Foreword

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It is amply recognised that intellectual property has a particular bearing in the area of pharmaceuticals. While it provides incentives for the development of new products where profitable markets exist, such products are unaffordable to a large part of the world population. Not surprisingly, a vivid debate has taken place on the public health implications of intellectual property protection, particularly after the Agreement on Trade Related Aspects of Intellectual Property Rights ("TRIPS") required all members of the World Trade Organization (WTO) to recognise product patents in pharmaceuticals. The adoption, in November 2001, of the Doha Declaration on the TRIPS Agreement and Public Health by the 4th Ministerial Conference of WTO[1] illustrated the depth of the concerns of developing countries and the need for an international action to address the interface between intellectual property and access to drugs.

Although trademarks are of key relevance in the pharmaceutical market, patents and the protection of test data have become the most controversial areas in intellectual property protection. Patents allow title-holders to charge prices above marginal costs, under the assumption that the extraordinary profits obtained will induce more research. This is done at the price of excluding competition, which is essential to drive the prices of medicines down. Patents are intended to reward inventors for genuine technical contributions to the state of the art. But in a context of drastic decline in the development of new drugs (particularly with new therapeutic value) there is a proliferation of patents on variants, sometimes trivial, of existing products and processes. This is the result from aggressive patenting strategies (sometimes called "evergreening") combined with deficits in the examination process and the application of low standards of inventive step.

This issue of *IJIPM* is devoted to some of the controversial issues around the protection of pharmaceuticals. In one of the papers I examine critical aspects of the patentability of pharmaceuticals. It addresses the extent to which variants of existing products or new uses thereof provide sufficient grounds for the granting of a patent. Although this will obviously depend on the standards applied by the competent patent offices, this paper alerts about the need to apply strict inventive step criteria, so as to avoid unwarranted distortions in the pharmaceutical market and a negative impact on public health. While patent offices must admittedly deal with a growing number of patent applications, they must also protect the public from the creation of undue limitations to legitimate competition. As noted by the US Federal Trade Commission the patent office must function

> "as a steward of the public interest, not as a servant of patent applicants. The PTO must protect the public against the issuance of invalid patents that add unnecessary costs and may confer market power, just as it should issue valid patents to encourage invention, disclosure, and commercial development."[2]

In another contribution by Professor M. Basso, the participation of the Brazilian national health authority in the assessment of patent applications relating to pharmaceuticals is

considered. There is nothing in the TRIPS Agreement or in other international treaties against such participation, which may enhance the quality of patent grants. The Brazilian framework may provide a model for other countries if the appropriate training to the relevant personnel is provided. It is worth noting that the intervention of the health authority does not mean, in the examined case, the introduction of additional criteria of patentability, but a strict review of the applications taking public health interests into account.

Closely related to this subject is the paper by S. Mukherjee on the 2005 amendment of the Indian patent law. Among other elements, the amendment has incorporated a specific provision to deal with pharmaceutical inventions and avoid the granting of patents over trivial developments. Interestingly, the law has specified 'efficacy' as one of the elements to assess patentability. The application of the inventive step or utility standard to pharmaceuticals may require a demonstration of efficacy. In a well known US decision in *re Brana* the Court observed that

> "FDA approval is not a prerequisite for finding a compound useful within the meaning of the patent laws … Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans."[3]

Even if this doctrine were accepted (different approaches may be adopted in other jurisdictions), it would not exclude the possibility of requiring evidence of increased efficacy with regard to modifications of existing drugs, such as salts, polymorphs, ethers, etc. since in these cases it is not the efficacy of the drug as such what is at stake, but the justification for granting patents on incremental changes.

Compulsory licensing -including government use- has been another controversial issue in this field. Compulsory licences are regarded by developing countries as an essential tool to mitigate the powers conferred to title-holders and address public interests. The grant of compulsory licences may be particularly relevant to protect public health. Several developing countries have threatened to use or effectively used in recent years such mechanism to acquire medicines at lower prices. This issue is addressed in the paper by C. Oh. Useful lessons may be drawn from these experiences for other countries. The possibility of granting compulsory licences and the right to determine the grounds therefore have been confirmed by the above mentioned Doha Declaration.

In addition, the General Council of the WTO adopted, through its Decision of August 30, 2003, a complex system to permit the exportation and importation of pharmaceutical products in cases where the importing country has no manufacturing capacity in pharmaceuticals. Canada was the first country to adopt legislation to implement this system as an exporter. The paper by R. Elliott contains an analysis of the Canadian legislation on the subject. Canada was later followed by Netherlands, Norway, India and the European Union, which passed Regulation EC/816 in May 2006. So far, no developing country has notified its intention to use the system and no actual transaction has taken place using it. Despite this, in December 2005 WTO Members agreed to incorporate the Decision as article 31b*is* of the TRIPS Agreement (subject to ratification in accordance with WTO rules).

Several Free Trade Agreements (FTAs) have recently been negotiated between the USA, the European Union or the European Free Trade Area (EFTA) and developing countries with specific provisions on intellectual property. These agreements contain

TRIPS-plus provisions in different areas, notably with regard to patent and test data protection. For instance, US FTAs incorporate, *inter alia*, an extension of the patent term to compensate for delays in the examination of patent applications and in the procedures for the approval of pharmaceutical products: They also establish a minimum term of five years of data exclusivity (counted from the date of the marketing approval in the country where protection is sought). This extended rights (not required by TRIPS) can significantly limit access to medicines, particularly in cases where data exclusivity applies in the absence of or after patent protection has expired. A detailed analysis of the FTA TRIPS-plus provisions and some of its implications for public health are contained in the papers by J. Morin, P. Roffe and C. Spennemann, and F. Rossi.

Finally, R. Weisman considers 'public health-friendly options' for protecting pharmaceutical test data. While recognising that TRIPS does not require data exclusivity, this contribution is premised on the assumption that the USA will insist on some form of protection of test data beyond TRIPS. It, therefore, explores compensation mechanisms that could mitigate the negative public health impact of the unavailability of test data for the registration of generic products. This paper contains interesting information about the US practice with a compensation scheme under the Federal Insecticide, Fungicide, Rodenticide Act (FIFRA). A compensation scheme was unsuccessfully proposed by Colombia, Peru and Ecuador during the FTAs negotiations with the USA, which pushed for (and finally obtained) a data exclusivity regime despite the resistance of those countries. Such a scheme is, however, an option contemplated in some FTAs entered by EFTA.

In sum, this issue of *IJIPM* addresses a set of complex themes that are currently under consideration at the national and international level and which are of critical importance for industry and public health policies. No doubt, the issues discussed here may raise a range of different opinions. Our objective will be fulfilled if the presented materials contribute to advance the debate and to find solutions, adapted to the circumstances of different countries, to protect and improve public health.

Notes

[1]WT/MIN(01)/DEC/W/2, 14 November 2001.

[2]Federal Trade Commission (FTC) (2003) To promote innovation: the proper balance of competition and patent law policy, available at http://www.ftc.gov, p.14.

[3]51 F.3d 1560 (Fed. Cir. 1995).