

Prof Trevor M Jones CBE. CIPIH :Minority Dissenting Report. March 26th 2006

Although I support much of the report that outlines the need for more sustained innovation in R&D for diseases that primarily affect the developing world, the important role of Public Private Partnerships in that regard and the need for governments to make a stronger commitment and increase in funding for such R&D plus healthcare provision ,delivery infrastructure and financing, I have serious reservations and do not agree with a number of the conclusions that relate to Intellectual Property Rights and Access. It is implied (in various Chapters, but particularly in Chapter 4) that there is a direct link between the possession of a patent, the price of that product and access to it in the developing world .This is not correct. Firstly it is extremely rare that patents confer a monopoly in any particular therapeutic field; competition being provided by alternative products- whether still in patent or out of patent. Secondly, patents are not the basis for price setting .Rather, companies set prices largely on the ability /willingness of healthcare providers/payors and/or patients in different countries to pay, also taking into account the nature and extent of the disease being treated... and local regulation. Therefore, the assumption in the report that a time-limited patent on new inventions results in higher prices to consumers is generally not valid; particularly in most countries in the developing world and especially since companies do not usually file or enforce patents in the poorest countries.

In my opinion the report does not adequately explain company pricing policies. Throughout their history, research based pharmaceutical companies have set their prices in a differential manner in each country/market. In addition, most if not all companies offer discounts on the basis of volume purchased in line with internationally recognized competition law principles. Furthermore, many companies have developed schemes specifically for the medically indigent within a country where this is compatible with local government regulation. In some cases, companies also tier prices against a particular formula between and within a country depending upon whether products are supplied to the public or private market. Also, companies provide medical products through donations as part of a company or consortium schemes.

Generic companies also operate some of these schemes for patent expired products along similar principles. Thus, the possession of a patent *per se* should not be confused with the price of that product in any particular market. Further, in many places within the report, reference is made to the “price” of medicines without qualifying whether this applies to the originator company price, the generic companies price, the list price from the manufacturer or the price the patient /purchaser is asked to pay including taxes, tariffs, supply chain mark-up’s etc .Such distinctions are a necessary part of the analysis of the impact of the price of a medical product and are not given sufficient attention within the report .

The report also confuses this issue (and indeed other matters related to IPR) by the frequent use of the generic term “developing world”. This is defined in Chapter 1 using

the World Bank definition and recognizes that the heterogeneity of such countries and their disease burdens has important implications due to the widely varying resources capacities they possess .However, most of the subsequent references to “developing countries” fail adequately to distinguish between the situation that relates to the least developed nations, the various and different emerging industrial economies and those in between.

For example, in many countries, especially those that are least developed, medicines (and other essential goods) are simply unaffordable from whatever source and whatever the price or patent status . It is a sad fact that even the products included in the WHO Essential Drugs List (which although originally the fruit of innovation by research based pharmaceutical companies are now virtually all out of patent generic products and cost “pennies”) are still not available to the majority of poor people. This is referred to...albeit as a footnote... in the report but its implication with respect to IPR is not adequately explained. The WHO, in its analysis of the uptake of drugs that comprise their Essential Drugs List has stated that *“about 30% of the world’s population lacks regular access to essential medicines; in the poorest parts of Africa this figure runs to over 50%”*

Also implied in the report (again primarily but not solely in Chapter 4) is the need for further reform of the patent system (a term that is not defined in the report).It is certainly the case (as with product regulatory agencies) that there is a need to improve the competence of patent agencies in developing world countries and enforcement procedures ,but this does not mean that the basis of granting a patent needs reform nor that further reform of the TRIPS agreement is necessary ;especially following the formal resolution of outstanding issues at the WTO General Council on December 6th 2005.This decision effectively resolves the final policy issue regarding the TRIPS Agreement and public health and does not weaken its obligations. In particular Article 31 of the TRIPS Agreement and paragraph 5 of the Doha Declaration provides the basis for the rights of WTO members regarding the grounds for such matters as compulsory licensing, declaring a national emergency and authorizing parallel trade .Some of the recommendations in the CIPIH report do not make this adequately clear and infer, incorrectly, a “carte blanche” situation with regard to these flexibilities.

I hold the view that that patents are an essential component of innovation for medical products for both the developed and the developing world and that a strong and efficient process for review and grant of patents together with an effective system of enforcement is both desirable and necessary as a basis new products for both existing and potentially new diseases. The basis upon which a patent may be granted is well established and now works effectively in the developed world. What is needed is for the same principles to be applied more widely. In fact, over the last decade or so, a number of developing countries (e.g. China, Mexico, Chile and Korea) have seized the opportunity to build up their R&D capacity by adopting TRIPS or even higher standards.

The report also discusses, but in my opinion lack clarity on, the patenting of so-called upstream technologies and whether they could deter downstream and follow on

innovation by successive inventors, so limiting technological progress, This has been the subject of wide debate in recent years and I suggest, for current technologies, is now essentially resolved. As noted in Chapter 2, a recent report by the United States' National Academies of Sciences on this subject reached the conclusion that :

“the number of projects abandoned or delayed as a result of difficulties in technology access is reported to be small, as is the number of occasions in which investigators revise their protocols to avoid intellectual property issues or in which they pay high costs to obtain intellectual property. Thus, for the time being, it appears that access to patented inventions or information inputs into biomedical research rarely imposes a significant burden for biomedical researchers”⁽¹⁾

The CIPIH report (again in Chapter 4) places too great an emphasis on so-called “evergreening”. Whilst research based pharmaceutical companies regularly introduce entirely new “breakthrough” products (for example the new Papilloma vaccines from GSK and Merck that are just becoming available which could be of profound benefit to women worldwide) it is abundantly clear from the examples given in Chapter 4 of the report that incremental innovation is the lifeblood of medical progress (e.g. the array of antiretroviral drugs now available for effective combination therapy) and indeed through new processes for economically efficient manufacture. The so called “evergreening” issue that arose in the USA in late 1990’s was dealt with and related to the particular historical situation of lucrative products in a large, indeed, rich market with price freedoms. The issue is not the same as incremental innovation which requires strong IPR as a stimulus to further innovation, particularly by those emerging economies such as India which have proved themselves to be successful in that regard but, for the lack of effective patent protection before 2005, have traditionally not been able adequately to enjoy the economic benefit of their endeavour. Further, the suggestion (Chapter 3) that public private partnerships tend to seek breakthrough products rather than incremental innovation as compared to the industry is simply wrong and fails to understand both the reality of their portfolios and the process of drug discovery and development.

The report (Chapter 4) proposes that companies should avoid filing patents in developing countries or enforcing those that have been so granted. The presumption... although not explicit in the report... is that this would then permit such countries to manufacture these products locally and/or purchase them as generic products from other countries that are legally entitled so to supply. The economic and practical arguments for such activities are not, in my opinion, adequately made. The fact is that companies do not patent in countries where there is an insufficient market and where enforcement is not possible due to a lack of local expertise, resource or will. This does not mean that research based companies will not then make those products available in those countries nor price their products appropriately, albeit provided that they can as far as possible ensure that the products remain within the country of purchase rather than leak back to the developed world markets so depriving those in the country for which they were intended. Furthermore, by advocating a policy of non patenting in developing countries the report in effect suggests a disincentive to those companies emerging in the developing world whose R&D focus could be directly relevant to diseases that mostly afflict their populations.

Ensuring that robust Intellectual Property agencies and processes obtain in the developing world is a necessary step as those countries grow their intellectual and innovative capacity so that their economies can emerge to the benefit of their people and, in particular, the impact this will have, together with new medical products, in terms of their health and well being.

When it comes to access ,patents are NOT the issue but ,as mentioned albeit briefly in the report, the overwhelming poverty of the individuals, the absence of state financing of healthcare ,the lack of medical personal , transport and distribution infrastructure and ,regrettably the imposition of taxes, tariffs and mark-up's which can make affordable products unaffordable - no matter how low the ex-manufacturers (originator or generic company) price. It is unfortunate that in its (brief) discussion on the supply and distribution chain costs (Chapter 4) the report isolates patent owners and importers as a focus rather than the many other contributors to the price the patient actually pays e.g. wholesalers, distributors, pharmacists and other agents and agencies.

A number of the recommendations in the report assume that Compulsory Licencing will increase access. A rational analysis for this assumption is not made; not only in the context of final products (Chapter 4) but especially in the possible use of this procedure in the promotion of discovery research (Chapter 2) It is not necessary for pharmaceutical and biotech companies to give away their intellectual property rights-including patents-in order for patients in developing countries to gain the benefit of their innovations. Companies can and do retain these rights whilst making alternative arrangements for access to their know-how and products. A recent example is that of Roche and its offer to make available technology for the manufacture of Tamiflu. Whilst it is important that countries should have the right to enact Compulsory licensing (consistent with the conditions laid down in the TRIPS agreement) surely this should only be used *in extremis* when all other reasonable steps have been taken.

Whilst I fully support the call in the report to increase significantly the resource that is devoted to research that addresses the health needs of developing countries, I am disappointed that insufficient emphasis is given to propose solutions for those diseases (so-called Type III diseases) that afflict so many in the least developed countries and that, currently, are largely neglected. Whilst our international efforts in search of improved ways to combat HIV/AIDS, tuberculosis and Malaria MUST continue, these remains also an urgent and desperate need to pay much greater attention to R&D on Type III disease.

In my view the report also fails adequately to recognise both the historical and continuing contribution that the research based pharmaceutical industry makes to diseases that primarily affect people in the developing world. Box 4.4 in Chapter 4 provides some examples of this contribution but the recital is a rather small "snapshot" of what is, in reality, a much larger activity ;see, for example, the IFPMA report "Building Healthier Societies through Partnerships" ⁽²⁾ . Over the period 2000-2005, the research based pharmaceutical companies collectively contributed an estimated \$4.4billion through donating drugs to patients in low-income countries, measured at wholesale prices ⁽³⁾ ;a

figure that the London School of Economics (University of London) in their independent audit of that figure regard as “conservative”! ⁽⁴⁾ Of course the pharmaceutical industry can (and I believe will) do more to contribute to the discovery, development and delivery of medicines and vaccines for diseases of the developing world, but surely what is needed is that all parties, particularly governments, build on this willingness by the industry, respect the different roles and contributions that they can play and work together more effectively. Concerning access to medicines and vaccines, it is not patents nor the industry that is “the problem”. The real issue that faces us all is how to provide real benefits through new discoveries and deliver these to the benefit of the health of people in the developing world. This will not be solved by polemic but demands that we find common ground in an effective partnerships that address the real issues that we face in solving what is clearly the world’s major problem.

References

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