TMPDF

Trade Marks Patents and Designs Federation

INTEGRATING INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT POLICY

Report of the Commission on Intellectual Property Rights

Comments of the Trade Marks Patents and Designs Federation

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GENERAL ISSUES

Introduction to the TMPDF

The Trade Marks Patents and Designs Federation represents the views in the intellectual property field of innovative British companies that depend on intellectual property for their livelihood and the contribution they make to the prosperity of the UK and global economies. A list of members is appended.

Starting point

1. We agree that the starting point of the CIPR report is right: to consider whether and how intellectual property rights (IPRs) could play a role in helping the world meet internationally agreed targets – in particular by reducing poverty, helping to combat disease, improving the health of mothers and children, enhancing access to education and contributing to sustainable development.

How significant are the supposed negative effects of IPRs?

2. True, IPRs enable the IPR-holder to affect the supply and prices for innovative and creative products. But the products would usually not have been available without the stimulus of IPRs and if the market can be undermined in developing countries by non-authorised copies, this stimulus will be weakened and, in some cases, destroyed.

3. The report does not seek to quantify the relative importance of IPRs in comparison to other factors affecting development. Its focus on IPRs (perhaps understandable in the light of its terms of reference) thus gives the impression that IPRs are of great importance in the context of the objectives it, understandably, seeks to pursue. For instance the report places great emphasis on the potential negative effect on supply and prices in particular sectors e.g. the health sector. However the influence of IPRs in the health sector in developing countries e.g. in the HIV/AIDS crisis is negligible. The main problem is lack of resources. Attacks on IPRs are dangerous in undermining a major incentive to produce health products and also as they distract attention from other ways in which negotiations in the WTO context could improve the economic position of developing countries e.g. by agreements in which developed countries lower their tariffs against imports from developing countries. Despite acknowledging the inconclusive and contested nature of the economic evidence and its paucity, the Commission reaches sweeping and generally negative conclusions about the effects of IPRs on development. It puts forward no evidence that IPRs have **in fact** retarded development. Several of its more important conclusions, from which its recommendations flow, simply cannot be justified on the evidence.

Positive effects of IPRs

4. The main positive effect is primarily a dynamic one: a stimulus to innovation both by rewarding local innovators and by rewarding companies etc prepared to make or at least to

market locally new products developed elsewhere. This is steadily underestimated in the report. We believe this to be the main failing of the report.

Our conclusions

5. The report significantly overestimates any negative effects of IPRs and underestimates their positive effects. The balance and tone of the report is therefore of great concern.

6. The report's recommendations should not be endorsed in such a way as to imply that the UK Government believes that IPRs have a negative overall effect on development. Nor should the UK Government accept that the recommendations should be implemented in the way they appear designed by the Commission to be i.e. to remain within the TRIPS framework but to weaken IPRs and thereby undermine the dynamic positive effects of IPRs. The opportunity for the UK Government to recommend maintaining and introducing systems that would give a real stimulus to development in relevant developing countries should not be lost, even if this would at times contradict the approach of the Commission. Endorsement of the report's recommendations without significant qualification would not only do nothing to promote development, but would also reduce the opportunities for companies, e.g. UK companies, to develop and to market innovative products for such countries, leading to slower development in the country and lower profits for UK companies. The UK is a knowledge-based economy and if the knowledge-based products of UK industry can simply be copied we will have less return with which to finance the next product.

7. Any changes in IPR systems intended to help with such crises as HIV/AIDS in developing countries should be implemented in ways which damage as little as possible the dynamic effect of IPRs in stimulating the development and introduction of medicines.

8. Perhaps most importantly, and addressing the title of the report, Integrating IPRs and Development Policy, the conclusion should be that government departments such as DFID should monitor the effect of IPRs on development. However their energies and those of the EU should be concentrated where intervention can have much greater impact. The Government, particularly DFID, should not at present make recommendations to developing countries on IPRs based on slim evidence, which, even if the recommendations were sound, would make little difference to the countries' development now at the cost of stunting their future development and innovation, as well as harming the innovative capacity of the UK and other developed countries.

CHAPTER 1 - INTELLECTUAL PROPERTY AND DEVELOPMENT

Our general comments explain that we consider that the dynamic effects of IPRs have been given too little weight by the Commission. The Commission would, we suspect, agree that there is no conclusive evidence that IPRs are on balance pernicious. Perhaps contrary to the Commission we consider that the evidence points to the positive contribution of IPRs as a stimulus to development and the introduction to the market of innovative products.

A thread in the Commission's thinking is concern about patents as possibly inhibiting or restricting development of science and technology e.g. inventive development from a patented product or process. The summary of the evidence is rightly cautious but the conclusions are bold. It is our experience that competition almost always, perhaps always, ensures that market needs are met and, if they are not, this is due to factors other than IPRs including, importantly, poverty.

In the section headed The Evidence About The Impact of IP there are a number of references to the dynamic impact of IPRs. To quote "The main conclusion seems to be that for those developing countries that have acquired significant technological and innovative capabilities, there has generally been an association with "weak" rather than "strong" forms of IP protection in the formative period of their economic development. We conclude therefore that in most low income countries, with a weak scientific and technological infrastructure, IP protection at the levels mandated by TRIPS is not a significant determinant of growth. On the contrary, rapid growth is more often associated with weaker IP protection. In technologically advanced developing countries, there is some evidence that IP protection becomes important at a stage of development, but that stage is not until a country is well into the category of upper middle income developing countries."

We would make two comments. First, as we have said, we consider that the evidence from across the world, e.g. including developed countries, points to the success of IPRs as a stimulus to introduction to the market of innovative products. We see no reason why that should not apply to countries such as India and China with their scientific and technological capacity. Although without effective IPRs they could copy what they liked, with strengthened IPR protection their and the world's citizens benefit as their skills are increasingly directed to genuinely innovative products. That has been the historic experience, slower in the past but, because of increased ease of communication and increased speed of national development in such countries, much faster in recent decades. Secondly, the idea that weaker protection for innovators is better than proper protection is unsound. We return to that when considering Chapter 6 on patents.

The section correctly states that IPRs will limit copying, although sometimes the inference is that they will prevent copying and destroy all "imitative industries". The discussion is somewhat diffuse. At least it should be made clear that, for patents, copying of what is not protected by a valid patent is allowed, and in practice, most technology in current use is not protected by patents; for copyright, independent creation and copying of ideas is not infringement; and for trade marks, identical products can be made under trade mark law if the trade mark, or something confusingly similar, is not used. Only a very small minority of products are the subject of patent rights, the only IPR which covers realisation of technical

ideas in industrially applicable forms. In addition it is a very rare patented product which is not in competition with unpatented products i.e. cannot be substituted with a non-patented product. Imitative industries in all countries have plenty of products which they are free to imitate without the need to weaken IPR protection.

Countries across the world, of course including developing countries, have benefited immensely from knowledge developed in other countries. This has been an accelerating process over the last century or two. The section on Technology Transfer does not give this sufficient emphasis. A major factor in conversion of such transfer of knowledge into local skill is the introduction by companies of products and processes developed by them in other countries. There is major local acquisition of skills relating to the technology, marketing, servicing, etc of such products inherent in the sale of innovative products, let alone in the local manufacture of such products. The report does not give this the recognition it deserves.

The analysis of history, from which the Commission appears to infer that weak IPR protection has in the past promoted development, is simplistic. For every fact suggesting this is the case, a fact could be cited suggesting the opposite.

Comments on the recommendations

The specific recommendations from Chapter 1[1], with our comment, are:

Much of the technology transfer agenda goes well beyond our *[I.e. the CIPR's]* brief but we think the following measures need to be seriously considered:

- **Appropriate incentive policies in developed countries to promote technology transfer, for instance tax breaks for companies that license technology to developing countries.**

This is but one possibility. Establishing sound IPR systems in developing countries is also an important factor in facilitating the transfer of technology.

- **Establishment of effective competition policies in developing countries.**

Agreed but policies which are predicated on an anti-IPRs position will not be effective in furthering development. The balance between IPR enforcement and competition is a fine and sophisticated one and this apparently unobjectionable recommendation is too simplistic to be helpful.

- **Making more public funds available to promote indigenous scientific and technological capability in developing countries through scientific and technological co-operation. For instance, supporting the proposed Global Research Alliance between developing and developed country research institutions.**

[1] Throughout these comments we reproduce recommendations from the report in bold.

Agreed but excluding market mechanisms and skilled commercial companies would be ill-judged.

- **Commitments to ensure that the benefits of publicly funded research are available to all.**

It cannot be sound to say that the results of all publicly funded research everywhere have to be available to all. Defence research is one example where even publication will often be inappropriate. But in the context of the report more significant is that often the best way to convert the results of publicly funded research into products is to grant exclusivity to companies to undertake the necessary further research and development. We support the concept that developing countries should benefit from such processes.

- **Commitments to ensure open access to scientific databases.**

Insisting on open access would be equivalent to expropriation in most cases if applied to privately established data bases and would even conflict with our comments on the last point if applied to many publicly established data bases. However we agree that open access to publicly funded scientific data bases for e.g. further research should be the normal practice.

CHAPTER 2 - HEALTH

We would repeat our awareness of the dreadful suffering and the economic disasters which epidemics such as HIV/AIDS give rise to. Our basic points are that IPRs provide incentives for innovation and technology transfer and that these are very important positive factors in development policy. These are factors that have delivered existing drugs of major benefit to health in developing countries and will deliver even better in the future **if** IPR systems are allowed to function, rather than being undermined, in both the developed and developing worlds.

The Commission states:

"Our starting point in this analysis is that healthcare considerations must be the main objective in determining what IP regime should apply to healthcare products. IP rights are not conferred to deliver profits to industry except so that these can be used to deliver better healthcare in the long term. Such rights must therefore be closely monitored to ensure that they do actually promote healthcare objectives and, above all, are not responsible for preventing poor people in developing countries from obtaining healthcare."

Of course that is a sound starting point. If the conclusion led to boundaries having to be drawn between healthcare inventions and other inventions then there would be the usual legal wrangles of little profit to anybody but lawyers - but society could live with that. That is not our problem with Chapter 2. The problem lies in the Commission's consideration of the two factors it rightly states to be important: Do IPRs promote healthcare objectives and, above all, are they responsible for preventing poor people in developing countries from obtaining healthcare?

- Do IPRs promote healthcare objectives? It surely is accepted that IPRs promote the development and delivery of healthcare products *when there is a market for the products*; our emphasis with which we would expect the Commission to agree. To quote the Commission: "The heart of the problem is the lack of market demand sufficient to induce the private sector to commit resources to R&D." So a key issue is how to develop or create such markets to serve the needs of developing countries. Another is how to develop other mechanisms for developing and delivering such products. The two are not mutually exclusive. The Commission's report correctly emphasises the latter. But it steadily undermines the former.

- Are IPRs responsible for preventing poor people in developing countries from obtaining healthcare? Although the report's summary of the position indicates that lack of money and lack of infrastructure are among the factors most responsible for preventing poor people in developing countries from obtaining healthcare, both the summary and the report itself give the impression that IPRs are a factor which contribute significantly to this grave problem. This is simply not the case.

IPRs, regrettably mainly IPRs in developed countries, are a significant factor in the development of a high proportion of medicines currently used in developing countries, a major contribution to healthcare. On the other hand, over 95% of the medicines on the

WHO's Essential Medicines List are out of patent cover and yet 30% of the world's population has no access to them. In India, a country with very limited protection for pharmaceuticals and a successful generics industry, the percentage of patients receiving HIV drugs is no higher than in Africa. Despite these facts the report holds IPRs largely responsible. Although we agree that the effect of IPRs should be monitored, the evidence clearly establishes that they are not a significant barrier to access to medicines now. Recommendations relating to IPRs therefore will not have a significant beneficial effect on alleviating the current access crisis. However, weakening IPRs may well significantly reduce the already low incentives for private industry to develop products for which there is no market of the conventional kind. There is already some evidence that research into HIV/AIDS is declining and that one (of no doubt many) factors which has led to this is the perception that patent protection across the developing world will weaken.

Supply by generic producers in other countries is perceived as a necessary factor in bringing down prices. The evidence referred to in the previous paragraph is one of the reasons we remain pessimistic as to whether it will be a significant factor in providing the poor with increased access to healthcare. Establishing systems which undermine the exclusive rights of patent owners will certainly be damaging to the incentives for innovation if, as seems increasingly likely, this is not coupled with international support for laws and enforcement mechanisms to prevent leakage of such products to other more prosperous countries including other developing countries.

Differential pricing must be fostered. The report recognises that but not the role it plays in enabling companies to charge lower prices in poorer countries when the law and enforcement agencies are supportive in preventing such products being sold on into more prosperous countries. Such sales undermine the innovators' profits and hence the development of future products.

Comments on the recommendations

We take the recommendations from the report

- **Public funding for research on health problems in developing countries should be increased. This additional funding should seek to exploit and develop existing capacities in developing countries for this kind of research, and promote new capacity, both in the public and private sectors."**

In the executive summary this is prefaced with the clause: "Because the IP system does little to stimulate research on diseases that particularly affect poor people".

As with many of the recommendations we support this recommendation **but** with important qualifications. IP systems will be a necessary stimulus for developing such capacity in the developing countries e.g. by transferring effort by generic companies from replicating existing drugs to R&D to develop new drugs.

However the help of the research-based pharmaceutical companies from the developed world both in doing the research and development and in bringing a new medicine to

production status is likely to be essential if the results are to reach those who need them. They are much less likely to take part without an effective intellectual property system. As the report acknowledges, the existence of a market is the essential pre-condition to investment of the resources required to develop a new medicine. Because medicines are generally easy to copy, the innovator will not benefit from such a market without the exclusivity derived from IPR protection. IPR protection is therefore a necessary, but not sufficient incentive for development of new medicines. The report fails to recognise this key fact and, in doing so unjustifiably undermines one of the principal policy justifications for IPRs (principally patents) in the developing world. Research institutes and other players in both developed and developing countries can also have a role. But there is no track record of the public sector alone bringing medicines to market.

- **Countries need to adopt a range of policies to improve access to medicines. Additional resources to improve services, delivery mechanisms and infrastructure are critical. Other macroeconomic policies need to be in harmony with health policy objectives. But so also does the IP regime. Countries need to ensure that their IP protection regimes do not run counter to their public health policies and that they are consistent with and supportive of such policies.**

Again as such this recommendation is sound. The problems lie in

1. The overall message of the report that IPRs are negative to developing countries at least until they are at a relatively high stage of development.

2. The failure to recognise that, in comparison to other macroeconomic policies, weakening IPRs is unlikely significantly to improve access and is likely to undermine the already weak incentives to develop new medicines for the developing world.

It is in the interests of all countries to ensure that IPRs are respected i.e. to support the development of innovative products.

We quote the remaining recommendations from the executive summary. (The report discusses these in more detail.)

- **The IP system can help to establish differential pricing mechanisms, which would allow prices for drugs to be lower in developing countries, while higher prices are maintained in developed countries. If differential pricing is to work, then it is necessary to stop low priced drugs leaking back to developed countries. Developed countries should maintain and strengthen their legislative regimes to prevent imports of low priced pharmaceutical products originating from developing countries and to help maintain the price differential. However, developing countries should aim to facilitate in their legislation their ability to import patented medicines if they can get them cheaper elsewhere in the world. TRIPS allows countries to set their own rules on what are technically called parallel imports.**

Overall benefit is achieved when differential prices are maintained. To quote the report "in establishing a system of differential pricing … markets need to be segmented to prevent low priced products undermining high priced markets." This applies not only between developing and developed countries. Patients in the poorest countries will suffer if suppliers or arbitrageurs can redirect products to developing countries where higher prices prevail. Any implementation of the Doha declaration should not impinge on patents in general.

- **Developing countries should establish workable laws and procedures to allow them to use compulsory licensing. They should also make similar provisions for what is called "government use." Many developed countries have such laws that allow their governments to make use of patented inventions without infringing a patent under a wide range of circumstances.**

Very few compulsory licences have been granted in developed countries and there has carefully limited use of "government use" provisions. The report clearly intends this recommendation as a measure to be used regularly to reduce what it sees as the impact of patents and wrongly fails to recognise the damage to future innovation in general and in particular on health products relevant to developing countries.

- **How the issue of facilitating compulsory licensing for developing countries with inadequate manufacturing capacity is to be resolved is currently being debated in the TRIPS Council. It raises a number of quite detailed legal and practical matters. A way needs to be found to reconcile the nature of the solution adopted with the objective of providing medicines of the appropriate quality at the lowest possible cost. If that cannot be achieved, the solution will have little practical reality. Nor will the option of compulsory licensing be effective as a negotiating tool with companies. Whatever the solution adopted, it should be capable of quick and easy implementation to ensure that the real needs of poor people in developing countries are given priority. And it should establish conditions that provide potential suppliers with the necessary economic incentive to export medicines that are needed by these countries.**

A number of detailed legal and practical matters are raised. But what the Commission leaves to one side are a) the lack of evidence that IPRs are a real part of the problem, b) the evidence that other factors are clearly critical and c) the evidence that IPRs are a positive effect on innovation to the benefit of developing countries and therefore the need to implement the commitment at Doha in a way which does not damage that positive effect.

Because patents are not a significant cause of the access crisis, resolution of this issue will not have a significant beneficial effect. However, a broad solution could have very negative effects both on future innovation and by undermining the commercial incentives for innovative pharmaceutical companies to introduce their products in many poorer developing countries and to retain their presence in those countries. That presence contributes to the education, training and infrastructure in those countries and is unlikely to be replaced by generic companies. This is simply not addressed by the Commission.

- **TRIPS allows considerable flexibility in how countries may design their patent systems. Since most developing countries do not have a significant research capability, they have little to gain by providing extensive patent protection as a means of encouraging research, but they stand to lose as a result of the impact of patents on prices. Therefore developing countries should aim for strict standards of patentability to avoid granting patents that may have limited value in relation to their health objectives. Such systems should aim to promote competition, and provide safeguards in the event of abuses of the patent system.**

Proper standards properly applied by patent offices and courts is what is wanted. Proper standards include non-obviousness and scope not going beyond the contribution made by the invention. If that is what is meant by "strict" fine but we suspect the Commission wants developing countries to treat "strict" as "stop patents getting granted when on health products". The sentence finishes with "to avoid granting patents that may have limited value in relation to their health objectives". No evidence is given that patents "of limited value in relation to their health objectives" are being granted or that this is creating a problem. The patent system does not and cannot make this complex assessment. The market does this. If a patented product has limited health value, there will be no demand for it – there will be demand for unpatented competitive products. Thus, patents will not be depriving anyone of a product that is needed. If the product is needed, patents are the incentive for its creation.

- **For instance, most developing countries should exclude diagnostic, therapeutic and surgical methods from patentability, including new uses of known products, as permitted under TRIPS.**

Why should innovation on diagnostic, therapeutic and surgical methods not benefit from the incentives of the patent system? As we have already explained, exclusions from patenting make work for lawyers. To get the same result as far as surgeons are concerned is more sensibly achieved by excluding use by surgeons from infringement. On "new uses of old products": without the possibility of patents, there will be no incentive to develop such new uses for known products and such new uses have been of significance in health care.

- **Developing countries should also make provisions in their law that will facilitate the entry of generic competitors as soon as the patent has expired on a particular drug. One of these provisions (the "Bolar exception") allows generic companies to develop their versions of patented drugs during the term of the patent without infringing it. Another one would be to make it easier and cheaper for generic companies to get regulatory approval for drugs similar to registered drugs, while providing for the protection of test data (e.g. clinical trials data companies require to get approval from regulators such as the FDA in the US) against unfair commercial use.**

What appears to be overlooked is that such provisions reduce the incentives provided by the patent system to innovate.

- **Those LDCs which already provide pharmaceutical protection should consider carefully how to amend their legislation to take advantage of the Doha Declaration. The TRIPS Council should review the transitional arrangements for LDCs, including those applying to join the WTO, in all fields of technology.**

To the first sentence: Yes, but LDCs should be made aware that most drugs are out of patent, most patented drugs are not patented in LDCs and they should support measures to prevent implementation of the Doha declaration undermining the incentive effect of patents.

As to the second sentence, TRIPS Article 66.2 already contains a power to extend the implementation period for LDCs.

CHAPTER 3 - AGRICULTURE AND GENETIC RESOURCES

Nobody could disagree with the report's summary of the parlous state of the world's food supply and the need to raise agricultural productivity. It is also correct in saying that in much of world agriculture the crops grown are old traditional varieties (referred to as "landraces") which, although highly adapted to local climatic conditions and pest pressures, tend to be low yielding or nutritionally deficient or both. Its comments on the decline in public research are also correct.

The comments that the Commission makes on IPRs (Patents and Plant Breeders' Rights) in agriculture are not at all unexpected. If the Commission's proposals were to be implemented they would not greatly affect commercial activities in the supply of seeds.

The questions which the Commission seeks to address are set out on page 59 of the report:

- *Can intellectual property protection on plants and genetic resources help to generate the technologies required by farmers in developing countries*
- *Will IP protection affect the access of farmers to technologies they need?*
- *How could the intellectual property system contribute to the principles of access and benefit sharing enshrined in the CBD and the ITPGR?*

(CBD = Convention on Biological Diversity: ITPGR = International Treaty on Plant Genetic Resources)

There does not seem to be any attempt by the Commission to answer these specific questions but instead the report just discusses, correctly in most cases, the real and potential obstacles to agriculture in the developing world. However the general tone is far too negative about IP rights and seriously underestimates the contribution which TK has made to the development of innovative agricultural products.

Under the heading of "The Impact of Patents", the Commission fails to recognise that what is needed is a research exemption in USA. This is a US problem predominantly and it is difficult to appreciate what possible impact the deviant idiosyncrasies of US law could have on the developing world: this observed deficiency in US law only affects those to whom it applies, parties carrying out agricultural R&D in the US. It is believed that the Commission's intention here is simply to warn off the developing world from adopting the US model.

The Commission does identify the US utility patent for plant varieties as an issue but fails to identify what the objections actually are. Again this is specifically an issue peculiar to the USA.

Two main issues are access to plant genetic resources and farmers' rights. Much of the developing world uses landraces of various crops and these have come into being because from the dawn of history indigenous farmers have saved the seeds of the best plants in their fields. The question is whether the activities of farmers in conserving these varieties merit

the recognition of some sort of pseudo-IP right. In practice, the Commission may be making too much of this: a plant breeder will not lightly choose to go back to what is essentially a semi-wild plant variety for a breeding program unless he has to. It is accepted that landraces constitute valuable resources that must be conserved and the work of local farmers in conserving such plant lines probably does merit some compensation from a breeder seeking to introgress genes from the landrace into a commercial variety.

Comments on the recommendations

We take the Commission's recommendations from the Executive Summary:

- **Because of the restrictions patents may place on the use of seed by farmers and researchers, developing countries should generally not provide patent protection for plants and animals, as is allowed under TRIPS. Rather they should consider different forms of sui generis systems for plant varieties.**

We consider that the issue of retention of seed can be met when there is patent protection; see our comments below. We consider it is unnecessary and it would lead to complications if a *sui generis* right is chosen. If any such system is introduced it must include protection for farmers' and breeders' rights.

- **Because they are unlikely to benefit from the incentives to research offered by the patent system, but will have to bear the costs, developing countries with limited technological capacity should restrict the application of patenting in agricultural biotechnology consistent with TRIPS, and they should adopt a restrictive definition of the term "micro-organism.**

This is generally unhelpful to developing countries which have benefited from the incentive IP rights provide for the production and marketing of innovative agricultural products. On the particular: it could be problematic if the definition of "micro-organisms" were restricted to bacteria thereby allowing fungal, plant and animal cells to be excluded from patentability because they are "Parts" of plants and animals. Additionally the term "agricultural biotechnology" is rather broad.

- **However, countries that have, or wish to develop, biotechnology-related industries may wish to provide certain types of patent protection in this area. If they do so, specific exceptions to the exclusive rights, for plant breeding and research, should be established. The extent to which patent rights apply also to the harvested crop also needs to be carefully examined. It is important that a clear exception to the patent right is included in the legislation to allow for farmers' reuse of seed.**

Countries which have no realistic chance to develop a biotechnology-related industry benefit from IP rights because such rights provide first an incentive to develop innovative biotechnology and secondly an incentive to market the products e.g. in such countries. As stated above, some form of protection for varieties which incorporates farmers' and breeders' privileges is needed. In the context of patents, purchasers of the seed should be

allowed to retain seed for resowing on their own farms and some limited freedom for informal low volume sale or exchange could be permitted as it is in USA ("brown bagging").

- **The review of the relevant provisions in TRIPS which is currently taking place in the TRIPS Council, should preserve the right of countries not to grant patents for plants and animals, including genes and genetically modified plants and animals. It should also permit countries to develop sui generis regimes for the protection of plant varieties that suit their agricultural systems. Such regimes should permit access to the protected varieties for further research and breeding, and provide for the right of farmers to save and plant-back seed, including the possibility of informal sale and exchange.**

See our comments above.

- **Because of the growing concentration in the seed industry, public sector research on agriculture, and its international component, should be strengthened and better funded. The objective should be to ensure that research is oriented to the needs of poor farmers; that public sector varieties are available to provide competition for private sector varieties, and that the world's plant genetic resource heritage is maintained. In addition, this is an area in which nations should consider the use of competition law to respond to the high level of concentration in the private sector.**

We would welcome increased public sector research. Bodies undertaking such research would be well advised to establish sensible policies on IP rights. We understand that some such bodies which initially took the position that they would not obtain IP rights have since appreciated that having IP rights has its advantages when managing roll out or commercialisation of successes. On mergers: all the recent mergers and acquisitions in the agricultural industries has been subjected to rigorous scrutiny by the competition authorities.

- **Developed and developing countries should accelerate the process of ratifying the FAO Treaty on Plant Genetic Resources for Food and Agriculture and should, in particular, implement the Treaty's provisions relating to not granting IPR protection on genetic material in the form received from gene banks protected by the Treaty. They should also implement at national level, measures to promote Farmers' Rights. These include the protection of traditional knowledge relevant to plant genetic resources; the right to participate in sharing equitably benefits arising from the utilisation of plant genetic resources for food and agriculture and the right to participate in making decisions, at the national level, on matters related to the conservation and sustainable use of plant genetic resources.**

On the FAO Treaty we would refer to our comments on the previous recommendation. On Farmers' Rights see our comments above, in particular on first and third recommendations. On traditional knowledge and related issues see our comment on Chapter 4.

CHAPTER 4 - TRADITIONAL KNOWLEDGE AND GEOGRAPHICAL INDICATIONS

The interaction between IP rights and implementation of the Convention on Biodiversity both generates a great deal of heat, from both "sides" and probably need not give rise to many problems when the debate has progressed sufficiently and those problems become practical ones rather than of principle. We hope this is not too optimistic. It certainly does not stem from a desire to denigrate, misuse or ignore the position of holders of traditional knowledge.

The report in Box 4.1 correctly distinguishes two types of patents which give rise to issue: (a) The granting of 'wrong' patents. These are patents granted for inventions that are either not novel or are not inventive having regard to traditional knowledge already in the public domain. (b) The granting of 'right' patents. Patents may be correctly granted according to national law on inventions derived from a community's traditional knowledge or genetic resources. We agree that the distinction is important. The solutions to (a) are easy to state and could be easy to implement. On (b) the devil lies in achieving clarity on the principles and then in the detail of implementation.

Comments on the recommendations

We take the Commission's recommendations from the Executive Summary

- **At this early stage in the debate on traditional knowledge, there is much to gain by considering the issue in a number of fora, while ensuring coherent approaches are developed and that effort is not duplicated.**

We agree. As general points we would suggest that any right introduced needs to be equitable and practicable. It should add to overall well-being.

- **With such a wide range of material to protect and such diverse reasons for "protecting" it, it may be that a single all-encompassing *sui generis* system of protection for traditional knowledge may be too specific and not flexible enough to accommodate local needs.**

We agree that an all-encompassing *sui generis* system is an unrealistic goal.

- **The digital libraries of traditional knowledge that are now being created, should, as soon as it is practical, be incorporated into the minimum search documentation lists of patent offices therefore ensuring that the data contained within them will be considered during the processing of patent applications. Holders of the traditional knowledge should play a crucial role in deciding whether such knowledge is included in any databases and should also benefit from any commercial exploitation of the information.**

We agree with the first sentence.

The last limb of the recommendation needs further refinement if it is not to reduce the flow of knowledge and the incentive to market products the world needs. It recommends: "Holders of the traditional knowledge should play a crucial role in deciding whether such knowledge is included in any databases and should also benefit from any commercial exploitation of the information." We submit that if the traditional knowledge is publicly disclosed and the commercial exploitation is not based on traditional knowledge obtained in an illegal manner then implementation of this part of the recommendation would hinder the progress of science and knowledge in general as well as hinder the development of innovative products.

- **Countries that only include domestic use in their definition of prior art should give equal treatment to users of knowledge in other countries. Account should be taken of the unwritten nature of much traditional knowledge in any attempts to develop further the patent system internationally.**

We agree.

- **The principle of equity dictates that a person should not be able to benefit from an IP right based on genetic resources or associated knowledge acquired in contravention of any legislation governing access to that material.**

The legislation has to be equitable, and practicable, for the recommendation to be sound. Otherwise we agree. However, laws in this field should not affect the basic rules on validity and ownership of IPRs.

- **In such cases the burden should generally lie with the custodian of the knowledge to prove that the IP holder has acted improperly. But this requires that the custodian is aware of what has been done.**

and

- **For this reason, all countries should provide in their legislation for the obligatory disclosure of information in the patent application of the geographical source of genetic resources from which the invention is derived. This requirement should be subject to reasonable exceptions as, for example, where it is genuinely impossible to identify the geographical source of material. Sanctions should be applied only where it can be shown that the patentee has failed to disclose the known source or where he has sought to deliberately mislead about the source. The Council for TRIPS should consider this in the light of the review of this issue recommended in the WTO Ministerial Declaration at Doha.**

and

- **Consideration should also be given to establishing a system whereby patent offices examining patent applications which identify the geographical source of genetic resources or traditional knowledge pass on that information either to the country concerned, or to WIPO. WIPO may act as a depository for patent related**

information of this nature. Through these measures it will be possible to monitor more closely the use and misuse of genetic resources.

We are puzzled why genetic resources are singled out. But important factors in producing an equitable and practicable solutions are (a) whether the material or information was publicly available and (b) whether they were obtained improperly. We would oppose the imposition of onerous conditions on patent grant concerning e.g., disclosure of details of extraction licence agreements Most important is the sensible advice in recommendations 1 and 2.

- **In respect of geographical indications, further research should be undertaken by a competent body, possibly UNCTAD, to assess the benefits and costs to developing countries of the existing provisions under TRIPS, what role they might play in development, and the costs and benefits of various proposals to extend geographical indications and establish a multilateral register.**

We see "geographical indications" as giving rights which need to be clearly justified. They must not restrict society from using terminology e.g. "Cheddar cheese" which it has become customary to use generically for goods not originating from the geographical area indicated. Subject to that, we would have thought that "geographical indications" might well be a way in providing protection and recognition to many products or processes of specifically local societies. Developing countries are keen to extend protection provided by geographical indications and the issue is under discussion in the TRIPS Council of WTO. Moreover, WIPO both is and should be heavily involved.

CHAPTER 5 - COPYRIGHT, SOFTWARE AND THE INTERNET

The new digital environment offers the developing world enormous opportunities to access knowledge in ways never before possible. The Internet makes a vast range of information available, and that information can be obtained easily and cheaply by accessing the Internet and then disseminated within the local economy. We are optimistic about the ability of the Internet to help deliver progress in the developing world.

The report illustrates graphically the problems poverty imposes on the developing world in being able to afford the infrastructure that enables them to access and transmit knowledge. The general solution of the report is to weaken copyright, but we do not think it has made out its case that this is the best solution to the problems identified. Even with a weakened copyright these infrastructure problems would remain, and a more direct and proactive policy in supplying the information itself and in helping develop the infrastructure to disseminate it seems the more fruitful course in helping close the knowledge gap.

We fully realise the desperate shortage of resources in the least-developed countries, but investment in the infrastructure of the Information Society will give a very rapid pay-back and should be considered both by the country itself and by donors. Any point of access to the Internet is a doorway through which information can flow into the country concerned.

As the report acknowledges in Chapter 1, copyright does not protect ideas as such. It is not a monopoly right. It protects the particular form in which ideas are expressed - the skill and creativity put into assembling the vehicle to transmit the information - but it cannot control the flow of ideas themselves. Therefore, increasing the extent to which free use of that particular vehicle is possible is never the only way to get the information to those who might use it. Against that background, the general approach of the report in recommending a weakening of copyright in developing countries is unfortunate, because it will undermine the incentive for creators of knowledge-based products around the world to invest in new products and make them available to all.

Comments on the recommendations

We take the recommendations from the Executive Summary

- **Publishers, including those on-line, and software producers should review their pricing policies to help reduce unauthorised copying and to facilitate access to their products in developing countries. Initiatives being undertaken by publishers to expand access to their products for developing countries are valuable and we encourage an expansion of such schemes. The extension of free on-line access initiatives for developing countries to cover all academic journals is a good example of what could be done.**

Initiatives to lower prices for information products are worthwhile on their own merits in encouraging access. In the absence of any recommendation to abolish copyright altogether, it is unfair and wrong to suggest lowering of prices simply to reduce the temptation for unauthorised copying. It is also likely to be ineffective. Those who make unauthorised copies are likely to continue to do so however low the price.

The report, of course, does not recommend abolishing copyright, because it rightly acknowledges that copyright is useful in fostering local creative and information industries and in allowing the home country to benefit from exploitation of its works in the potentially larger markets of the developed world. Copyright has long depended on international recognition by each country of the copyright in works from other countries. Though the report mentions the US's rejection of this principle in the 19th Century, it wisely refrains from recommending the same course today.

- **In order to improve access to copyrighted works and achieve their goals for education and knowledge transfer, developing countries should adopt pro-competitive measures under copyright laws. They should be allowed to maintain or adopt broad exemptions for educational, research and library uses in their national copyright laws. The implementation of international copyright standards in the developing world must be undertaken with a proper appreciation of the continuing high level of need for improving the availability of these products, and their crucial importance for social and economic development.**

This recommendation appears at first sight to be suggesting an unlimited exception for educational, research and library uses. An exception of that breadth would clearly be inconsistent with Article 9.2 of the Berne Convention. However, the report rightly does not suggest that developing countries should leave the Berne Convention. It is therefore important for the UK government in commenting on this recommendation to make it clear that any exceptions for the purposes mentioned need to be limited so as to remain consistent with the Berne Convention. It would be unfortunate if developing countries were to infer from this recommendation that it is possible to introduce a general right to copy for educational, research or library uses and still remain within international copyright standards.

- **Developing countries and their donor partners should review policies for procurement of computer software, with a view to ensuring that options for using low-cost and/or open-source software products are properly considered and their costs and benefits carefully evaluated. In order that software can be adapted to local needs, developing countries should ensure that their national copyright laws permit the reverse engineering of computer software programmes, in ways that are consistent with relevant international treaties which they have signed.**

Developing countries would indeed be sensible to examine all the options for obtaining software. Increasingly, there is good open-source packaged software available, and use of this software would provide useful competition to proprietary suppliers. It seems better to encourage developing countries to follow that approach rather than to become dependent on the products of particular suppliers and then seek to compensate for that dependence by weakening the copyright protection that applies to those products.

The report states that, under TRIPS, developing countries are permitted the flexibility to allow reverse engineering of software. Unfortunately, the report does not back up that assertion with any analysis of what TRIPS permits in this area. TRIPS itself does not mention the subject explicitly. We are therefore left with its overall statements, of which

the relevant ones appear to be Article 9.2, which confirms that copyright does not apply to ideas, and Article 13, which allows exceptions on conditions equivalent to those of Article 9.2 of Berne.

It is clear that it is possible to have a reverse engineering exception within TRIPS that permits lawful users to discover interoperability information not readily available otherwise. Such an exception is already present in the European Software Directive and is recognised in the US case-law without any suggestion of non-compliance with international treaties. We can certainly endorse developing countries introducing an equivalent exception in their laws.

But the report goes further, stating that the exception should go "beyond the requirements for inter-operability, consistent with the relevant IP treaties they have joined". And the recommendation from the Executive Summary quoted above explains the purpose as being "in order that software can be adapted to local needs". The interoperability exception permits information to be obtained for what is accepted to be a socially necessarily purpose, but is specifically limited in that the resultant product must not infringe copyright. It is hard to see how an exception for reverse engineering for the purpose of local adaptation can have any function other than to create a resultant program that does infringe the copyright in the original program, because it will be a derivative work. Such a use is clearly outside international standards and it is no more acceptable to permit infringements that are local adaptations than infringements that are the original product.

- **Internet users in developing nations should be entitled to fair use rights such as making and distributing printed copies from electronic sources in reasonable numbers for educational and research purposes, and using reasonable excerpts in commentary and criticism. Where suppliers of digital information or software attempt to restrict "fair use" rights by contract provisions associated with the distribution of digital material, the relevant contract provision may be treated as void. Where the same restriction is attempted through technological means, measures to defeat the technological means of protection in such circumstances should not be regarded as illegal. Developing countries should think very carefully before joining the WIPO Copyright treaty. Countries should also not follow the lead of the US and the EU by implementing legislation on the lines of the DMCA or the Database Directive.**

Unless further qualified, the statement about rights to make and distribute (especially distribute) copies from electronic sources is open to the same objection as discussed in relation to the suggested "broad exemptions", that is, that that the recommendation is to introduce exceptions beyond those permitted under the Berne Convention.

The report is unduly hostile to the need of copyright owners to rely on technical protection measures if they are to have any ability to prevent their digital works from being copied and distributed so widely as entirely to undo their ability to benefit from the creativity put into their works. It is entirely understandable that the WIPO Copyright Treaty should require adequate legal protection against the circumvention of such measure as a world-wide standard - in the age of the Internet, no country is a data island and circumvention in

one country can be disastrous to the copyright owner in all. It is very regrettable that the report suggests that developing countries should not ratify the WIPO Copyright Treaty.

The Commission is concerned that technical protection might rescind fair-use exceptions. There is undoubtedly a tension between the two. But rather than recommending developing countries not to legislate on technical protection and therefore not to join the WIPO Copyright Treaty, the report would have done better to support solutions such as the one adopted in Europe in its recent Directive on Copyright and Neighbouring Rights in the Information Society, which is intended to permit EU member states to ratify the Treaty. The directive gives strong legal protection against circumventing technical protection, but it balances that protection with a requirement for a procedure to ensure that copyright owners themselves make the benefit of specific exceptions available to beneficiaries of the exception despite the protection.

The security offered by technical protection measures will encourage copyright owners to invest in the creation of new works and to release them in the digital age. The wide availability of new works is, in turn, a benefit to all consumers. The report fails to address the advantages that technical protection offers in developing new business models that give consumers greater choice as to the way they enjoy the work concerned - for instance the ability to pay a small amount to view or hear a work once, and a greater amount for a permanent copy. With a greater discrimination in ways of delivering works comes a need to be equally discriminating in what is “fair use”. It is not reasonable to expect a right for the user to make a permanent copy under fair use when he has paid only for a single view. The report makes the mistake of applying hard-copy thinking to electronic copies.

Besides all that, the Internet will offer, and continue to offer, enormous volumes of useful material without any technical protection at all.

On database protection, the report is needlessly fearful of solutions like the European Union’s Database Directive. The international norm is already far beyond the requirement to protect original collections of copyright works under copyright, which the reader of the report could be forgiven for concluding is all that is required under the Berne Convention. Yes, it requires such works to be protected under copyright, but it is universally understood that its general provisions also require the protection under copyright of collections of items other than works where the collection itself possess the necessary originality. That understanding is put beyond doubt in TRIPS, which in Article 5 requires collections of data or other materials that are original (“the author’s own intellectual creation”) in their selection or arrangement to be protected by copyright. The Database Directive does indeed protect the investment put into making collections of data or other material. Most collections of other than the most mundane facts will also be protected by copyright and it remains to be established that databases that are protected only under the database right contain information that scientists in developing countries need to access to help in the development of their country.

The report fears that scientists and researchers in developing countries will be unable to access the data in databases because they will be unable to afford the subscriptions. It is hard to see what mechanism will permit them to access the database if they cannot afford

the subscription, because access is a physical procedure under the control of the person running the computer holding the database.

Developing countries should be encouraged to consider introducing database rights, which could be a useful intellectual property right for protecting traditional knowledge.

Concerns that IPRs restrict the availability of the results of publicly funded work should not be allowed to weaken IPR systems. They are best addressed by policy decisions by the relevant bodies to ensure that such results are available as they desire, whether or not the subject of IPRs. That in turn may entail their ensuring that the right licensing terms are in place with intermediaries who may publish or otherwise make the work available.

CHAPTER 6 - PATENTS

There has always been a problem applying established sound patent law concepts to a new area of technology. Patent Offices and courts take some time to establish the way the basic tenets of the patent system - novelty, non-obviousness, industrial applicability and justified scope - should be applied in the new field. This has been true of computer-related inventions and biotechnology. There are examples of patents granted on technology either known or obvious and others of patents with far too broad scope. This phenomenon has substantially been brought under control as courts (and patent offices) have asserted the basic principles. This process has not been taken into account sufficiently in the report.

We support the Commission's recommendations which argue for application of proper standards for patentability. We disagree when these explicitly or implicitly argue for more restrictive standards or for blanket exclusions.

Another thread in the Commission's thinking is concern about patents as possibly inhibiting or restricting development of science and technology e.g. inventive development from a patented product or process. To the extent that there is a problem at all (which the report alludes to but does not demonstrate) **sensible** application of compulsory licences and research exemptions can be used to alleviate it.

Comments on the recommendations

- **Limiting the scope of subject matter that can be patented**

As long as an invention is in a field of technology constraints are suspect. They lead to boundary/interpretation disputes. Exempting particular activity from infringement (e.g. surgical use) is better than a blanket exclusion from patentability. The exclusions in European law listed at the top of page 115 are there to make clear that the listed categories are outside the scope of patenting. This is because they are outside the scope of technology. The exclusions of Articles 52 and 53(b) generate money for lawyers and heat for activists to very little benefit to innovators and patients or other customers. Exclusions on moral and ethical grounds are common in European patent law but have two problems. First, a patent is a negative right i.e. to stop somebody else. It does not permit the patentee to perform his or her invention. So why not leave permission to perform some immoral or unethical act to a branch of law where such prohibitions are usual? Secondly, what is immoral or unethical varies with time and different cultures, often within single national boundaries. Why foster such an exclusion except to allow undermining of the incentive effect of a good patent system?

- **Applying standards such that only patents which meet strict requirements for patentability are granted and that the breadth of each patent is commensurate with the inventive contribution and the disclosure made**

The current standards accepted in the developed world are sound i.e. novelty, non-obviousness (to the man skilled in the relevant "art" i.e. subject matter) and industrial applicability even if they are sometimes not applied properly. Scope is also recognised in

the developed world to be important. Appropriate scope is increasingly recognised to be the scope the contribution the invention has made. If I invent the wheel and you invent a wheel-barrow have you not used my invention? Isn't this true whether or not I have disclosed a wheelbarrow? Of course, you can obtain a patent on the wheel-barrow but if use of the wheel is still under patent - only 20 years at most - a licence may still be necessary, unless you bought the wheels for the wheel-barrow from me. And rightly so, since your wheelbarrow makes use of my contribution to society.

See also our comments on the similar recommendation in Chapter 2.

- **Facilitating competition by restricting the ability of patentees to prohibit others from building on or designing around patented inventions**

See our comments on the previous recommendation e.g. our example of a wheel in relation to "building on". Proper application of the requirement to limit the scope of a patent to the contribution the invention has made allows designing round patented inventions without weakening the incentive to innovate provided by patents.

- **Providing extensive safeguards to ensure that patent rights are not exploited inappropriately**

We would agree that proper compulsory licence provisions safeguarding against real abuse and balanced competition laws surely are necessary safeguards, but are concerned that the report does not discuss the boundaries of use of such concepts, instead implying that they should be regularly and extensively used.

- **Considering the suitability of other forms of protection to encourage local innovation**

Any constraint on innovation has to be viewed with suspicion and shown to be justified. Patents are such a constraint because they require a follower to invent an alternative or to come to terms with the patentee, but we believe they are justified as an incentive in the developing as well as the developed world. What the Commission appears to be suggesting is that other rights should be introduced. Any new right introduces complications. Any right with lower standards or lower rights should be rejected. Lower standards implies that e.g. somebody could be stopped from doing something obvious. Such rights might be taken out in large numbers and would hardly be good for innovation. Lower rights reduce the incentive to innovate.

We note that all of recommendations above are also in Chapter 2 of the main text as well as in Chapter 6. We agree with the writers of the executive summary that they lie better under the general heading of "Patents". We continue in response to this chapter to address the recommendations in the executive summary.

- **Developing countries which provide patent protection for biotechnological inventions should ensure that patenting guidelines are such that the use of patented inventions by other researchers is limited as little as possible. For**

instance, if patents over genes are allowed, the guidelines should provide that the patent only covers uses set out in the patent, not other uses of the same invention which others may uncover. This will facilitate further research in the area of the patent.

As mentioned in our opening comments on this chapter, the patent system has adapted to the difficulties which arose in applying traditional concepts to this new field of technology, without evidence of real harm in the interim period being shown. The ordinary requirements for patentability are appropriate and should apply to this field of technology as to others. But it would defeat the incentive purpose of patents if claims were limited to uses effectively disclosed in the patent specification if that is construed in a too limited way. What is important is that claims should be limited to the contribution made by the invention.

Proper application of traditional patent law principles, together with properly drawn research exemptions, are better means of ensuring that research is not hindered than general rules about limiting the scope of patents in particular technological fields.

- **Policy makers in developing countries should consider the establishment of utility model protection for stimulating and rewarding such innovations, rather than diluting patentability standards. This should help to provide incentives for the incremental type of innovations that predominate in many developing countries.**

In the main text the recommendation shows suitable caution e.g. research is needed to assess the precise role that utility model protection might play in developing countries. Our comments on the recommendation to consider introducing new forms of protection apply. Incremental developments which are obvious should not have any protection as such and would not under a patent system. On the other hand we disagree with the implication underlying this recommendation and in many places in the report that the patenting of incremental developments that do meet patentability requirements, e.g. the requirement of non-obviousness, are somehow pernicious. Of course for the life of the patent they could stop the marketing of further developments that make use of the inventive idea but, as pointed out above, the ability of competitors to invent around claims of proper scope and, alternatively, the application of market forces and balanced competition provisions (including possibilities of cross-licensing) prevent most, perhaps all ill effects. Of course, by definition, the development was not obvious to his or her peers so a patent is, on balance, a reasonable reward/incentive.

Whilst there is a role for IP in developing countries' public research institutions to promote the transfer and application of technologies, it is important that:

- **Generating alternative sources of funding is not seen as the principal goal, which is rather to promote technology transfer.**

Agreed, although we assume that "technology transfer" is in this context shorthand for dissemination of knowledge and stimulation of the means of meeting the technology requirements of developing countries, in particular and especially the poor, be it in

agriculture or health or elsewhere. (This wording is we hope identical in spirit with the wording of the next recommendation)

- **Care be taken to ensure that research priorities, particularly as regards the technology requirements of the poor, be it in agriculture or health, are not distorted by the search for a larger licensing income.**

Agreed but note the suggested expansion of the wording as indicated in our comment above.

- **Patenting and licensing should only be undertaken where it is judged necessary to encourage private sector development and the application of technologies.**

Agreed but again it may be better to make clear that the underlying purpose would be to facilitate introduction of means to benefit developing countries, particularly the poor.

- **Careful consideration be given to the need to take out "defensive" patents on important inventions, particularly for use as a bargaining tool where complementary technologies are owned by private sector entities and cross-licensing may be required to access those technologies.**

We would suggest that this could be considered more broadly e.g. public research institutes should consider the advisability of taking out patents on inventions which are not directly relevant to stimulating the introduction of technology in developing countries but could be a money-earner. This is broader than the rather sterile concept of defensive patents.

- **Getting the balance right requires the development of expertise in IP in public sector institutions which traditionally have had none, without losing sight of the objectives of public policy for research."**

Agreed but achieving this will require both a positive attitude and continuing effort by e.g. WIPO.

- **It is important in developing initiatives aimed at facilitating access to essential research tools, that attention continues to be paid to opportunities to improve patent systems, in both developed and developing countries, to obviate some of the problems these initiatives are seeking to address.**

The discussion in the main text makes clearer than the necessarily brief recommendation that there are three issues here. First, there is the issue whether research tools should be patentable. Second, there is the issue whether research should benefit from a blanket exemption from infringement. Third, there is the issue of products or processes subject to a number of patents held by different companies or bodies.

On the first: the development of research tools should and does benefit from the incentive that the patent system provides. That does not mean that public bodies should necessarily

patent research tools developed by them, nor that they necessarily should not. On the second: we consider that the incentive to develop research tools would be drastically undermined if there was a blanket exemption. Public bodies would suffer. On the third: the market is a remarkably efficient mechanism for resolving such situations. Licensing and cross licensing of patents is a common feature of many area of technology. The grant of patents lacking novelty or with overbroad claims in new areas of technology such as biotechnology is addressed at the beginning of this chapter. This issue affects all countries, but in particular more developed countries.

- **Developing countries need to identify a strategy for dealing with the risk that further harmonisation of patent laws internationally will lead to standards that do not take account of their interests. Such a strategy might seek a global standard reflecting the recommendations of this report. It could seek continued flexibility in the standards. Or it could be done by rejection of the process if it appears that the outcome will not be in the interests of developing countries.**

We hope that our input will convince the Commission and those considering the report's recommendations that it is not in the interest of the developing world for there to be weaker standards of patentability. However there is a need to harmonise and to reduce the costs of the patent system. Mankind's innovative capacity is immense. The patent system is an important way of energising that real and latent capacity and converting it to technology of benefit to all mankind.

CHAPTER 7 - INSTITUTIONAL CAPACITY

Although there are costs involved in establishing and running effective IP systems, it is by no means clear that they are significant in the context of impeding development. Further, the running costs of patent offices are normally met by users – patent offices can be made self-financing.

Costs can be reduced by co-operation and sharing of resource between patent offices, thus maximising the benefits which would ensue from creation of strong IP systems. There are many examples where this occurs e.g. in regional groupings and use of the EPO as examining authority by countries outside the EPC.

It should be noted that the costs of establishing patent offices and enforcement systems are unlikely to be greater where the IPR regime is relatively strong than where the IPR regime is relatively weak

Comments on the recommendations

We take the Commission's recommendations from the Executive Summary:

- **Developing countries and donors should work together to ensure that national IP reform processes are properly "joined-up" with related areas of development policy. Greater efforts are needed to encourage more participation by national stakeholders in IP reforms. In providing technical assistance, donors should help build the capacity of local institutions to undertake IP policy research and dialogue with stakeholders, in addition to providing international experts and legal advice.**

More knowledge and consideration of the issues would undoubtedly help.

- **Developing countries should aim to recover the full costs of upgrading and maintaining their national IP infrastructure through the fees charged to users of the system. They should also consider adopting a tiered system of fees for IPR registration. The level of charges to users should be regularly reviewed to ensure that they enable full recovery of the costs of administering the system.**

The report constantly implies or states that IP systems are not of benefit to all or many developing countries. We consider that IP systems are of benefit to developing countries. On that basis it is in the interests of the developing countries to introduce effective systems. It is normal practice for the running costs of the granting systems to be paid for in practice by those applying for IP rights. That is not necessarily equitable. But there is a much more important general point: we should be increasing our efforts to avoid multiple handling and evaluating of IP rights before and after grant. With proper harmonisation and respect for the systems involved introduction of an IP system need not involve heavy costs.

- **In order to minimise costs, developing countries should ensure that their IP legislation and procedures emphasise, to the maximum possible extent, enforcement of IPRs through administrative action and through the civil rather**

than criminal justice system. Enforcement procedures should be fair and equitable to both parties and ensure that injunctions and other measures are not used unduly by IP right holders to block legitimate competition. Public funds and donor programmes should mainly be used to improve IP enforcement as part of broader strengthening of the legal and judicial systems.

Our comments on the previous recommendation apply. It would have been healthy to balance the comment "ensure that injunctions and other measures are not used unduly by IP rightholders to block legitimate competition" with one like "and that rights holders are afforded adequate remedies against infringers e.g. prevention and compensation at a level to inhibit future infringement".

- **Developed countries should implement procedures to facilitate effective access to their intellectual property systems by inventors from developing nations. These might include, for example, fee differentials that favour poor or non-profit inventors, pro bono systems, arrangements for recovery of legal fees by prevailing parties in litigation, or inclusion of appropriate IP implementation costs in technical assistance programmes.**

Our experience of procedures in favour of particular groups is that they lead to misuse. There is a risk of proliferation of ill-judged applications for IP rights and of ill-judged litigation. But if effective measures can be developed, and the costs are not borne by other IP users, then we would be supportive of them.

- **Developed countries and international institutions which provide assistance for the development of IPR regimes in developing countries should provide such assistance in concert with the development of appropriate competition policies and institutions.**

We agree but with a reminder that international co-operation should be aimed at reducing multiple consideration of the same issues.

- **WIPO, EPO and developed countries should significantly expand their programmes of IP-related technical assistance. The additional financing required could be raised though modest increases in IPR user-fees, such as charges for the PCT (the international system for filing patent applications) rather than from already over-stretched aid budgets. Donors could also seek to direct more technical assistance at LDCs in view of their special needs in developing an IP regime, as well as the wider institutional infrastructure they require for effective enforcement and regulation."**

  IP-related technical assistance should be organised in relation to an individual country's specific development needs and priorities. One way to do this is to incorporate such assistance within the Integrated Framework for Trade-Related Assistance which aims to facilitate better integration of national development plans and donor assistance strategies."

WIPO is the appropriate organisation for providing technical assistance in IPR matters and has systematically expanded its programme of assistance to and co-operation with developing countries over the past few years. There is an on-going tailored programme for each country and regional group. This expansion has been paid for mainly by users of the PCT, since receipts from PCT users meet nearly all WIPO costs. The remainder of WIPO costs are met mainly by the financial contributions of developed countries. The rate of expansion is determined to a considerable extent by the capacity of developing countries to absorb the assistance. Assistance is given in matters such as office modernisation, information technology, including free provision of personal computers and networks, documentation, and law modernisation. Appropriate training courses in IPR law, practice and procedures and related issues such as competition law, valuation of IP and finance, are an important part of the assistance. The courses are run, expenses paid, in European countries and Europe based organisations, other developed countries, and in the developing countries themselves. Many officials and others such as attorneys and academics from developing countries have benefited from the courses, though it can often happen that officials are transferred to non-IP duties afterwards. Developing countries should have a responsibility to ensure that trained staff are subsequently assigned to IP related duties.

Through the high fees it pays to the PCT system, industry already meets a high proportion of the cost of expanding development co-operation. Likewise, the development co-operation activities of the EPO and national patent offices are entirely funded from the fees for application processing paid by users. We do not agree that the EPO should significantly expand its development co-operation activities. The time of its very expensive staff should be mainly devoted to processing European patent applications.

- **Donors should strengthen systems for the monitoring and evaluation of their IP-related development co-operation programmes. As an important first step, a working group of donors and developing countries should be established to commission and oversee a sector-wide impact review of IP-related technical assistance to developing countries since 1995. A team of external evaluators should carry out this review.**

We would welcome informed debate. Such monitoring and evaluation would be a useful input.

CHAPTER 8 - THE INTERNATIONAL ARCHITECTURE

The report mentions that concerns have been expressed in some quarters about whether the advice from WIPO to developing countries "fully takes account of the flexibilities in TRIPS". (This is a euphemism for providing as few rights as possible within the existing TRIPS framework, an approach which we regard as wrong.)

In our experience, the activities of WIPO in giving advice to developing countries are opaque – there seems to be little if any outside consultation, especially not with industry, which nevertheless has to operate within whatever framework of legislation is recommended. This can give rise to concern in the opposite sense to that mentioned in the report. WIPO can and does recommend the adoption of laws that contain inappropriate exclusions and exceptions from protection, that impose unnecessary (and legally difficult) requirements on applications for rights and that establish additional forms of registered protection, e.g., for utility models and integrated circuit topographies, that may store trouble for the future.

The report recognises that developed countries have an interest in the IP standards of their trading partners, though this recognition is qualified so as to dismiss what may be valid concerns. We emphasise that in trade arrangements aimed at encouraging the free movement of goods, all countries need to have regard for the viability of the innovative industries that largely create the knowledge base and whose technology will be transferred and copied.

Comments on the recommendations (as they appear in the executive summary):

- **WIPO should act to integrate development objectives into its approach to the promotion of IP protection in developing countries. It should give explicit recognition to both the benefits and costs of IP protection and the corresponding need to adjust domestic regimes in developing countries to ensure that the costs do not outweigh the benefits. It is for WIPO to determine what substantive steps are necessary to achieve this aim but it should as a minimum ensure that its advisory committees include representatives from a wide range of constituencies, and in addition, seek closer co-operation with other relevant international organisations such as the WHO, FAO, UNCTAD and the World Bank.**

- **Unless they are clearly able to integrate development objectives into their operations by means of appropriate reinterpretation of their articles, WIPO member states should revise the WIPO articles to allow them to do so.**

- **WIPO should take action to make effective its stated policy of being more responsive to the need to adapt its IP advice to the specific circumstances of the particular developing country it is assisting. It, and the government concerned, should involve a wider range of stakeholders in the preparation of IP laws both within government and outside, and both potential producers and users of IP. Other providers of technical assistance to developing countries should take equivalent steps.**

- **WIPO should expand its existing schemes for financing representatives from developing countries so that developing countries can be effectively represented at all important WIPO and WTO meetings which affect their interests. It would be for WIPO and its member states to consider how this might most effectively be done and financed from WIPO's own budgetary resources.**

These recommendations are aimed at WIPO and its member states. It should be kept in mind that WIPO is an organisation that brings both developed and developing countries together. The needs of all its members must be kept in balance, while artificial grounds for potential conflicts should not be created. Users of the international registration treaties, e.g., the PCT, Madrid (trade marks), Hague (industrial designs) and Lisbon (appellations) will be concerned if significantly more costs are loaded upon them in relation to development co-operation.

We note (from e.g., the annual information handbook and the activities programme accompanying the biennial budget) that a main task of WIPO consists in co-operation with developing countries in their efforts for development as far as intellectual property is concerned. We also note that a substantial number of senior WIPO staff (senior professional and policy advisors, directors and above) is from developing countries, including the Director General himself. Many of these staff have transferred from their home administrations or missions in Geneva. There are two committees for development co-operation attended by member states mainly from developing countries, while the majority of WIPO member states are developing countries. In the circumstances, it is unlikely that WIPO advice would disregard development needs, and indeed we observe that a number of intellectual property laws in developing countries, established with assistance from WIPO, include provisions of the sort advocated in the report. For reasons given elsewhere in our comments, we consider that, by and large, provisions that derogate from the conventional intellectual property protection afforded by most developed countries are misconceived.

- **LDCs should be granted an extended transition period for implementation of TRIPS until at least 2016. The TRIPS Council should consider introducing criteria based on indicators of economic and technological development for deciding the basis of further extensions after this deadline. LDCs that have already adopted TRIPS standards of IP protection should be free to amend their legislation if they so desire within this extended transition period.**

- **Although developing countries have the right to opt for accelerated compliance with or the adoption of standards beyond TRIPS, if they think it is in their interests to do so, developed countries should review their policies in regional/bilateral commercial diplomacy with developing countries so as to ensure that they do not impose on developing countries standards or timetables beyond TRIPS.**

We are concerned about recommendations such as these that encourage countries to defer for a long time any consideration of the changes that they need to make, and that encourage resiling from changes that have been made. It has been our observation that

many countries wait until the very end of a transition period before even beginning to think about their obligations. For example, many developing countries did not complete the necessary legislation in the transition period to 1 January 2000. Even after the new legislation has been put in place, it can be several years before it is brought into satisfactory use and several, indeed many, more years before reliable enforcement is possible by suitable courts. (Other enforcement facilities, such as policing of markets and interception at borders, may take even longer to establish.) It is not unreasonable to expect countries that intend to benefit from WTO membership to take steps to meet their obligations within a clear time frame that is not of unduly long duration.

The TRIPS Agreement was part of the overall trade package that established the WTO. For developed countries, it entered into force within one year of the other components of the package and long transitional arrangements were a privilege for developing countries. Countries that considered that the package was against their interests need not have joined.

We do not accept the underlying theme of the report that it is generally against the economic interests of developing countries to implement the TRIPS Agreement in a full and speedy way. The report underestimates the dynamic effects of intellectual property. These are (i) encouraging innovation by local firms and organisations - even in poor countries there are numbers of research bodies - and by local subsidiaries and associates of foreign enterprises; (ii) spurring competitors into finding alternative solutions to problems and marketing alternative products more competitively and (iii) very importantly, providing part of the necessary infrastructure to give confidence to foreign enterprises to engage in the transfer of technology and/or to establish local operations and/or subsidiaries. Rights will underpin investment in the infrastructure for distribution and supply, repair and maintenance and training and information. These benefits apply regardless of the technological field.

Only if a country does not aspire to introduce and use new technology would it make sense not to provide intellectual property protection of a high and comprehensive standard. There are good examples to show that industries that rely on being able to copy do not develop innovative capacity and also that outside enterprises will do little by way of investment or technology transfer. Historical comparisons can be misleading, but intellectual property protection in industrialised countries goes back a long way – over 200 years in several cases. The report points out elsewhere that the pace of innovative development is increasing rapidly under present intellectual property regimes. How much more rapid would development have been in past times if the regimes had always been as they are now!

The last of the recommendations quoted above seems to be saying developed countries should not seek TRIPS-plus in bilateral deals. Developing countries normally agree to TRIPS-plus in return for market access in excess of that required by the WTO Agreements, and such mutually agreements should not be discouraged.

- **UNCTAD should establish two new posts for Intellectual Property Advisers to provide advice to developing countries in international IP negotiations. We**

suggest that DFID should consider the initial funding of these posts as a follow-up to its current TRIPS-related project funding to UNCTAD.

- **WTO and WIPO should increase the opportunities for civil society organisations to play their legitimate roles as constructively as possible. For instance, this could be done by inviting NGOs and other concerned civil society groups to sit on, or observe, appropriate advisory committees and by organising regular public dialogues on current topics in which NGOs could participate.**

- **Research sponsors, including WIPO, should provide funds to support additional research on the relationships between IP and development in the subject areas we have identified in our report. The establishment of an international network and an initiative for partnership amongst research sponsors, developing country governments, development agencies and academic organisations in the IP field could help by identifying and co-ordinating research priorities, sharing knowledge and facilitating wider dissemination of findings. In the first instance we recommend that DFID, in collaboration with others, take forward the definition of such an initiative.**

Again, these proposals are mainly aimed at the member states. There is no doubt that wide consultation with well-informed bodies, as well as well-informed and impartial research, can only be beneficial. However, the problems in finding impartial advisers with sufficient real expertise and no agenda of their own should not be minimised.

Industrial and commercial enterprises are the major users of intellectual property world-wide and also, very importantly, the major enterprises affected by the intellectual property rights of others. It is deplorable that there is negligible reference in the report to the good sense of consulting them on these issues. Industrial and commercial enterprises, mainly from developed countries, play a pivotal role in development co-operation. They are major contributors to technical infrastructures in developing countries. They generate the wealth of the developed countries and pay a large part of the taxes and fees (including PCT fees) that finance, among other things, development co-operation on IP. It is their products and technology which are transferred to and between developing countries. If the report's recommendations are implemented as they are intended, the incentive for enterprises to invest in producing new products will be reduced. This will be a major long-term drag on efforts to increase prosperity and well-being in developing countries.

12 December 2002

TMPDF

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