Phil Thorpe
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A POSITIVE AGENDA FOR PATENT REFORM AND HARMONISATION FOR DEVELOPMENT

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Introduction

In his paper to accompany this session of the dialogue, Carlos Correa provides an extremely useful summary of the history of international patent harmonization. He also goes into some detail on various aspects of patent law likely to figure in any future debate. It is therefore not necessary for me to dwell on these issues in this paper other than perhaps to provide "evidence in reply" in certain instances. Instead I shall seek to supplement Carlos' paper by providing a broader developed country perspective on the various issues. I shall endeavour also to illustrate how the position of developed countries towards patent harmonization has evolved and also to assess the impact of that on the current discussions on this issue particularly in WIPO.

Discussions within the Standing Committee on Patents

As noted by Carlos a serious attempt to harmonise substantive patent law came to an unsuccessful conclusion at a diplomatic conference in 1991. The package under consideration at that conference was extremely wide ranging covering all aspects of patent law. That no agreement was reached at that conference was due to reluctance of certain members to accept the concept of first to file together with more widespread opposition from developing countries. It is also possible that certain developed countries became more convinced that their ambitions might be met elsewhere especially in the GATT negotiations, that, at least in terms of Intellectual Property (IP), were coming towards a conclusion at that time. Although the 1991 conference broke up with no agreement it is perhaps worth stressing that the mere fact that a conference was convened points to there being a considerable amount of common ground among the various Member States of WIPO most notably among developed countries.

Since 1991 the climate surrounding IP has changed considerably. The entry into force of the TRIPS Agreement brought IP comprehensively into the international trading system. The patent provisions in TRIPS satisfied many of the demands of those countries that had earlier been pressing for further patent harmonization within WIPO. IP has also moved to the fore in economic and trade policy considerations among many leading developed countries who increasingly view strong international protection for IP as a trade priority.

There has also been an increase in interest in the impact of IP on development. Whilst most attention has been on the possible adverse impact of high standards of IP protection in developing countries, particularly in relation to access to essential medicines, there has also been a wider debate about the role of IP in some developed countries. For example considerations of further harmonization of patent rules applicable to computer implemented inventions and biotechnological related inventions within the EU have, at least compared with previous harmonization efforts, been enriched by contributions from a broader base of "users" of the patent system, These include not only representatives of applicants and patent attorneys but also civil society in general. This certainly made reaching consensus within the EU more difficult. It has also perhaps made policy negotiators within the EU more appreciative of the views of those resisting further increases in the level of IP protection. Whilst this may have manifested itself in a less aggressive approach to IP in bilateral trade agreements, certainly when compared with the US, and perhaps a greater willingness to seek more common ground in international IP fora, it has not significantly diminished the support among governments within the EU for effective international systems of patent protection. Indeed the EU continues to promote the

full implementation of the TRIPS Agreement including specifically the provisions within that agreement and others relating to the enforcement of IP[1].

That said the rationale for the current EU support for further harmonization of patent laws in WIPO does not primarily come from a desire to impose higher levels of protection within developing countries but rather from a need to address concerns about the functioning of the patent system in mainly developed countries

The US also continues to seek better enforcement of patent protection whilst also seeking to secure enhanced levels of patent protection in developing countries especially in the area of pharmaceutical products. Like the EU and Japan, the US seems content to seek progress in these areas mainly outside of the WIPO process.

WIPO's Standing Committee on Patents – current objectives of the developed countries

The EU, Japan and the US have drastically reduced their immediate ambitions for patent harmonization within WIPO. This was in response to evident divisions, North-South and to an extent North-North, on many of the provisions in the more comprehensive initial draft treaty that was proposed earlier. The latest proposal for a reduced package (the trilateral proposal) gives priority to what they term "prior art related issues". These are:

- Definition of prior art
- Grace Period
- Novelty
- Non-obviousness/inventive step

Harmonization in these areas will, it is claimed, reduce uncertainty and costs for patent applicants, deliver more consistent examining standards throughout the world, improve patent quality and reduce the work performed by patent offices[2]. The US in particular suggest these topics are non-controversial, non-political and purely technical. In his paper however Carlos suggests they are crucial and directed to key issues concerning patentability standards. Any agreement in these areas would he argues take away the flexibility provided by TRIPS which allows. It perhaps worth looking in briefly in a little more detail at each of these topics

Prior Art

One of the key areas for harmonization of the definition of prior art relates to the extent to which non-written disclosures, for example through use, can form part of prior art for assessing novelty and inventive step. Currently the vast majority of countries recognise such material however the US is a notable exception recognising only such disclosures made in the US. This issue is particularly important in the context of ensuring that patents are not granted for inventions based for example on traditional knowledge which most often originates from developing countries and which has not been disclosed in written form. It is likely that any harmonisation will be based on a broad acceptance of unwritten disclosures as prior art. Whilst being "TRIPS plus", this will nevertheless benefit developing countries and would be consistent with the recommendation of the UK's Commission on Intellectual Property Rights[3].

Carlos highlights a number of other aspects relating to the definition of prior art where achieving consensus may not be straightforward. Whilst there may well be differences on issues such as the

[1] See for example EU Commission's **Strategy for the Enforcement of Intellectual Property Rights in Third Countries** **http://europa.eu.int/comm/trade/issues/sectoral/intell_property/strategy_tc.htm**
[2] See interventions by the US and Japan at the May 2004 meeting of the SCP - paragraphs 17-21 SCP/10/11
[3] Page 83 of the Report of the UK's Commission on IPR 2002.

relevance of secret prior commercial use, the date of availability and indeed the availability of certain prior art the actual impact for developing and indeed developed countries is likely to be small. I confess in my nearly 15 years associated with the examination of patents I have yet to encounter a case where the relevance of a potent citation hung on whether it was deemed to have been disclosed at the beginning or end of a particular month. I nevertheless accept that the issue of who gets the benefit of doubt and on whom the burden of proof falls is significant in a more general sense.

Grace period

As recognised by Carlos many countries including many developing countries[4] already provide for a grace period. The value of such grace periods is however undermined if protection is also sought in countries, including those states bound by the European Patent Convention (EPC), which do not provide extensive grace periods[5] . Any harmonisation in this area is likely to lead to a uniform grace period. Movement by the EU on this issue coupled with a commitment by the US to move to first to file are in fact prerequisites for any harmonisation package. The beneficiaries of movement to a uniform grace period are likely to be those applicants seeking widespread protection who might need to seek support for their applications prior to filing. These are unlikely to include larger corporations from developed countries.

Novelty

The test in the United Kingdom and indeed all Member States bound by the European Patent Convention as to whether a document is relevant to the question of novelty is as follows:

> *Subject-matter described in a document can only be regarded as having been made available to the public, and therefore as comprised in the state of the art, if the information given therein to the skilled person is sufficient to enable him, at the relevant date of the document to practice the technical teaching which is the subject of the document, taking into account also the general knowledge at that time in the field to be expected of him*[6]

In respect of so called "selection inventions" which are available in all Member States of the EPC the test, at least in respect of selections from a previously disclosed broader range is also as follows:

> *A sub-range selected from a broader numerical range of the prior art is considered novel, if the selected sub-range is narrow compared to the known range; the selected sub-range is sufficiently far removed from any specific examples disclosed in the prior art and from the end-points of the known range; the selected range is not an arbitrary specimen of the prior art, i.e. not a mere embodiment of the prior art, but another invention.*[7]

It can be seen from both of these examples that a fairly broad approach is taken when determining whether a particular piece of prior art is considered relevant to the assessment of novelty. Whilst other countries may currently adopt a narrowly approach, it seems likely that any international harmonisation in this area would be generally consistent with the approach taken under the EPC. The discussions to date within the Standing Committee on Patents would seem to support this[8].

[4] For example both Brazil and India have 12 month grace periods.
[5] The European Patent Convention currently provides a limited grace period essentially only in respect of prior disclosures at a certain recognised exhibitions. EPC Art 55.
[6] Para 7.3a of the EPO's Guidelines for Examination http://www.european-patent-office.org/legal/gui_lines/e/c_iv_7_3a.htm
[7] ibid para 7.7
[8] See discussions on for example the proposed Rule 14 in the SCP

Non-obviousness/Inventive Step

Defining and more importantly rigidly applying the notion of inventive step is indeed critical in ensuring that patents for unworthy inventions are not granted. The standard set by the European Patent Office, which among users of the patent system is generally recognised as applying a high standard of inventive step, is based on the following provision:

> *An invention is considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art.*[9]

A similar level of inventive step can be found in many other countries including developing countries[10] even though TRIPS provides flexibility in this area. In some developing countries the level might actually prove be lower. For example the recent reform of the Indian Patent Law provides that

> *inventive step means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art*[11].

In Europe by comparison, commercial success or economic significance alone has not been regarded as indicative of inventive step although it may contribute to a broader assessment of inventive step.

Indications from the SCP point to a level of inventive step comparable to those mentioned above. It should again be stressed that it is perhaps the lack of a rigid application of the inventive step criteria that can lead to the proliferation of so called "trivial" patents rather than deficiencies in the standard itself. Reducing the workload pressures on many of the larger patent offices should in practice allow examiners more time in which to consider, apply and maintain inventive step objections.

Possible Benefits of the trilateral package

The trilateral proposal seeks to harmonise a limited number of prior art related provisions. The benefits that might flow from such harmonisation include reduced costs for applicants seeking protecting in multiple jurisdictions as they will not need to unduly tailor their applications to the respective jurisdiction. Clearly, in the short term, this benefit will accrue largely to applicants from developed countries although it should also be noted that international applications originating from developing countries are on the increase albeit from a very low base. Greater uniformity on these issues should also enable national and regional patent offices to make use of searches done by other patent offices on corresponding applications. This too could feed through to lower costs for the applicants whilst also helping patent offices to manage their workloads more effectively. Reducing the time taken to grant or refuse patent applications is in the interest of all particularly when combined with a commitment to ensuring a high quality of the examination.

Much is made of the implications for developing countries of adopting so called TRIPS plus levels of protection. Signing up to something along the lines of the trilateral proposal will clearly take away some of the flexibilities provided for by TRIPS. However as demonstrated above in some areas this may bring specific gains to developing countries whilst in others it would merely harmonise along existing standards. Indeed the greatest impact of applying the trilateral proposal will fall on the EU

[9] Art 56 EPC
[10] Article 13 of the Brazilian Patent Law as notified to the WTO in IP/N/1/BRA/I/1 states that an invention is endowed with inventive step provided that, to a technician versed in the subject, it is not derived in an evident or obvious way from the state of the art
[11] IP/N/1/IND/P/2 Section 2 (ja).

who would be expected to provide a more comprehensive grace period and the US who would be expected to move to a first to file system. Indications suggest that there might be scope for movement by both the EU and the US on these issues. It should however be stressed that attempts to broaden the range of issues under consideration by any party to the discussions could see any enthusiasm for it quickly melt away especially in the EU and I suspect also in the US and Japan. I do not believe that this means it is a choice between the trilateral proposal and nothing. There remains some room for negotiation however the extent of that is perhaps not as great as some believe or would like.

Linking progress on patent harmonisation with progress elsewhere

Nearly everyone now accepts that the informal consultations culminating in the meeting in Casablanca could and indeed should have been handled better. Nevertheless the outcome of that meeting – the so called 4+2 proposal[12] did seek to take forward patent harmonisation whilst at the same time addressing some of the concerns of developing countries. The proposal sought to fast track consideration of the trilateral proposal in parallel with consideration of the issues of genetic resources (essentially the question of disclosure of origin) and sufficiency[13].

The Casablanca proposal has already been rejected by certain developing countries, partly because of the process leading up to it but also because it is perceived as being too selective in terms of issues for patent harmonisation and because it is seen as ignoring many other aspects of the so-called development agenda. There is clearly a broader issue of how the discussions on the development agenda in general impact on progress on patent harmonisation however that is considered outside the remit of this paper.

In terms of patent related issues the Casablanca proposal should perhaps not be so easily dismissed. As I have noted any enthusiasm for patent harmonisation in developed countries will quickly disappear if additional issues are added to the agenda that are considered to increase uncertainty in the patent system or undermine significantly the standards provided by TRIPS. This does not mean that other issues could not be included. For example incorporating provisions similar to those of Articles 7 & 8 of TRIPS may be a possibility.

Insistence on anything more substantial is however likely to lead to the collapse of the WIPO patent harmonisation process at least in the short to medium term. The process would most likely still continue outside of WIPO with involvement essentially limited to Group B countries plus others falling under the trilateral umbrella. Developing Countries would then be prevented from influencing the debate although ironically the likely outcome of any restricted debate would probably not be too dissimilar to that which might come out of any WIPO sponsored debate. This is not a reflection of the negotiating strengths of developing countries within WIPO but rather a recognition that resolving the main issues between especially the EU and US is likely, as discussed above, to result in provisions that appear generally consistent with the current objectives of, or positions in, many developing countries.

Of greater concern perhaps with negotiations moving outside of WIPO will be loss of any potential leverage that developing countries might have to secure progress on other issues of interest to them most notably disclosure of origin. It may be that this calculation has already been made and that developing countries or at least those leading on the development agenda within WIPO, are satisfied that progress might still be possible on their broader agenda either within WIPO or in other fora. It should also be noted that developing countries will still be exposed to bilateral pressure to increase standards of patent protection although this is likely irrespective of progress within WIPO.

[12] WIPO Statement adopted at the end of informal consultations in Casablanca 2005 http://www.wipo.int/edocs/mdocs/scp/en/scp_11/scp_11_3.pdf

[13] This is taken to relate to the requirement on patent applicants to disclose their invention in a manner sufficient for it to be put in practice in the country in which protection is sought. Some argue that this requires greater disclosure in resource-constrained and less developed countries.

The question is, therefore, would a limited patent harmonisation package, including possibly a few general provisions, coupled with agreement to consider disclosure of origin and sufficiency and possibly also movement on some of the less controversial aspects of the broader development agenda, satisfy developing countries. It is to be hoped that it does. If not then it seems inevitable that discussions within WIPO on patent harmonization and also perhaps the development agenda in general will run into the sand. Indeed it is possible that this may have already happened and that securing support even from some developed countries for the above mentioned package may no longer be possible.

The current debate is perhaps not helped by the mistrust clearly evident between some of the key players. This mistrust, which obviously needs to be overcome if there is to be any chance of progress, seems to be borne in part from a lack of any clear understanding of the aims and objectives of the other side. For example from the developed countries perspective it is still not clear whether the real intent of those promoting the development agenda is simply to stifle any discussions on further harmonisation within WIPO or whether it is a genuine attempt to address within WIPO real concerns among developing countries about the role of IP in their development. Some may argue that these two possible objectives overlap. A number of developed countries have genuinely sought to reach out to developing countries in the discussions although, to date, with little success. It is of course possible that the gap between the opposing sides is simply too great to bridge at this time.

Conclusion

In this paper I have sought to shed some light, possibly from a different angle to other commentators, on the current discussions within WIPO on patent harmonisation. The paper by necessity has addressed the issue in relative isolation from the broader debate that is happening within WIPO although it does recognize that the two are clearly interlinked. I have sought to demonstrate that moving forward with a proposal based essentially on the trilateral package is unlikely to have any serious adverse impact on developing countries and indeed in a number of areas may address some of their concerns. Involvement in such a process may also enable developing countries to secure progress in other areas.