appeal, South Africa.

<sup>3</sup> After completion of this paper I became aware of the book by P Drahos (ed) *Death of Patents* (2005) but have not yet been able to access it. According to the book review by Anna Feros it says much the same: [2006] *EIPR* 257.

<sup>4</sup> Mainly as a result of the Paris and Berne conventions and, lately, Trips and the globalisation of the world economy.

<sup>5</sup> Cf Christopher May 'The Denial of History: Reification, Intellectual Property Rights and the Lessons of the Past.'

<sup>6</sup> Quoted in TED Case Studies 649 of Jan 2002.

<sup>7</sup> Tao Te Ching section 10 translated by Jorn K. Bramann and Jonathan Kress. The full text reads:

To give birth, to nourish,  
To bring forth without taking possession,  
To produce without appropriation,  
To create without controlling -  
That is the hidden virtue.

<sup>8</sup> For a recent debate on information: Susan Corbett "A Human Rights Perspective on the Database Debate" [2006] *EIPR* 83.

<sup>9</sup> 'A Politics of Intellectual Property: Environmentalism For the Net?' [1997] *Duke Law Review* 87.

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<sup>10</sup> Joseph S. Fulda in an 'Online Computing Review'.

<sup>11</sup> For an analysis along similar lines in respect of copyright, see Ysolde Gendreau 'The Image of Copyright' [2006] *EIPR* 209. She points out that, at least in the common-law tradition, 'there is no signature doctrinal school' for copyright.

<sup>12</sup> Robert Pikethley 'The European Patent System: Implementing Patent Harmonisation.' Richard C Levin 'A New Look at the Patent System' said:

'In theory, a patent confers perfect appropriability by granting legal monopoly of an invention for a limited period of time in return for a public disclosure that assures, again in theory, widespread diffusion of social benefits after the patent's expiration. The rationale for this social contract rests on the recognition that technological knowledge has certain attributes of a public good. From this perspective, knowledge, once created, is believed to be freely appropriable by others, and the 'free-rider' problem thus limits the incentive to create new knowledge. By conferring property rights that restrict temporarily the wide use of new knowledge, the patent system is supposed to create the incentive to engage in inventive activity and to undertake the costly investment typically required to reduce an invention to practice.'

<sup>13</sup> The latest proposals of the British government may go some way in resolving the problems.

<sup>14</sup> The label of Pravigard Pac, a drug used to prevent heart disease, specifically says it should not be taken by anyone under age 18. But that did not stop the medication's manufacturer from getting a six-month patent extension to test the drug's possible benefits for children. This was one of the justifications of the USA Lower PRICED Drugs Act (Lower Prices with Increased Competition and Efficient Economic Development of Drugs). "We need to stop drug companies from using patent loopholes to keep lower priced generics off the shelf and out of patients' hands," said Senator Stabenow.

<sup>15</sup> I wish to thank our moderator for this information.

#### Brazilian Law 9279/96

Article 183 - A crime is committed against a patent of invention or a utility model patent by he who:

I - manufactures a product that is the subject matter of a patent of invention or a utility model patent, without authorisation of the patentee; or

II - uses a means or process that is the subject matter of a patent of invention, without authorisation of the patentee.

Penalty - detention of 3 (three) months to 1 (one) year, or a fine.

Article 184 - A crime is committed against a patent of invention or a utility model patent by he who:

I - exports, sells, exhibits or offers for sale, maintains in stock, hides or receives, with a view to use for economic purposes, a product manufactured in violation of a patent of invention or of a utility model patent, or that is obtained by a patented means or process; or

II - imports a product that is the subject matter of a patent of invention or of a utility model patent or is obtained by a means or process patented in this country, for the purposes mentioned in the previous item, and that has not been placed on the external market directly by the proprietor or with his consent.

Penalty - detention of 1 (one) to 3 (three) months, or a fine.

Article 185 - Supplying a component of a patented product, or material or equipment for carrying out a patented process, provided that the final application of the component, material or equipment necessarily leads to the exploitation of the subject matter of the patent.

Penalty - detention of 1 (one) to 3 (three) months or a fine.

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Article 186- The crimes of this Chapter are committed even if the violation does not affect all the claims of the patent or if it is restricted to the use of means equivalent to the subject matter of the patent.

<sup>16</sup> International Herald Tribune 29 March 2006: 'Free trade agreements signed with Central America and other places, for example, restrict the use of generics by allowing brand-name companies to keep their clinical data a secret for five years. The Central American agreement also prevents anyone from registering a generic product without the patent holder's agreement during the life of a patent. The agreement with Morocco allows pharmaceutical companies to extend their monopolies by patenting new uses for old medicines. In 2000, President Bill Clinton, under pressure from global health campaigners and developing countries, signed an executive order that barred Washington from asking sub-Saharan Africa to accept tighter restrictions on generics than the World Trade Organization requires. President George W. Bush reaffirmed that decision when he came into office in 2001.'

<sup>17</sup> A patent troll is company that purchases a patent, often from a bankrupt firm, and then sues another company by claiming that one of its products infringes on the purchased patent or somebody who tries to make a lot of money off a patent that they are not practicing and have no intention of practicing and in most cases never practiced.

<sup>18</sup> They can be gleaned from the Biotech Directive of the EC (at least as far as biotech patents are concerned): David Vaver and Shamnad Basheer 'Popping Patented Pills: Europe and a Decade's Dose of Trips' (to be published in the May 2006 edition of *EIPR*).

<sup>19</sup> *The Hindu*, 10 December 2004.

<sup>20</sup> A good example is the case of Schapelle Corby. The Australian public believed in her innocence on a charge of drug smuggling (in spite of the Indonesian courts holding otherwise) and the matter became such a *cause célèbre* that the Australian government became involved. When a few months later a South African woman, Linda Martin, was apprehended in Australia on the same charge and proffered the same defence. The Australian court did not believe her, and no one could be bothered, maybe because she was 52 and a grandmother.

<sup>21</sup> Blackenterprise.com: 'Brazil and India's claims of biopiracy are intended to undo established agreements on intellectual property rights in the World Trade Organization and World Intellectual Property Organization. As you know, biopiracy is a term coined by countries engaged in rampant piracy to falsely accuse pharmaceutical companies of not paying their fair share for genetic natural resources.'

<sup>22</sup> The proposed amendment would add a new Article (Article 31 bis) to the TRIPS Agreement following the original Article 31. Article 31 bis contains 5 important waivers that were in the Decision. In particular, it waives an exporting country from being limited by the condition of "predominantly for the supply of the domestic market" (Article 31 (f) of the TRIPS Agreement), in cases where a compulsory license is issued for the purposes of production of a pharmaceutical product and its export to an importing country which has insufficient or no manufacturing capacity. However, to use Article 31 bis Members have to follow certain procedures and these are laid out in an Annex to the TRIPS Agreement (the system). See also the Hong Kong declaration: 'We reaffirm the importance we attach to the General Council Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, and to an amendment to the TRIPS Agreement replacing its provisions. In this regard, we welcome the work that has taken place in the Council for TRIPS and the Decision of the General Council of 6 December 2005 on an Amendment of the TRIPS Agreement.'

<sup>23</sup> It has been said that the rise of German industry during the close of the 19<sup>th</sup> C was due to compulsory licences. On the other hand, it is also said that since WW2 no compulsory licences have been granted in Germany. I am relying on my memory and I do not know what this proves.

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<sup>24</sup> E.g. 'Trips, AIDS and generic drugs' at [www.avert.org](http://www.avert.org).

<sup>25</sup> Dr John Kilama (President of Global Bioscience Development Institute) 'Aids quick-fix won't save Africa'.

<sup>26</sup> Cudjoe is director of Imani, a policy think-tank in Ghana, and contributor to the Civil Society Report on Intellectual Property, Innovation and Health ([www.policynetwork.net](http://www.policynetwork.net)). Article in Business Day, 12 April 2006.

<sup>27</sup> It is not clear to me how this provision dovetails with Trips but, presumably, it means that in the case of a national emergency a country is not bound by Trips on the *vis major* principle.

<sup>28</sup> For an assessment, with which I do not necessarily agree in all respects, see Ethél Teljeur 'Intellectual Property rights in South Africa: An economic review of policy and impact' The Edge Institute. So, too, Faizel Ismael 'Intellectual Property - TRIPs and Public Health' (Speech to International Bar Association) AGOA.info.

<sup>29</sup> The Patents Amendment Act 76 of 1988 provided that pending the final determination of an application for a compulsory licence the applicant could not, except under special circumstances, be prohibited by interdict from infringing the patent. In granting the compulsory licence, the court could backdate it to the date of application. This has been repealed.

<sup>30</sup> In 2001 Aspen had secured its first voluntary license from GlaxoSmithKline to manufacture AZT and 3TC. Since then, it has secured voluntary licenses from Bristol-Myers Squibb (for stavudine and didanosine), Boehringer Ingelheim (for nevirapine) and Merck Sharp & Dohme (for efavirenz). The MSD deal is particularly significant as efavirenz is currently the most expensive drug in government's first-line treatment regimen.

<sup>31</sup> The otherwise reliable Ahmad Siddiqi 'Patents and Pharmaceutical Drugs: The Need for Change' [Spring 2005] *Intellectual Property Review* gave this version, gleaned from press reports, of the facts:

'Responding to the alarming growth of HIV infections in the country, South Africa passed a law in 1997 giving the government "blanket powers to...produce or import cheap alternatives to the brand-name drugs for HIV and other diseases." Thirty-nine pharmaceutical companies raised a court challenge to prevent South Africa from implementing the law. John Barton, former chair of the UK Commission on Intellectual Property Rights, observes that this move "became a public relations debacle for the industry." A multitude of NGOs, including Oxfam and Medecins Sans Frontieres (MSF), sharply criticized the pharmaceutical companies for attempting to restrict health access. With pressure mounting, the companies eventually dropped their challenge, "after threats that the amount of public support for the development of the relevant drugs would be publicized in the hearings."

<sup>32</sup> Paul Edward Geller 'Dissolving Intellectual Property' [2006] *EIPR* 139.

<sup>33</sup> Again *Lao Tzu*.