



## Know IP - Stockholm Network Monthly Bulletin on IPRS

### **Topic of the Month**

#### **WTO Decision of 6 December 2005 on the Amendment of the TRIPs Agreement - Patrick Ravillard\***

After more than two years of intensive debate about how to make permanent and transpose a provisional decision originally adopted on 30 August 2003 into the TRIPs Agreement, the WTO Members agreed on 6 December 2005 to amend the TRIPs Agreement. This allowed the granting of compulsory licences for the purposes of manufacturing of pharmaceutical products for export to countries facing public health problems.

The WTO General Council has submitted the proposed amendment to the WTO Members for acceptance. Once accepted and in force, this amendment will complete a process that began in 2001 with the ministerial Declaration on the TRIPs Agreement and Public Health. This is the first time that a core WTO agreement has been amended.

#### **The Doha Declaration on TRIPs and Public Health**

On 14 November 2001, at Doha, the WTO Ministerial Conference adopted the Declaration on the TRIPs Agreement and Public Health. The ministers instructed the TRIPs Council to find an expeditious solution to the problem faced by the Members with insufficient or no manufacturing capacities in the pharmaceutical sector and which also could not import

---

\* Patrick Ravillard is Principal Administrator, Directorate-General for Trade of the European Commission (Brussels). He is responsible for TRIPs matters, including TRIPs and Public Health.

The views expressed in this article are those of the author and do not necessarily represent the views of the European Commission

the medicines they needed. The TRIPs Agreement indeed provides that compulsory licences on patents<sup>1</sup> can only be authorised predominantly for the supply of the domestic market.

#### **The waiver Decision of 30 August 2003**

On 30 August 2003, the WTO General Council adopted the provisional Decision allowing WTO Members to export patented medicines to third countries with insufficient or no manufacturing capacities in the pharmaceutical sector, by making use of compulsory licences. To give comfort to the US, this Decision was accompanied by a Statement made by the chair of the WTO General Council, describing Members' 'shared understanding' on how the decision is interpreted and implemented. The Decision takes the form of a provisional 'waiver' and provides for its replacement by an amendment to the TRIPs Agreement, on which work was to be completed by mid 2004.

Following the adoption of the waiver Decision, the European Commission (EC) presented a proposal for a Regulation of the European Parliament and of the Council, on 29 October 2004, on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems. The objective is to create a legal basis, at the EU level, to enable the relevant authorities of the EU Member States to grant compulsory licences for the production of pharmaceuticals and their export to eligible importing countries. The Regulation was definitively adopted on 27 April 2006.

---

<sup>1</sup> . A compulsory licence is an authorisation granted by government to an economic operator to use a patent protected technology, without the consent of the right holder.



## Know IP - Stockholm Network Monthly Bulletin on IPRS

### **The negotiations on the amendment**

The negotiations on the amendment were more difficult than expected. WTO Members were unable to respect the deadline scheduled in the waiver Decision. Indeed, certain Members attempted to re-open discussions on substantive issues. The debate focused on the legal form and content of the future amendment.

From the outset, the EC took the view that the nature of the amendment process should remain essentially technical, precisely in order not to re-open the discussions on substantive issues<sup>2</sup>. The amendment should faithfully reflect what was agreed on in the waiver Decision because it is the result of a delicate balance that was difficult to strike. In any event, for the EC, the fact that the TRIPs Agreement should be amended meant that textual changes should have to be made to the TRIPs Agreement itself, in order to transpose the relevant paragraphs of the decision into TRIPs language. As to the WTO General Council Statement, the EC said that the relationship between the waiver decision and the Statement should be preserved but the legal status of the Statement should not be upgraded.

The African Group saw an opportunity in the amendment exercise to re-open the discussions on substantive issues and tabled a proposal for an amendment in December 2004. They adopted a 'pick-and-choose' approach, i.e. their proposal did not take up several provisions of the waiver Decision while redrafting others. The rationale was that a number of the Decision's provisions would be either redundant in the context of an amendment or would be otherwise served by existing TRIPs provisions on compulsory licences and enforcement.

---

<sup>2</sup> IP/C/W/416 of 21 November 2003.

Other developing countries generally welcomed the African proposal as a good basis for further discussion. Their main concern was the status of the Statement that they all did not want to involve in the amendment process.

The US, while agreeing on the technical approach, sought to incorporate - or to refer to - the Statement into the TRIPs Agreement. In particular, they suggested that a reference to the Statement could be made in a footnote of the TRIPs Agreement. In March 2005 they circulated a submission in which they asked to preserve a reference to the Statement explicitly in the amendment or the principles included therein while arguing that they did not seek to elevate the legal status of the Statement.

Due to a lack of real progress, the EC, as an honest broker, informally circulated a paper in the WTO in September 2005 putting on paper its ideas on how the waiver Decision should be transposed into the TRIPs Agreement. This initiative injected new momentum in the discussion. Technically, the amendment should consist of the insertion of an exception to Article 31(f) allowing WTO Members to issue compulsory licences for export under the conditions agreed in August 2003. These conditions would be inserted in an annex to the TRIPs Agreement, so as not to overload the body text of the TRIPs Agreement. As to the Statement, the EC proposed that the statement should be reiterated by the Chairman of the General Council at the time of adopting the amendment.

While the EC proposal was not formally submitted to the TRIPs Council, it actually served as a basis for further consultations conducted by the Chairman of the TRIPs Council. Consultations also took place between the EC, the African Group and the US in order to narrow down differences in



## Know IP - Stockholm Network Monthly Bulletin on IPRS

the respective approaches. The EC and the African Group had very similar positions on the amendment and both wished to find a solution to clear the ground before the Hong Kong Ministerial Conference scheduled in December 2005.

### **The decision of 6 December 2005**

Work intensified in the run-up to the Hong Kong meeting and finally WTO Members reached an agreement on 6 December 2005. The new rules will allow any WTO Member to export medicines made under compulsory licence for the purpose of supplying developing countries in need. They will be formally incorporated into the TRIPs Agreement. The amendment takes effect for the WTO Members that have accepted it when two thirds of the WTO Members accepted the amendment and thereafter for each other Member upon acceptance by it. WTO Members have set themselves until 1 December 2007 to do this. The waiver Decision remains in force for each Member until the amendment becomes effective for that Member.

### **Contents of the amendment**

The amendment is designed to stick to the waiver Decision as closely as possible. The contents of the amendment are therefore the same as that of the waiver Decision. The amendment itself is composed of three parts. First of all, five paragraphs come under Article 31bis of the TRIPs Agreement (i.e. an additional article after Article 31), in particular the one which allows pharmaceutical products made under compulsory licence to be exported to developing countries in need. Other paragraphs deal with avoiding double remuneration to the patent owner, regional trade agreements involving least-developed countries, non-violation and situation complaints, and retaining all existing flexibilities under the TRIPs Agreement.

A further seven paragraphs are in a new annex to the TRIPs Agreement. These set out terms and conditions for using the system. Finally, an appendix to the annex deals with assessing the lack of manufacturing capacities in the importing country. This was originally an annex to the waiver Decision. In order to preserve the legal meaning and weight, and the relationship between the Statement and the new rules, the Statement has not been incorporated in the amendment but was reiterated by the Chairman of the WTO General Council prior to the adoption of the proposal for an amendment. This reflects the approach that the EC had defended during the negotiations.

A group of developed countries, including the EC, has announced that they would not use the system to import. High income developing countries announced separately that if they used the system as importers it would only be for emergencies or extremely urgent situations. All WTO Members have the right to act as exporters.

### **Acceptance of the amendment by the EC**

The EC played an important role in these negotiations. As the EC is competent to conclude agreements in the field of commercial aspects of intellectual property, the amendment has to be accepted on behalf of the EC. On 27 April 2006, the European Commission presented a proposal for a Council Decision accepting, on behalf of the EC, the amendment. This new initiative, together with the newly-adopted Regulation on compulsory licences of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems, demonstrate the commitment of the EC to the WTO process and confirm its willingness to really facilitate access to medicines for poor countries.



## Know IP - Stockholm Network Monthly Bulletin on IPRS

### **Policy Initiatives**

#### **Patent Mediation Services – Intellectual Property & Innovation Directorate, UK Patent Office \***

On 3<sup>rd</sup> April 2006 the UK Patent Office (UKPO) launched their Mediation Service and in doing so took the lead in promoting alternative dispute resolution (ADR) in Intellectual Property (IP) disputes. This move strengthens their efforts to raise the general awareness of alternatives to court litigation and introduces a team of UKPO Mediators.

So what is Mediation?

Mediation is just one form of ADR, which allows opposing parties to talk about their dispute and, hopefully, come to an agreement without the need for a court hearing. The mediator's job is to work through what the parties' objectives are and how these might be realised or best catered for in any settlement. There are no fixed results in mediation and both sides must agree on the solution. The mediator is simply there to help and does not make a decision; that is down to the opposing parties. The discussions are 'without prejudice', that is, they are not binding and parties can continue with legal proceedings if mediation fails.

There are many benefits to mediation, most notable being that disputes are on the whole settled more quickly and at less cost to litigation. In addition, mediation can deal with a broad range of issues that may go wider than a particular dispute and consequently result in a more comprehensive solution. Mediation can result in the win-win scenario by leading to

---

\* We wish to thank Ms. Sarah Meredith of the Intellectual Property & Innovation Directorate, The UK Patent Office

licensing agreements or supply contracts, such benefits will not come from a court case.

This is not the UKPO's first step towards ADR. Their non-binding Opinions service, introduced in October 2005, provides another way to resolve patent disputes. This service, aimed in particular at helping SMEs avoid having to get involved in extended litigation proceedings, focuses on perhaps the two most important areas of dispute – whether a product infringes a patent and whether a patent is valid. Anyone may request an opinion, and all interested parties have the opportunity to put their case, but there is no formal hearing or trial. Instead the Office issues a non-binding, but fully reasoned, opinion within no more than 3 months of the request and for a fixed fee of just £200 to the requester. As with mediation, parties can continue with legal proceedings if they wish. Guidance is available from the UKPO's website ([www.patent.gov.uk](http://www.patent.gov.uk)).

For trademarks, a streamlined opposition procedure (introduced in 2004) means a longer cooling off period during which both sides have the chance to negotiate a settlement which could result in savings in terms of both time and costs.

The launch of the UKPO's Mediation service that follows these earlier initiatives marks the bold introduction of a team of in-house mediators, all of whom are experienced Hearing Officers and have received training and accreditation from the Centre for Effective Dispute Resolution (CEDR). Their services cover all types of IP disputes, from the unregistered copyright and design rights, to the registered rights of patents, trademarks and registered designs. Cases can be referred to the Team from the courts, by the disputing parties themselves or from a Hearing Officer on reviewing a



## Know IP - Stockholm Network Monthly Bulletin on IPRS

request to initiate litigation proceedings at the Office.

As part of this initiation and to raise awareness of mediation as a form of dispute resolution, the UKPO has issued a range of literature aimed at encouraging parties to consider it as a viable alternative to litigation. The focus is on choice and all of their information emphasises the options that are available to the disputing parties.

Firstly, parties involved in proceedings before the office are invited to consider mediation; it is not mandatory that they do and whilst they consider the invitation to mediate the proceedings will be suspended, typically for 14 days. In assisting this decision, the UKPO's website ([www.patent.gov.uk](http://www.patent.gov.uk)) includes background information on mediation and guidance on when mediation may be a suitable option for the disputing parties. Secondly, if they elect to mediate, the parties have free choice of the mediator that will facilitate their mediation; use of the UKPO mediators is not an obligation. The UKPO website has helpful pages such as 'Issues to consider when selecting a mediator' and details of other mediation providers in the UK. Thirdly, there is the option to use the Patent Office simply for accommodation to host the mediation for a nominal fee of £100 (plus VAT) per half day at either their South Wales or London office.

The benefits of choosing UKPO mediators, however, are self-explanatory. At a fee of £1000 (plus VAT) when using the London office and £750 (plus VAT) when using the South Wales office, they will provide a Mediator and neutral accommodation to host the mediation for a full day. The fee is fixed and so there are no 'hidden' expenses such as travel or administration charges to add. In addition, when using a UKPO Mediator

the Office will arrange the handling of all fees and issue all written notices. This includes the drafting of the document central to a successful settlement, a Mediation Agreement, which the parties have to sign to confirm that they agree to the terms of the mediation.

It is clear from the number of mediators that the UKPO list on their website that the IP world is no stranger to ADR, but the Office's publicity, and prompting from Hearing Officers where necessary, will ensure broader awareness of the ADR options throughout the IP community. The setting up of the UKPO Mediation Service and the helpful information on their website should smooth over many of the initial obstacles that might dissuade parties from pursuing mediation and turn awareness into actual take up.

All in all the mediation project's impact will be to improve rights holders options for enforcing their IP effectively and economically so that it can do the job it was designed for, driving innovation and prosperity.

### **Knowledge Resources**

#### **Support Initiatives to European SMEs explored at the March 8<sup>th</sup> 2006 event held by the Stockholm Network and Managing Intellectual Property Magazine**

Following recent discussions on patent harmonisation and patentability of computer-implemented innovations in Europe, both the pro-IP camp and the anti-IP camp have claimed that they speak on behalf of the small and medium sized enterprises (SMEs) that comprise 99% of all European enterprises. The Stockholm Network has followed and participated in this discussion, and decided to investigate the question more thoroughly than the special interest groups.

## Know IP - Stockholm Network Monthly Bulletin on IPRS

So on the 8<sup>th</sup> March we invited SMEs, policy-makers, academics, big industry, lawyers, politicians, the think tank community, trade associations, media and other interested parties to a workshop to discuss the topic. We asked the following question:

*Do IPRs represent a barrier to innovation or an engine for growth for SMEs?*

The conclusion drawn from the workshop was that IPRs can certainly represent an engine for growth if the company has the resources to develop a clear IP strategy to take full advantage of and protect its knowledge assets.

Another conclusion reached was that despite the common belief that SMEs are being neglected by EU policy-makers seeking to create a viable IP environment, the opposite is true.

There are in fact a number of institutions set up with the specific aim of helping SMEs better understand the importance and benefits of intellectual property rights. The problem with regards to SMEs and IPRs seems rather to be one of coordinating these different efforts and of course to make the SMEs aware of them.

We are therefore happy to present a list of the most important of these initiatives:

### 1) The European Commission:

Under the FP6 the efforts to build a European Research Area (ERA) the European Commission offers information and resources to technology-oriented SMEs.

<http://sme.cordis.lu/home/index.cfm>

### 2) SME National Contact Points (NCPs):

As part of the above mentioned initiative, the Commission has also set up so-called NCPs for direct local help.

[http://sme.cordis.lu/assistance/direct\\_local\\_help.cfm](http://sme.cordis.lu/assistance/direct_local_help.cfm)

### 3) IPR Helpdesk:

The IPR Helpdesk offers free of charge assistance to potential and current contractors taking part in Community funded research and development projects on IPR issues.

<http://www.ipr-helpdesk.org/index.html>

### 4) WIPO SMEs Division:

Provides comprehensive web-based information and basic advice on IP issues to SMEs.

[http://www.wipo.int/sme/en/about\\_sme.html](http://www.wipo.int/sme/en/about_sme.html)

### 5) UK Patent Office, Patent Enforcement Working Group:

Investigated ways of assisting SME patent holders enforcing their assets.

<http://www.patent.gov.uk/about/enforcement/finalreportv1.pdf>

The Stockholm Network would be happy to continue to work as a facilitator of any policy initiative in Europe aimed at assisting SMEs.

## **News and Events**

### **The Progress & Freedom Foundation conferences on IPRs, Innovation and Developing Economies - Patrick Ross\***

Does IPR protection help a developing economy? Should software be patented? Should government favour one type of software over another? These were three critical questions debated at two recent conferences in South America co-hosted by the Progress & Freedom Foundation (PFF).

The consensus reached at both conferences was 'yes' to the first two questions, and a resounding 'no' to

---

\* Senior Fellow and VP-communications & External Affairs



## Know IP - Stockholm Network Monthly Bulletin on IPRS

the third. One result of the conferences will be congressional hearings in Brazil to build on the discussions, according to a Brazilian congressman in attendance at the Sao Paulo conference.

PFF co-hosted a conference in Buenos Aires, Argentina, April 7<sup>th</sup> with ESEADE and an April 11<sup>th</sup> conference in Sao Paulo with the Brazilian Intellectual Property Association,(ABPI). Both were day-long conferences, attended by well over 100 people.

Leaders of developing countries are often told that it is not in their best interest to protect IPRs, but speaker after speaker at the PFF events said otherwise. Attorneys representing innovators said developing nations that don't protect the work of their own innovators will see those creative minds go elsewhere, and the economic growth their innovations would have created will go with them.

Brazilian Undersecretary of Information Technology Policy of the Ministry of Science and Technology, Marilyn Peixoto da Silva Nogueira said her government was committed to increased economic output through IPR protection and anti-piracy measures. Brazil has a goal of increasing its software exports from (US) \$300 million in 2005 to (US) \$2 billion in 2007. Can this increase occur without stronger IPR, in particular without software patents?

Some speakers were sceptical, and that scepticism was also found in Argentina. In Buenos Aires, software attorney Martin Carranza Torres gave a compelling presentation in defence of software patents. He said trade secrets and/or copyright alone are insufficient to protect software innovation, as is some hybrid of copyright and patent. Patents can play a critical role in software protection, he said. This was echoed by PFF Vice President for Research and

Senior Fellow Tom Lenard, an economist, who presented statistics suggesting a correlation between patents and innovation. To the extent there are questionable software patents out there, attendees were told, the issue is with the awarding of poor patents, not with the concept of software patents itself.

Several prominent individuals spoke at the conferences. Along with Lenard, PFF was represented by its President Ray Gifford and Senior Fellow and Director of the Center for the Study of Intellectual Property James DeLong. Other speakers included ESEADE Rector Martin Krause and Brazilian Congressmen Julio Semeghini and Julio Lopes. Semeghini was in particular struck by the substance and relevance of the conference, and vowed to work with ABPI President Gustavo Leonardos to develop one or more congressional hearings on the topic of IPR.

One frustration found in both countries was an awareness that in high-technology exports and innovation, these countries are being surpassed by India and China. One hundred years ago, both Argentina and Brazil were primed to be major players in the world economy. Speakers seemed to recall that as if it were yesterday, and there was considerable resentment demonstrated at the fact that they have been passed by nations that were at one time considerably behind them. Brazilian government officials made it clear they viewed their nation as being a major software producer, and were focused on closing the gap with other countries. Is IPR protection a way to do that? Many seemed to believe it would be a positive step.

This belief, naturally, can lead to some resentment when US academics travel to South America and encourage those nations to adopt a new approach to software, namely one where it is given away.



## Know IP - Stockholm Network Monthly Bulletin on IPRS

SOFTEX Vice President Marcio Girao praised the Lula government in Brazil for including software in its economic growth agenda, but raised alarms about new proposals which would restrict government procurement solely to open source software. "People are [legislating] demand for free software," he said, adding he is "vehemently opposed to this." "We support free software" at SOFTEX and have participated in fora focused on its development, but said "we cannot be in favour of free software being put like in a cast into legal measures the government wants to do."

Nogueira seemed to understand this when she made clear, repeatedly, that the Brazilian government was not ready to bar the procurement of proprietary software. She brought a firm message to the conference attendees that she stated at the beginning of the conference and reiterated at the end. "We are not taking sides, we believe there must be a balance," she said. "It's not necessarily proprietary versus free. Of course, free is not necessarily free."