

# Commission on Intellectual Property Rights

## Workshop 2: Pharmaceutical and Vaccines Workshop

20<sup>th</sup> November 2001

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**Commissioners:** Daniel Alexander (Chair), Carlos Correa, Ramesh Mashelkar, Gill Samuels, Sandy Thomas

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**Summary:** There were presentations by the authors of the study papers commissioned by the Commission, which were followed by a response by two discussants and then general discussion of the papers. The first paper (Kettler and Collins) reviewed the evidence available on the impacts of the role of IPR in relation to the problems and solutions for increasing research and development (R&D) for neglected diseases and made a series of recommendations on the use of PPPs for enhancing R&D. The second paper (Abbott) focused on relative benefits to countries in the implementation of TRIPS, and the need for developing countries to exploit to the full the flexibilities in TRIPS. The second session looked into the relevance of IP to access to medicines in developing countries. The third session considered the implications of IP protection for R&D for neglected diseases. The final session highlighted the most important areas for the Commission to focus on.

### Session 1: Presentation and Discussion of Study Papers

#### Kettler and Collins Presentations

#### The role of IPR as a Problem/Solution for increasing R&D for Neglected Diseases

#### Key Points

- Private industry is essential for pharmaceutical innovation, and IP protection is a necessary condition to incentivise R&D by private and public actors. Any policy package must work from this starting point.

- IPR is only one part of the solution to the issue of lack of restricted access
- The new commercial model of PPPs uses IPR as a tool to increase R&D through creative licensing.
- This PPP model is an explicit statement to recognise IP as a tool to protect the various actors.
- Evidence was presented revealing that strong IP is related to higher prices, which restricts access
- Country evidence was presented to demonstrate that financial and political commitment is essential to address the AIDS pandemic where generally branded product prices have not matched income.

## Recommendations

### **R&D Direction**

- Different markets need different policies that address the need for IP protection as a necessary condition to incentivise R&D by public and private actors
- Limitations on resources and know-how in the public sector indicates the need to mobilise private sector capacity for relevant research.
- PPPs enable the drawing out of the major relative advantages of the private and public sectors.
- Use IPR as a tool to enhance the commercial model (which is a private-led process) to increase R&D into neglected diseases. Promote creative licensing approaches to deal-making in public-private partnerships.
- Review the management of PPPs and apply best-practices to new models to maximise effectiveness.

### **Pricing**

- Establish political and financial commitment by governments to prevent prohibitively high pricing.
- Differential pricing strategies should be promoted.
- Establish political commitment to control re-exportation of drugs.
- The threat of compulsory licensing should be seen as a necessary weapon to help bring prices of medicines down.

### **Discussant**

The paper was thought to be correct in asserting that patents play an important role in incentivising R&D but are not sufficient. Equally it was agreed that patents do present a barrier to medicines for poor people.

It was recognised that many assumptions made by the discussants were based on three models: the private, public and PPPs, and it is recommended that the efficiency of each model is ascertained in order to understand the strengths and weaknesses of each, identify where waste is occurring and validate or nullify some of the arguments. What could be said about the relative efficiency of private versus public research? How were research priorities set? The IP system oriented priorities to the discovery of new drugs, rather than the survey of the existing portfolio for new uses.

It was recommended that the feasibility of using the roaming patent be investigated. Issues such as who sets the priorities for R&D, who pays for R&D and commercialises new discoveries need to be addressed. Spending by the public sector, including the NIH, on relevant research needed to be increased. The very small proportion of even publicly funded research in areas relevant to developing countries (e.g. through the NIH) was noted.

Issues of access also include rational selection of drugs, pricing, financing and reliable health systems. The Brazil AIDS programme was interesting but not, on the face of it, replicable.

It was recognised that the flow-back of price information to the North (which would effectively be paying for drugs provided to the South) was a major problem in establishing a tiered pricing system. More use of voluntary licensing needed to be considered. Packaging and branding of drugs could help prevent problems of physical flow-back to high price markets. The overall problem was how to establish differential pricing in a manner that was sustainable and predictable.

## **Discussion**

The role that the IP system played in stimulating innovation in today's competitive landscape was debated. The case of countries that had industrialised without a patent system was considered (see, for instance, Eric Schiff "Industrialization without National Patents: The Netherlands 1869 - 1919, Switzerland, 1850 -1907" Princeton University Press, 1971).

Incentive regimes needed to be devised to serve the needs of low value markets. An international orphan drugs agreement might be considered offering tax and other incentives to stimulate R&D internationally.

## **Abbott Presentation**

The main points made in the paper can be summarised as follows:

- Present TRIPS Agreement standards will principally benefit commercial pharmaceutical enterprises located in the OECD countries, and more specifically in the United States, Japan, Switzerland, Germany and the United Kingdom.

- Increased developing country R & D on medicines and vaccines brought about by adoption of strong patent protection is highly unlikely to yield the development of new pharmaceutical products the income from which would offset increased patent rents that will flow from the developing to the developed countries based on the introduction of such protection.
- Developing countries should take advantage of the policy options afforded by the TRIPS Agreement including the granting of compulsory licenses and authorization of parallel importation. Price controls may be effective in specific contexts. Restrictions on exports of tiered-priced drugs may be useful in specific contexts.
- Substantial subsidization of developing country purchases of medicines is necessary if highly active antiretroviral (ARV) treatment (HAART) is to be provided to address the HIV/AIDS pandemic.
- Funding for R & D on medicines and vaccines of particular relevance to developing countries is inadequate. Private enterprise will not undertake such research as a consequence of lack of perceived market incentives. Mechanisms to facilitate R & D on medicines and vaccines of particular relevance to developing countries should urgently be developed and put into operation.

The principal questions at this stage of inquiry are less directed to the objectives that need to be met, but rather to the best policy options for accomplishing these objectives. It was recommended that there should be:

- Increased reliance on production of medicines and vaccines by generic producers, facilitated by relaxation of TRIPS Agreement rules;
- An enhanced leadership role for the IMF and World Bank in arranging the financing necessary to respond to epidemic disease, in particular to facilitate production and acquisition of low cost medicines and vaccines, and;
- Increased reliance on public sector R & D for the pursuit of new medicines and vaccines of relevance to developing countries, supported by public financing.

Regarding production of existing medicines and the conduct of R & D, the author's recommendations differ to a modest extent from those of the majority of the WHO Macroeconomics Commission. In respect to financing, they differ from the current emphasis on establishing a Global Fund through new contributions by OECD governments, suggesting potential political advantages of increased reliance on existing multilateral financial institutions

### **Discussant**

It was felt that settling the compulsory licensing for export issue, where Doha had postponed a decision, was an absolute priority for poor countries.

Figures were presented on the number of scientists in relation to the population in a variety of countries which served as an indicator of the extreme lack of scientific and technological capacity, particularly in most of Africa. The fact was that it was unrealistic to think of creating such a capacity, even in the medium term or to expect that such countries could contribute significantly to the development of new drugs relevant to developing countries.

In those circumstances, one needed to look at what the private sector could offer. The example of integrated circuits was given where the private sector, not government, had spearheaded innovation. Setting up large funds (such as the Global Health Fund) was one approach but there were political problems in the explicit use of taxpayers' money in this way. A system of tax credits, that could be calibrated to make relevant R&D expenditure by firms costless or even remunerative, might be a more feasible solution.

## **Discussion**

What effect will the Doha declaration have? In the context of the issue of compulsory licensing for export, the case of India (as a potential exporter) was noted. Only the four latest ARV drugs would be likely to be patentable after 2005 and it would take several years for these to be examined and granted. That left eleven important ARV drugs which could be freely imported from India as generics. Thus TRIPS would bite only very gradually.

The WTO meeting at Doha was seen as a mechanism for clarification of the rights within TRIPS, but was not a relaxation of the agreement. Doha attempted to balance the interpretations of Article 7 & 8, which had been too narrowly read by some countries, and was thought to have been successful in this attempt.

## **Session 2: Relevance of IP to Access to Medicines**

Following from the previous session, the debate was essentially divided into two broad categories – 1) How to get drugs to the poor at affordable prices, and 2) How to promote R&D in appropriate directions to address neglected diseases.

Issues of access encompass delivery systems, infrastructure, safety issues, and so on.

It was generally agreed that a package of policy mechanisms should balance access, pricing and R&D direction issues, but the emphasis varied among participants.

## **TRIPS**

Changes in attitudes in exploiting the flexibilities in TRIPS were evident from the outcome of Doha. There was some confidence, post-Doha, that a feasible solution could be found on the question of compulsory licensing for export.

It was said that an opportunity had been missed in the Uruguay Round to leverage, say 10% of R&D, for developing countries in exchange for the developing countries accepting TRIPS. An analogy was drawn with the US/Canada deal where US firms agreed to move R&D facilities to Canada in exchange for Canada removing its liberal compulsory licensing regime. This had apparently been successful, although it was argued that the additional investment was more on clinical trials than R&D.

### **IP Strategies and R&D Investment**

It was agreed that IP is a necessary incentive to innovation for private, public and PPP sector activities. The private sector, it was argued, has the necessary know how and some resources not currently available to the public sector and is a necessary part of the solution. The private sector should be incentivised to work alongside the public sector in neglected disease areas through a range of IP and fiscal mechanisms that address the dual goals of making a profit whilst saving lives.

Issues were raised again as to whether there was waste in expenditure by the private sector and it was suggested that further research is carried out into the efficiency of R&D investment.

IP is viewed as necessary in PPPs, which have been, to some degree, pushed by private industry. Patents have ensured good prices and returns on investment, which have in turn enabled R&D into neglected areas because they do not have other issues regarding 'access' to prevent commercial interest. Debate ensued as to whether a package of fiscal incentives would be sufficient, or whether, without the promise of a market, there will be little incentive for private partners to join PPPs at all.

It was argued that the patent system should be less money-driven and should revert to its original purpose, which was to provide a time-limited monopoly to provide incentives for innovation.

The impact of Bayh-Dole in the US was discussed. It had had a rather profound impact on universities' approach to research. There were varied views as to whether this was a good thing (through increased innovation) or whether it introduced undesirable distortions into research priorities.

### **Developing Countries IP and Pricing**

It was argued by some that prices are higher in LDCs as a result of patent protection, although some prices have reduced dramatically recently as companies respond to political pressure. The contrary contention that patents were not widespread in low income countries, and therefore for the most part

could not affect prices was noted. In any case, it was felt that the consumption of drugs by the poor was very sensitive to price, as most drug purchases were privately as opposed to state funded. It was agreed that the IP issue was only one among many factors affecting access to medicines, but there was obviously less agreement as to whether it was hardly relevant at all, or quite important.

### **Asymmetries in technical capacity**

It was argued that different countries should tailor their IP system to fit their particular circumstances, in particular variations in their levels of scientific and technological development. IP protection for a country without significant manufacturing capacity or intellectual capital was largely irrelevant in stimulating R&D. But it had costs, both in terms of establishing IP capacity and enforcement, and in the costs inherent in conferring patent monopolies.

### **Generics and IP**

It was argued that it was important, in the context of compulsory licensing, that there was competition. It was suggested that five suppliers of a particular drug might be appropriate to achieve competition, and drive down price. Given the size of the market in poor countries, this suggested the need to look at how compulsory licensing might be done on a regional, or even global, basis.

Countries such as India have created drugs in an IP vacuum, through reverse engineering and imitation, which requires sophisticated scientific ability and high manufacturing and safety standards. But it was also argued that generic manufacture was very simple, and the constraints should not be overstated.

### **Compulsory Licensing**

It was argued by some that compulsory licensing should be encouraged to foster the generics industries to produce cheaper medicines. On the other hand, liberal use of compulsory licensing could act as a deterrent to foreign investors and that R&D and manufacturing investment in developing countries could be adversely affected.

### **Current Patent Practices**

Evidence was presented that some current patent practices were not so much about innovation, as about maximising profits and commercial advantage by exploiting aspects of the system to prolong monopolies e.g. so-called "evergreening". Of the thousands of patents issued per year to the pharmaceutical industry, around only 80 patents were issued for NCEs. The rest are incremental, and have little to do with innovation as such. It was also noted that the generics industry can introduce the "older, non-evergreened" product.

### **Session 3: The need for IP protection to encourage R&D for diseases affecting developing countries – The Evidence.**

#### **The R&D Problem – A Result of Inadequate IP Protection or Lack of Effective Demand?**

Lack of effective demand for products of research was argued to be at the core of the 'R&D Problem'. The existence of IP protection was not sufficient to stimulate R&D for products whose sole markets were in poor countries. The necessary demand had to be provided through the greater involvement of public money, nationally and internationally. If the private sector was then to be involved, through PPPs or otherwise, then how IP rights were allocated, and the conditions for licensing technologies became important.

It was recommended that an inventory of incidence of disease in developing countries be undertaken to ascertain priorities in R&D for neglected diseases.

For products that had global markets, IP was important.

#### **Developing Countries with Scientific Capability**

Weak IP protection in developing countries with scientific capability is an issue for developed country industries, because of the competitive impact of generic industries in such countries. On the other hand some developing countries can also see advantages in appropriate IP protection, in particular to stimulate a transition to a research-based pharmaceutical industry. However, because Northern markets were also the most attractive to low cost research-based firms, it was not apparent that IP protection in such countries would increase R&D in neglected areas significantly, despite the potential for much lower cost R&D than in developed countries.

#### **Capacity Issues**

Given that in many developing countries patents were arguably a factor in limiting access to medicines, and had little or no impact on relevant R&D, it had to be asked, in view of the substantial costs of setting up and running an IP protection system, what the benefits were to developing countries in this category.

#### **Recommendations for PPPs**

It was suggested that research should be undertaken into the specific roles, incentives and motivations of actors in PPPs alongside a report on the rate of progress of each PPP model.

It was argued that a series of IP lawyers should be rallied to provide a blueprint of IP 'value' for various stakeholders in a range of models to establish codes of practice for PPPs.

## **Session 4: Conclusions and Recommendations**

This session dealt with the issues participants felt the Commission should focus on its report. The following is a list of what each participant raised, and not necessarily points with which all agreed.

These included:

### **TRIPS**

- The compulsory licensing issue for export arising out of Doha (Article 31 f, inter alia)
- Transfer of technology issues in TRIPS (Article 66.2, inter alia)
- Data Protection issue (Article 39.3)
- Should TRIPS be a ceiling as well as a floor?
- Transition periods for Idcs; indicators for transition.
- Should the review of TRIPS be used to effect fundamental reform – not just review implementation?
- The relationship between IP and competition policy (Article 8.2 and 40)
- Non violation and related procedures and how they affect developing countries
- Changes to the way the TRIPS Council works

### **IP System More Generally**

- Imposition of TRIPS Plus through bilateral agreements
- Role of WIPO in encouraging (too) high IP standards e.g. Patent Law Treaty
- Evergreening of patents
- Research tool patenting
- Implementation of differential pricing; how to avoid read-across to developed country prices
- Desirability of Bolar exception in national legislation
- Creative use of IP in private-public partnerships
- How can IP be used to encourage research on neglected diseases? An international treaty? How can fair burden sharing to cover costs of research be set up?
- Will fiscal incentives be effective in promoting private sector R&D and technology transfer? Do they overcome the market constraint?
- How does compulsory licensing affect R&D incentives?
- Need for competition and the issue of compulsory licences – more generally how to develop competition policy in developing countries as a complement to IP protection
- High costs of establishing and running IP systems in developing countries

