



## Know IP - Stockholm Network Monthly Bulletin on IPRS

### **Commentary**

#### **TRIPS vs. Bayh-Dole - Helen Disney & Meir P. Pugatch\***

What is the most critical and influential institutional IP framework affecting the ability of countries to engage in, and to be more attractive to, technology transfer activities? It depends on who you ask. But for the sake of simplicity we'll divide the IP tech-transfer world into two camps.

One camp argues that the 1995 WTO TRIPS Agreement is the most important and significant paradigm shaping the link between IPRs and technology transfer (their perspectives, however, about the positive and negative effects of TRIPs on tech-transfer activities remain as divided as ever). The other camp argues that the 25-year old US-based Patent and Trademark Law Amendments Act of 1984 (commonly referred to as the Bayh -Dole Act), and the Federal Technology Transfer Act of 1986 (commonly referred to as the Stevenson-Wydler Technology Innovation Act) practically laid the foundations for technology transfer activities that are based on public-private partnerships<sup>1</sup>, and from which the term PPPs has eventually emerged.

Interestingly, the two camps, while focusing on the same end-result: the successful transfer and utilisation of knowledge from one entity to another, and from one country to another, do not seem to take a keen interest in the other camp's activities or agenda. Some would even go as far as to

---

\* Helen Disney is Director of the Stockholm Network. Dr. Meir Perez Pugatch, Haifa University, heads the Intellectual Property and Competition Programme of The Stockholm Network

<sup>1</sup>. For Bayh-Dole see: US Code, Title 35, Chapter 18 (USC35, 200-212); US Code, Title 15, Chapter 63 (USC15, 3701-3714)

argue that the two camps practically ignore one another.

There are many explanations as to why this detachment is taking place. The TRIPS paradigm is ultimately placed in the context of international economic relations in general and in international trade in particular. The discussion over TRIPS is also undoubtedly linked to debates over developmental policies and the north-south tensions. The Bayh-Dole/Stevenson-Wydler paradigm is much more business orientated. It focuses on the avenues of the management, exploitation and commercialisation of knowledge. And it is also ultimately linked to the debate over the role of public and government institutions in the dissemination of knowledge.

If one looks at the tech-transfer discussion in broader economic terms, one could argue that the camp focusing on TRIPS is more engaged with the demand-side approach, while those focusing on the Bayh-Dole/Stevenson-Wydler Acts may be associated with the supply-side approach.

The demand-side approach focuses on the extent to which countries' compliance with a given international IP standard (the TRIPS regime) encourages the diffusion of technology from developed countries to developing ones. In other words, and from a tech-transfer perspective, the debate over the TRIPS framework is about its ability to meet the DEMANDS of developing countries for the increased inflow of technology transfer.

Critics of the TRIPS Framework, on the other hand, argue that it has failed to secure this result. Referring to Article 7 of TRIPS, which states that 'the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the



## Know IP - Stockholm Network Monthly Bulletin on IPRS

transfer and dissemination of technology', they argue that this element of TRIPS has underperformed and that developing countries have not enjoyed the benefits of technology transfer.

Supporters of the TRIPS framework are equally passionate in their belief that developing countries, by adopting the global IP standard established by TRIPS (and even higher standards), will be able to secure their needs for greater inflows and pace of technology transfer and foreign direct investments. They will point to different studies that support this proposition, such as a recent OECD study which concludes that: 'the empirical analysis presented in this study provides general support for the proposition that the strengthening of IPRs - as measured by the selected indicators - has had a net positive effect on international licensing of technologies between unaffiliated parties during the 1990s.'<sup>1</sup> The study also finds that 'the growth in international licensing alliances between developed nation licensor firms and developing nation licensee firms also seem to correlate positively with patent reform'.

The supply-side approach – as manifested by The Bayh-Dole/ Stevenson-Wydler Acts – focuses on the manner in which public and government research bodies are able to utilise and disseminate their knowledge and technologies by transferring them to the private sector. In other words, the Bayh-Dole/ Stevenson-Wydler Acts intended to open up the door for a new SUPPLY of knowledge, deriving from academic institutions and public research bodies, such as the National Institutes of Health (NIH).

---

<sup>1</sup>. Park, W, Lippolds, D. (2005) *International Licensing and the Strengthening of Intellectual Property Rights in Developing Countries during the 1990s*, OECD Economic Studies, Paris, p. 17

Surprisingly, the debate over the positive and negative effects of the Bayh-Dole/ Stevenson-Wydler Acts does not revolve around their economic impact. Here the data is much more conclusive and visible. Before 1980, fewer than 250 patents were issued to U.S. universities each year and discoveries were seldom commercialised. In contrast, between 1993 and 2000, these universities were granted some 20,000 patents (almost 4,000 patents were issued in 2003) and more than 3,000 new companies were established. These activities generated income of more than \$US 1.2 billion to academic and government institutions alone.<sup>2</sup> Rather, this debate focuses on the 'appropriate' nature of technology transfer by research institutions that are not privately funded: should these bodies behave like private entities and adopt similar strategies? Or does their public nature require them to adopt a different and less commercially-orientated approach to the disclosure and transfer of knowledge?

No matter which camp one sees oneself as a part of, the time to link the TRIPS paradigm with the Bayh-Dole/ Stevenson-Wydler platform is long overdue. In fact, some organisations such as the Oxford-based Centre of the Management of Intellectual Property in Health Research and Development (MIHR)<sup>3</sup> have been able to do so quite successfully, and even in developing countries! It is possible that the true application of TRIPS Article 7 lies in the Bayh-Dole/ Stevenson-Wydler legislation. After all, simple economics tell us that it is all about matching supply to demand.

---

<sup>2</sup>. For additional data see Association of Universities Technology Managers -

[www.autm.org](http://www.autm.org)

<sup>3</sup>. See [www.mihir.org](http://www.mihir.org)



## Know IP - Stockholm Network Monthly Bulletin on IPRS

### Topic of the Month

#### **Additional Patent Disclosure Requirements for Biotech Inventions in Play in WTO, WIPO and CBD** - Jacques Gorlin\*

Mandating the disclosure in patent applications of the source or origin of genetic material used in biotechnology inventions is currently on the table in the Convention on Biological Diversity (CBD), WIPO and the WTO. While the objective - mandated patent disclosure - is the same in all three organisations, the moves in the CBD are motivated by different rationales from those in WIPO and the WTO, the two international regimes that are directly charged with intellectual property protection.

#### History

The CBD was negotiated in 1992 and essentially became the response of the developing countries to TRIPS. If patented inventions were the gold of the North, then the genetic materials found in the plant species of the South and their associated traditional knowledge became the 'green gold' of the South.

The CBD has been engaged in defining and outlining the elements of a system that would provide for access to, and fair and equitable sharing of, the benefits arising out of the utilisation of this 'green gold'. Nearly all of these elements fall outside the international intellectual property system. The patent system, however, quickly came to be viewed as the preferred method to enforce such access and benefit sharing in the CBD. That is, many CBD members came to believe that

---

\* Dr Gorlin is President of the Gorlin Group, a Washington-based consultancy providing strategic advice and analysis on the nexus of intellectual property and international trade issues.

holding out the possibility that patents could be revoked for failing to properly disclose the source or origin of the underlying genetic material would both prevent the issuance of bad patents ('bio-piracy'), which relied on the prior art contained in traditional knowledge, and also permit them to share in the value-added generated by biotech patents. These contradictory assertions define the Access and Benefit Sharing (ABS) debate.

The motivation behind the drive to introduce a patent disclosure requirement in WIPO and the WTO was a bit more complicated. Patent disclosure was viewed as an end in itself and not as means to enforce ABS. The very real concerns of countries like India, which sought to have international agreements reflect their national patent disclosure obligations, have joined with the anti-intellectual property objectives of countries like Brazil. Seeking to placate the developing countries, both the Swiss Government and the European Commission have made separate proposals in WIPO that would essentially include the disclosure in patent applications of the source of genetic resources and traditional knowledge if the invention were directly based on such resources or knowledge. Neither proposal would, however, revoke the patent if the disclosure were subsequently to be found incorrect or incomplete.

In 1999, developing countries succeeded in getting the patent disclosure issue, formally known as the relationship between the CBD and TRIPS on the agenda of the WTO TRIPS Council. The developing countries, led by India, Brazil and Peru, have essentially sought to amend TRIPS to mandate a patent disclosure requirement in order, they claim, to deal with the inconsistencies between the CBD objective of access and benefit sharing and the absence of



## Know IP - Stockholm Network Monthly Bulletin on IPRS

any disclosure requirement from what is considered the premier international intellectual property agreement.

### **Current Status**

Discussions on the patent disclosure issue continue in all three organisations. The debate is being driven by the coalition of provider and anti-intellectual property countries. Industry, which supports ABS, is concerned that a mandatory patent disclosure obligation of any kind would radically increase uncertainty and make it very difficult to invest in bioprospecting. Industry cites the experience to date in developing countries that have adopted mandatory patent disclosure—for example, the Philippines, Colombia, Brazil and Peru—as supporting the view: that such requirements dilute property rights and therefore devalue the genetic resources in the ground. Nonetheless, these countries and India have continued to maintain a political position on the issue.

### **WTO**

Demandeur countries are now seeking to make the CBD/TRIPS issue part of the 'single undertaking' of the Doha Development Round. At the WTO Hong Kong Ministerial Meeting of last December, the Ministers agreed to conduct intensive consultations and revisit the issue before July 31, 2006. There remains a wide divergence of views within the WTO on whether TRIPS should be reopened to address the CBD/TRIPS issue and on whether there is a conflict between the CBD and TRIPS.

### **CBD**

While Ministers will consider the recommendations of the CBD ABS Working Group at the Conference of Parties (COP VIII) in Brazil in March, the actual timetable for final resolution of

the issue is measured in years, not weeks or months.

### **WIPO**

WIPO members recently renewed the mandate of the IGC to continue work on the patent disclosure issue, where the EC is expected to push for consideration of its patent disclosure proposal. Industry is concerned that the Swiss and EC proposals in WIPO may provide long-term legitimacy to those who seek to launch the WTO negotiations.

## **Expert's Corner**

### **Compulsory Licensing Under Competition Law: the Concept of Essentiality - Shamnad Basheer \***

The biopharmaceutical industry is characterised by the 'cumulative innovation' paradigm, wherein the discovery of a gene sequence is only the first step. In order to convert such sequence information into viable products, tests and cures for genetic conditions and diseases, vast amounts of additional time, effort and money have to be spent. It is feared that patents over upstream gene sequences may 'block' further downstream research and consequently adversely impact drug discovery, as many diseases today are known to have genetic origins.

The doctrine of essential facilities offers a potentially robust solution to this blocking impasse. Although the term is now widely used to refer to a class of

---

\* Shamnad Basheer, Associate, Oxford Intellectual Property Research Centre. This article draws upon and develops one of the themes in a recently published paper. See Shamnad Basheer *Block Me Not: How Essential are Patented Genes* Journal of Law, Technology and Policy (2005) Issue No 2, 55).



## Know IP - Stockholm Network Monthly Bulletin on IPRS

'refusal to license' cases that constitute an abuse of a dominant position under Article 82 of EC competition law, there is no standard definition for this term. Advocate General Jacobs in *Bronner Case (C-7/97 Oscar Bronner v Media Print GmbH [1998] ECR I-7791)* captures its essence best:

[A] company which has a dominant position in the provision of facilities which are essential for the supply of goods or services on another market abuses its dominant position where, without objective justification, it refuses access to those facilities. Thus in certain cases a dominant undertaking must not merely refrain from anti-competitive action but must actively promote competition by allowing potential competitors access to the facilities which it has developed.

Thus, for example, this doctrine would specify when a railroad must be made available on 'reasonable' terms to a rival rail company or a patented technology licensed to a competitor. In the specific context of a patented gene that blocks downstream research, a potential solution would lie in qualifying such a gene as an 'essential facility', to which access has to be granted, in terms of licensing it on reasonable license terms to downstream researchers who could then go on to identify a useful product based on the gene. As evident, where the facility in question is an intellectual property of some sort, the doctrine of essential facilities operates very much like a compulsory license.

With the recent decision of the European Court of Justice (ECJ) in the *IMS Health* case and with the Qualcomm dispute before the Commission (where companies such as Nokia and Ericsson filed complaints to the European Commission requesting that it investigate and stop Qualcomm's anti-competitive conduct in the licensing of essential patents for

3G mobile technology), the essential facilities doctrine has taken centre stage in Europe. However, the parameters of this doctrine are far from settled. Antitrust authorities do not have enough guidance on issues such as determining appropriate license fees for access, optimal number of licensees etc. What is even more surprising is that the core aspect of the essential facilities doctrine, namely the question of 'essentiality' or 'indispensability' has not been deliberated upon in any of the decisions.

The *Bronner* decision was one of the few to have touched upon this concept in some detail. In essence, the court held that a facility is essential only when duplication of the facility or creation of an alternative is impossible or extremely difficult owing to legal, technical and economic obstacles. Although this framework was implicitly adopted in later decisions as well, the precise parameters of what would amount to a legal, technical or economic obstacle is not clear. The only guidance offered by the *Bronner* court in this regard is that a mere economic disadvantage is not the same as 'economic non viability' and will not count while categorising something as an essential facility.

A focus on the 'essentiality' or 'indispensability' prong would lead one to question one of the basic assumptions by many that patented genes cannot be invented around. Although it is difficult to work around patented genes, it is not impossible, viable substitutes do exist. Thus, for example, since some animal genes are similar in structure and function to human genes, it may be theoretically possible to substitute an animal gene for a human one. In this way, the patent on the human gene could be circumvented and is therefore not 'essential'. Another excellent example is the creative deployment of a gene 'switching' technique by TKT to



## Know IP - Stockholm Network Monthly Bulletin on IPRS

circumvent Amgen's patents on erythropoietin (hereafter 'EPO') and its corresponding gene, spawning a series of law suits on both sides of the Atlantic. To this extent, not all patented genes would qualify as 'essential' for the purposes of the application of the essential facilities doctrine. Of course, one cannot merely rely on the theoretical possibility of substitutes, rather, one has still to assess as to whether such a substitute would be legally, technically and economically feasible. Substituting an animal gene may not be 'technically' viable in all cases. Similarly, TKT's loss in the US (where, in sharp contrast to the UK, it was held to infringe Amgen's patent)

### News & Events

#### **Stockholm Network Workshop on IPRs and SMEs – March 8<sup>th</sup> 2006 Brussels**

On the 8<sup>th</sup> March the **Stockholm Network** and **Managing Intellectual Property Magazine** will be co-hosting a publication launch and workshop on the topic of intellectual property rights (IPRs) and small and medium sized enterprises (SMEs).

Chaired by Dr Meir P. Pugatch, Head of the Stockholm Network IP and Competition Programme, the central theme of the workshop is: **IPRs and SMEs- A Barrier to Innovation or an Engine for Growth?**

The first session of the workshop will feature the launch of Stockholm Network's latest IP Publication: *Intellectual Property Frontiers- Expanding the Borders of Discussion*. The publication is a collection of essays from eighteen distinguished IP experts from academia, think tanks, industry and law firms, and addresses IP issues across the board.

To give workshop attendees a short introduction to the publication, three

of the authors will be speaking about their essays:

**Joseph Cook**, Vice President of NERA Economic Consulting, will speak about exploitation of IPRs.

**Geoff Gregson**, Lecturer in Innovation and Entrepreneurship at Edinburgh University, will address IPRs and knowledge-based companies.

**Anne Jensen**, Project Manager, Stockholm Network IP and Competition Programme, talk about IPRs and SMEs in Europe.

The second session of the workshop will feature a panel discussion on the topic of IPRs and SMEs. On the panel are:

**Tilo Bachmann**, Controlling Office, European Patent Office.

**Denis Dambois**, European Patent Attorney, European Commission, DG RTD.

**Liz Coleman**, Director of IP Policy, UK Patent Office.

**Shirin Elahi**, Project Leader, EPO Scenarios, European Patent Office.

**Ruben Schellingerhout**, European Commission, DG Enterprise and Industry

**Jonathan Zuck**, President, Association for Competitive Technology.

The third and last session of the workshop will feature two representatives from two different SMEs talking about their experiences in dealing with IPRs. Speaking are:

**Daniel Doll Steinberg**, CEO, Tribeka LTD.

**Annie Brooking\***, CEO, Astron Clinica (\*tbc).

If you are interested in attending this workshop, please e-mail Anne Jensen: [anne@stockholm-network.org](mailto:anne@stockholm-network.org). Places are limited.



## **Know IP - Stockholm Network Monthly Bulletin on IPRS**

### **European Commission Launches New Public Consultation on Patent Policy in Europe**

On 16<sup>th</sup> January, the European Commission launched a public consultation asking industry and other stakeholders for their views on the future of patent policy in Europe.

While the Community Patent remains a priority, the Commission is also seeking views on the European patent system in general and what measures could be taken to improve it. The three key areas for consultation will therefore be:

- 1) The Community patent.
- 2) How the current patent system in Europe could be improved.
- 3) The possible areas for harmonisation.

On its website The Commission writes that it is "(..) committed to boosting the competitiveness of EU industry and improving the framework conditions in which it operates. To this end, industrial property, which includes patents, has been identified as one of the seven major cross-sectoral policy initiatives in the Commission's new industrial policy".

Feedback obtained from stakeholders will form the basis of a hearing, which the Commission intends to organise in Brussels on the 13<sup>th</sup> June 2006.

Closing date is 31 March 2006.

For more information see <http://europa.eu.int/rapid/pressReleasesAction.do?reference=IP/06/38&format=HTML&aged=0&language=EN&guiLanguage=en>

### **UK Treasury – Gowers Review of Intellectual Property**

At an Enterprise Conference in December 2005 UK Chancellor, Gordon Brown asked Andrew Gowers to lead an Independent Review to examine the UK's intellectual property framework. The Review would form part of the Pre-Budget Report 2005 package.

The Gowers Review of Intellectual Property Website<sup>1</sup> states that: "the UK's IP framework is a critical component of our present and future success in the global knowledge economy. Our economic competitiveness is increasingly driven by knowledge-based industries, especially in manufacturing, science-based sectors and the creative industries". The website also states that "Intellectual Property Rights must provide the optimal incentives for private industry and individuals to innovate and invest to create value, whilst preventing excessive inefficiencies and monopoly costs which can reduce competition and impede incremental innovation".

The Gowers Review will examine whether improvements could be made and, as appropriate, make targeted and practical policy recommendations. Over the course of 2006, the review team will consult widely with anyone that wishes to share their point of view. The review will be evidence-led, and there will be a call for evidence in February 2006. The review will report to the Chancellor, the Secretary of State for Trade and Industry, and the Secretary of State for Culture, Media and Sport in autumn 2006.

---

<sup>1</sup>[http://www.hm-treasury.gov.uk/independent\\_reviews/gowers\\_review\\_intellectual\\_property/gowersreview\\_index.cfm](http://www.hm-treasury.gov.uk/independent_reviews/gowers_review_intellectual_property/gowersreview_index.cfm)