Intellectual Property Rights Series 11

# The Substantive Patent Law Treaty: The Dangers of Global Patent Policy Harmonization

Sangeeta Shashikant

TWN
Third World Network

# The Substantive Patent Law Treaty: The Dangers of Global Patent Policy Harmonization

Sangeeta Shashikant

TWN
Third World Network

**The Substantive Patent Law Treaty: The Dangers of Global Patent Policy Harmonization**
is published by
Third World Network
131 Jalan Macalister
10400 Penang, Malaysia.
Website: www.twnside.org.sg



Printed by Jutaprint
2 Solok Sungei Pinang 3, Sg. Pinang
11600 Penang, Malaysia

ISBN: 978-967-5412-01-1

# CONTENTS

# 1 "Exporting a Dysfunctional System"

SEVERAL speakers at the opening day of the World Intellectual Property Organization (WIPO) open forum on the draft Substantive Patent Law Treaty (SPLT) warned about the dangers of the global harmonization of patent laws that the SPLT is aiming at.

They warned that there were serious problems with the quality of patents in developed countries, and if the SPLT is based on that system, it would "export a dysfunctional system to the rest of the world". Some of them suggested alternative ways of approaching intellectual property (IP) and innovation that are more suitable for developing countries.

The speakers who cautioned against the upward harmonization of the patent regime included Nobel Prize winner Sir John Sulston, Professor Jerome Reichman from Duke Law School, and Prof Carlos Correa of the University of Buenos Aires.

The 1-3 March 2006 forum was mandated by the WIPO General Assembly to discuss issues related to the draft SPLT in an attempt to break the impasse in the negotiations in WIPO on the treaty. The negotiations have been deadlocked because of differences between developed and developing countries. The developed countries are pushing for a new patent treaty that harmonizes national patent laws in order to have common treatment of aspects including prior art, grace period, novelty and inventive step. Many developing countries are opposed to this narrow agenda and want the treaty to address public-interest flexibilities, anti-competitive practices, and disclosure in patent applications of the source of origin of genetic resources and traditional knowledge.

---

* This chapter first appeared as an article in the *South-North Development Monitor* (*SUNS*), No. 5978, 3 March 2006.

**“Pulling up the ladder”**

The first speaker on the forum’s opening day, Nobel laureate Sulston of the Human Genetics Commission, said that his experience in the human genome project highlighted tensions between the public and private sectors “over whether the human genome sequence should be freely released”. Sulston noted that harmonization of intellectual property is desirable in that it simplifies the process and avoids duplication in the work of patent offices, but it may not be so good for the rest of us, the ultimate users of the results, and for all patent holders equally.

He added that the world is diverse and people are not yet in a position to agree easily on the details of the ideal system, as solutions need to be effective overall, not just for the few. Balance is needed between developed and less-developed countries, discovery and exploitation in science, private and public interests, free release and monopoly.

Sulston also stressed that patents are only one instrument of incentive among many and should exist in balance, adding that most of the great discoveries of science were not made with intellectual property in mind at all but for fun and the joy of exploration.

He cautioned against giving patents too much credit for industrial success. He added that generally, developing countries which have shown the fastest economic growth are those that retained relatively protected markets until they reached a position of strength; the same is the case for Europe and the US a century ago. “Regrettably, harmonization is a way for those who have already arrived at a prosperous situation to pull up the ladder and stop others joining them.”

Sulston noted that given the imperfections of the patent system, harmonization should not be “the first thing to think of and indeed may do more harm than good”. The diversities of national law and practice are needed to make the system bearable particularly with regard to less- and least-developed countries. He also added that the flexibilities provided for by the World Trade Organization (WTO)’s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) are good on paper but difficult to apply.

Harmonization “is obviously desirable in the long term provided at the same time the world becomes egalitarian”, he added. He favoured gradual and piecemeal introduction where there is mutual benefit.

Progress, he said, will be greatly helped by restoring the remit of WIPO to promote creative activity as a whole rather than being entirely focused on the policing of existing intellectual property law. Some, he said, saw these themes as diversions from the real business of WIPO, but he saw it as a "positive impetus taking on board the range of existing and proposed instruments for handling IP."

He gave as examples the General Public Licence of the Free Software Foundation, CAMBIA's Biological Innovation for an Open Society (BIOS) open licences adapted for patent technologies in the life sciences, Creative Commons, and the World Health Organization (WHO) resolution submitted by Kenya and Brazil which "proposes better methods for handling IP in biomedical research and development".

He added that the US and European Union (EU) efforts to negotiate bilateral free trade agreements are intended to bypass international treaties and to promote stringent IP relationships with a number of smaller countries. The irony is that these free trade areas are a "return to old systems of most favoured nations and indeed imperialism". "It's a disturbing development, and needs a collective response," he added.

Sulston concluded that "simply heading uncritically down a road of more and stronger exclusivity is wrong for many of us: wrong for science, wrong for many small businesses, wrong for reducing the poverty gap. Wrong indeed for our very survival – for injustice breeds discontent wherever it comes from."

Kenji Kamata, a leading member of the Japan Intellectual Property Association, spoke on how the patent system was an indispensable part of industrial advancement and the importance of international harmonization of the patent system for industrial development in the world. The benefits of harmonization include improving the patent quality, timely examination, reduction of costs in applying a patent and elimination of duplication of patentability examination.

He said that the harmonization process should focus on the four issues of definition of prior art, grace period, novelty and non-obviousness/inventive step, which is the US-EU-Japan proposal in the SPLT talks.

At question time, Brazil asked why the developed countries did not harmonize among themselves if that was the way they wanted to go, and why they insisted that it take place in developing countries as well.

An official of the Danish patent and trademark agency responded that there had been several meetings in WIPO and it was looking forward to harmonization for the benefit of the users.

A representative from the non-governmental organization (NGO) Third World Network commented that what was important for development was "policy space". She said that a study commissioned by the intellectual property rights commission set up by the UK revealed that in Japan, food, beverages, pharmaceutical products and chemical compounds had been excluded from the scope of patent protection until 1975 and there were other features, such as that a patent application must be limited to a single narrow claim (until 1988). Studies also confirmed that the weaker patent system employed by Japan facilitated its absorption and transfer of technology by allowing reverse engineering.

She pointed out that because of this policy space, Japan was able to put in place policies suitable to its needs and to build its capacity. Unfortunately, the developing countries now face a shrinking of their policy space, due to the TRIPS Agreement which has led to a significant harmonizing of IP standards.

What is being negotiated in the draft SPLT is the "dissolution of policy space" as it aims at further upward harmonization of IP policy, going very much beyond the TRIPS Agreement. This will result in a one-size-fits-all law, irrespective of individual countries' level of development. She did not see how this treaty will be beneficial to developing countries.

Chile said that harmonization is being advocated on the grounds of efficiency, but asked what the argument is for wanting countries to change their IP norms.

To both these questions, Kamata simply said that IP does increase the entry of foreign technologies and stressed the importance of harmonization for increasing efficiency.

Narendra Zaveri, an advocate from India, asked whether developed countries were willing to raise the standards of patentability because otherwise trivial patents will lead to chaos for their system.

**Access and predictability**

In another morning panel, the discussion on international patent law harmonization continued. Jonathan Zuck, President of the Association for Competitive Technology, said small and medium-sized enterprises (SMEs) want fewer but better-quality

patents. SMEs need from the system "access and predictability." Predictability means that if a patent is granted it is worth something and if granted to someone else, it will be a good patent.

Daeshik Jeh, director of the Korean Intellectual Property Office, made the case that stronger IP protection is linked with economic growth. Korea introduced the modern IP system in 1961 and enhanced the system in the 1980s and after, and patent applications increased along with growth since the 1970s. The negative effect of the IP system was that large amounts of royalties had to be paid; on the positive side was the increase in the ratio of technology export to technology import. Korea is in favour of harmonization of patent laws.

Prof Jerome Reichman from Duke Law School in the US said that he was deeply sceptical of the draft SPLT. It was both unwise and premature to undertake another major substantive patent harmonization barely 10 years after the TRIPS Agreement, which came into force in 1995.

He said that it would have adverse impacts on developing countries which had just begun to absorb the social costs of the higher standards in the TRIPS Agreement, and they stood to lose most of the flexibilities in the TRIPS Agreement by engaging in the SPLT process. He gave the example of the low standard of "non-obviousness" in the draft SPLT, which would be imposed on developing countries.

He added that no one in the developed world at the moment really knew what a properly functioning patent system for the 21st century should look like. This could be seen in the tensions among developed countries with regard to just a few basic issues under the SPLT, such as novelty, non-obviousness and research exemption, as well as the growing difference in the treatment of compulsory licences.

There was agreement that the US patent system was in a mess, he said, quoting numerous studies. For example, a book by Jaffe and Lerner complained that the US was handing out patents to anyone who asked for one, resulting in a trend that "now undermines rather than fosters the crucial process of technological innovation". This trend was particularly acute in biotechnology and software patents.

He added that upstream patenting on experimental science had led to difficulty, with serious disruptions of biotech research efforts due to patent thickets, anti-commons effects and refusal to share research data or materials. He quoted studies which showed that patents are actually decreasing the incentive to invest in innovation.

The amount of litigation had also tripled between 1987 and 1997, and the costs of patent litigation now outweighed the value of patents to owners by about 2%, constituting a tax on overall research-and-development (R&D) investment.

On alternative regimes, he said there should be examination on the need to supplement the patent system with new kinds of intermediate or second-tier protection systems more attuned to present-day technological realities than either full patent protection or utility model laws.

He said a new technological epoch had been entered, in which experts had only tentative and divergent ideas about how to treat business methods, software patents, DNA patents, bioinformatics, small molecule compounds, micro-arrays and other diverse novel technologies.

At best, Reichman added, they were operating with a set of rudimentary working hypotheses that different countries were putting to the test, and the focus should be on the experimentations and new empirical findings based on the TRIPS standards. What was needed was not a closed-minded, premature adoption of standards based largely on ignorance and power politics that would in effect "export a dysfunctional system to the rest of the world".

WIPO, he said, should consider many other issues or initiatives such as dissemination of information about weak or bad patents and possibilities of defensive patenting, and facilitate open source and similar collaborative undertakings, identify and study different patent trends and practices emerging in both developed and developing countries to test empirically the different approaches to critical new technologies, etc.

**Prior art**

In another panel on prior-art-related issues, the speakers were Anne Rejnhold Jorgenson of the Danish Patent and Trademark Office, Prof Carlos Correa, Director of the Faculty of Law and Social Sciences of the University of Buenos Aires, and Begona Venero of the Peruvian Institute for the Defense of the Consumers, Competition and IP.

Jorgenson favoured having an SPLT, saying that otherwise it would be detrimental for users, especially small companies with limited resources. Patent offices were frustrated with the complexity and dissimilarities of the various patent systems. She added that harmonization in the definition of prior art, novelty and inventive step was in the interest of users. However, any kind of harmonization instrument,

including best practices and opt-out clauses, should be carefully considered, thus allowing all parties to adhere to the instrument when they feel ready to do so.

Speaking on "inventive step", which is a crucial issue targeted for harmonization, Correa said the draft SPLT proposed a low standard for determining what was an inventive step. The claimed invention would be assessed against the general knowledge of an ordinary skilled person, not the specialized knowledge in a field of technology.

One question was how to define a person having ordinary skill. Even in the US, many of the patents that were challenged in courts were found to be invalid, and on appeal many of the original decisions were also revoked. Thus, even in the US there was no agreement on how to define an ordinary skilled person. It was difficult then to apply the definition or standard internationally.

He added that having low standards of patentability would overload patent offices, increase litigation, promote ever-greening of patents, permit aggressive abuse of the patent system, and result in less competition and negative impact on social policies such as access to medicines.

He also said that a global patent policy should increase the level of inventive step in order to reduce overload in patent offices, reward genuine contributions, improve patent quality and raise R&D in industries.

He questioned whether the SPLT is the best way to achieve WIPO's objectives as it does not address the problem of opportunistic patenting and abuse of the system. He asked whether the treaty is desirable, since it could lead to there being less room for the design of innovation policy and adaptation to levels of development, to patent proliferation and less global competition and innovation in developing countries.

Correa proposed an alternative agenda which discourages the proliferation of opportunistic trivial patents, improves patent quality and the public domain, and differentiates according to innovation systems and countries' use of the system in line with their economic growth.

Venero, speaking on the treatment of traditional knowledge in the definition of prior art, gave examples of three patents granted in the US on a genetic resource that is traditionally known in Peru. He said the definition of prior art should take into account traditional knowledge in written and oral forms in any part of the world. The patent system should not be used to validate piracy of genetic resources.

During discussion, a participant said that the European patent system had harmonized the systems of its members, removing many differences, thus showing that harmonization is desirable. The idea of harmonization came from users of the system and "we work for users", he said.

Another participant rebutted that point, saying that the users' interest is secondary. The patent system is an incentive system, and the real interest is to generate output, and to qualify to use this system certain criteria of patentability have to be fulfilled.

This view was supported by Correa, who said it is a mistake to believe that patent offices should be working with users. They should work for the public good. Those working on patents should change the way they see the issue and their paradigm of the IP system.

Another participant, Prof Fred Abbott, said there seems to be consensus that there is a problem with patent quality in developed countries. The current draft of the SPLT really mirrors the developed-country standards, so how will harmonization improve patent quality?

The US challenged this, saying there is no such consensus about patent quality. There have only been a number of criticisms on individual cases.

Correa said the US seemed to have confirmed that the proponents of harmonization had the hypothesis that the process of harmonization will be based on standards currently existing and there is no systemic problem with these standards. He added that proponents of harmonization have to clarify on which standard the harmonization should be based since there are many different standards within or between countries.

Jorgenson responded by saying that in a system that is handled by humans there will always be mistakes and this problem will not be overcome by the harmonization process.

Another participant insisted that the US government had studies, in particular a study by the Federal Trade Commission in 2003, which showed that the quality of patents granted in the US is questionable. She said that a study on litigation cases revealed that 72% of cases filed were won by generic companies, an indication of the quality of patents that had been granted.

**Disclosure of origin of genetic resources**

In the final session of the day, on the disclosure of origin of genetic resources, Joshua Sarnoff, Assistant Director of the Glushko-Samuelson Intellectual Property Law Clinic at American University in the US, said that in any further initiative to harmonize substantive patent laws, the issue of mandatory disclosure-of-origin requirements should be addressed. This is because the patent system itself should deter rather than reward and perpetuate unjust conduct.

Individuals, indigenous peoples and governments from which genetic resources/ traditional knowledge has been acquired illegally should not have to shoulder the entire burden of preventing and remedying unjust conduct. Instead, the patent system should take some responsibility to address unjust conduct. Moreover, mandatory disclosure will help to develop and potentially to harmonize the complex legal and equitable principles that govern rights to own and to benefit from patents.

He added that issues about patentable subject matter, wide scope of claims, experimental use/academic use/product regulatory approval use/fair use, relationship of patent laws to other laws, compulsory licensing, government use and injunctive remedies, patent misuse and contractual licence restrictions, and patent terms should be carefully addressed to better ensure that technological and scientific progress is not impeded.

Yin Xintian, Director General of Legal Affairs in the China IP Office, said that the improvement of the patent system should focus not only on increasing efficiency but on a more important goal, to "contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare and to a balance of rights and obligations" (Article 7 of the TRIPS Agreement).

He said it is sensible to limit properly the scope of the future discussion (in WIPO's Standing Committee on the Law of Patents) but the topics should include at least some of the issues of concern to most developing countries. He proposed that the disclosure-of-origin issue be a top priority in the Standing Committee.

Two of the other speakers, Benjamin Zycher from Pacific Research Institute and Andre Bourgouin from Corporate Intellectual Property, were not in favour of having disclosure of origin of genetic resources in patent applications.

# 2 Basic Problems and Practical Difficulties

BASIC problems and practical difficulties in the attempt by WIPO members to globally harmonize patent laws were highlighted on the second day of the WIPO open forum on its draft Substantive Patent Law Treaty.

The difficulties brought up by various speakers included differences in approach by countries on requirements for disclosure of the claimed invention by the patent applicant, and differences of view on what materials should be excluded or exempted from patents.

Several speakers pointed out the problems that would arise should WIPO adopt a new SPLT that requires the developing countries to take on the standards and features of the patent system of developed countries, particularly the US.

**Disclosure disharmony**

In the first session on "Sufficiency of disclosure", Professor Carlos Correa from the University of Buenos Aires referred to the text in the draft SPLT on disclosure: "The application shall disclose the claimed invention in a manner sufficiently clear and complete for that invention to be carried out by a person skilled in the art. The disclosure of the claimed invention shall be considered sufficiently clear and complete if it provides information which is sufficient to allow that invention to be made and used by a person skilled in the art on the filing date, without undue experimentation."

He said that this text generally reflects the US view. He asked whether effective harmonization is feasible, adding that there are ambiguities in this provision. Firstly,

* This chapter first appeared as an article in the *South-North Development Monitor* (*SUNS*), No. 5979, 6 March 2006.

it allows the invention to be "made and used", but what is the level of information that is needed for the invention to be made and used, asked Correa?

Much, he said, depends on how one defines "a person skilled in the art". He said the outcome would be different if the person is an expert than if he is of "average" skill. Regarding the phrase "without undue experimentation", he asked what the degree of "undue experimentation" is.

Correa added that there is disharmony within national systems on disclosure requirements. In the US, there are different standards of disclosure applied to DNA patents as compared to software patents. In the former, sequences must be disclosed under a stringent written description rule, while in the latter case patents need to disclose virtually nothing about the detailed workings of the inventions. In DNA patents, a low-skilled "person having ordinary skill in the art" is required for "non-obviousness" while for software patents a highly skilled "person having ordinary skill in the art" is required. This, Correa added, shows diversity in the standards applied in the US.

He also asked which standard of disclosure should be adopted if harmonization continues. He referred to text in US free trade agreements which states: "Each Party shall provide that a claimed invention is sufficiently supported by its disclosure if the disclosure reasonably conveys to a person skilled in the art that the applicant was in possession of the claimed invention as of the filing date."

He also referred to the law in China which, in relation to disclosure of chemical process invention, states: "For the substance of the raw material used in the process, not only the chemical components and property parameter(s) etc., but also its source, shall be disclosed to make it identifiable." It also states: "If the substance of the raw material is a natural substance, besides its origin, disclosure shall be made of its basic chemical components or the basic parameter(s) capable of identifying the said substance."

He also referred to the text of the TRIPS Agreement, which states in Article 29.1 that "Members ... may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application." In Article 29.2, the agreement states that "Members may require an applicant for a patent to provide information concerning the applicant's corresponding foreign applications and grants."

Referring to these different texts, Correa called the US standard ambiguous, and also said that if harmonization is done using the TRIPS text, he would recommend

changing the word "may" to "shall". This, he said, is important to reduce the work of the patent office.

He concluded by saying that the differences in disclosure requirements are unlikely to be effectively harmonized. Disclosure requirements may also need to vary by sectors and skills in the country of application, and disclosure of best mode and of information relating to foreign applications should be mandatory.

Tim Roberts, a Council Member of the Chartered Institute of Patent Agents in London, appeared to agree with Correa about the importance of a sufficient disclosure requirement.

He said that the object of disclosure is to teach the public something new and useful. It is the only consideration for the exclusive right that the patentee gets and the information is for immediate use for private and some experimental purposes and any purpose outside the scope of claim. Thus, a good disclosure is in the public interest.

He added that the "flexible approach" is best, as it allows disclosure to be adapted to the needs of the technical field and the nature of the invention. Principles governing disclosure should be uniform for all patent offices. He was sceptical whether this is an area where there can be legislation.

**Exclusions from patentability**

Another panel on "Exclusions from patentability, industrial applicability and technical effects" was comprised of Graham Dutfield from Queen Mary College, University of London, Hugh Laddie, an IP consultant from Rouse & Co International, and Jeffrey Hawley, past president of the Intellectual Property Owners Association.

Dutfield said it has never been the case that "anything under the sun made by man" is patentable. Many ideas are filtered out through the patentability criteria, while statutes or courts may define or interpret "invention" in ways that exclude certain classes of original ideas such that they are not considered to be inventions at all. Further, certain subject matters are just excluded. Another filtering device is the requirement for the invention to have a "technical effect". It is not easy to define what is "technical".

He said there were various reasons for excluding certain things from being given patents, including to protect the public domain, to prevent foreign monopoly power in strategic fields, and to encourage copying for more local innovation.

He added that what "leaders" (i.e., the developed countries leading the harmonization process) want is harmonization based on globalizing or exporting their own standards. This is their idea of a level playing field. However, in contrast, the "followers" want differentiation based on levels of economic development.

He posed the issue of what the SPLT means, whether it is creating a level playing field or "kicking away the ladder" (i.e., rich countries preventing poorer ones from taking the route to success they themselves had taken earlier).

Dutfield referred to the section in the draft SPLT on public interest, which was bracketed, indicating disagreement. "What is the SPLT for, if its purpose is not to protect the public interest?" he asked.

Laddie stressed that in the history of economic development, "competition" has played a very significant role. In the European Patent Convention (EPC), patents are not given for methods of doing business but in the draft SPLT, everything is patentable. Schemes, rules and methods for performing mental acts are valuable exceptions in the EPC but if the draft SPLT goes through, Europe will have to allow patenting of these. He added that the US became the biggest commercial power without giving patents on business methods.

There has been vigorous commercial development over the years without the benefit of the patent monopoly that is now being advocated. Giving the example of Microsoft, he said that it became a multi-billion-dollar entity without the benefit of any computer program patents. The reality is that development is not dependent on the existence of patent rights.

He advised those involved in the drafting of the SPLT to ensure that it does not protect subject matter that does not promote technological growth.

Responding to a question, he said that the motor of Western economic development in most fields has been competition. He added that there would not be the Word 2005 word-processing software today if there had been patents in this area. "We would be at Word Perfect 1.2," he said, because the company having the monopoly would not have the incentive to change.

He said it is competition that drives growth, and "unless we get this clear, we will cripple industries." One hundred years of economic development has nothing to do with patents, he stressed.

Dutfield said there was "confusion at the highest level" regarding "what the patent system is for", especially in the US. He added that some people are even saying that intellectual property rights are a human right.

Hawley indicated that he favoured patent rights even for business methods and schemes, stating that since investments had been made, there was no reason for not granting exclusive rights.

However, following a spontaneous debate with Laddie, he agreed that patents should be granted for some inventions but not for others.

**Exceptions to patent rights**

In another session, Sisule Musungu from the South Centre spoke on "Exceptions to patent rights". He said that exclusions of certain subject matter from patentability were found in the TRIPS Agreement, as were exclusions of certain acts from the scope of the patent holder's exclusive rights.

He said that exceptions are prerequisites for achieving the aims of Articles 7 (objectives) and 8 (principles) of the TRIPS Agreement and similar objectives which justify patents. In WIPO, such exceptions are necessary to discharge the constitutional functions of WIPO as a UN agency responsible for promoting creative intellectual activity and facilitating technology transfer to developing countries. Further, virtually all national laws and practices recognize exceptions in one form or another.

He listed and countered arguments that have been presented against the inclusion of exceptions in the SPLT. The first argument is that WIPO's Standing Committee on the Law of Patents (SCP) agreed to limit the scope to exclude exceptions because the purpose of the SPLT is to establish best practices and deeply harmonize the substantive requirements. Musungu said it is difficult to believe that member states had bound themselves not to exercise their sovereign rights to make proposals for including exceptions in the treaty. He said there was no record of such a binding in the SCP.

The second argument is that the WIPO Intergovernmental Committee (IGC) was created to address issues related to genetic resources and associated traditional

knowledge and so the SCP should not deal with them. Musungu said that in 2003, when the mandate of the IGC was renewed, the WIPO General Assembly specifically decided that the IGC's work is "without prejudice to the work pursued in other fora."

The third argument is that matters relating to the Convention on Biological Diversity (CBD) and the TRIPS Agreement and to public health are being dealt with at the WTO (implying that WIPO need not deal with them). Responding to this argument, Musungu said that WIPO does not answer to the WTO and not all members of the former are members of the latter. He also said that just because the WTO's TRIPS Council is discussing these issues cannot be the basis for excluding them from WIPO.

The fourth argument is that it is more effective to evaluate the social and economic consequences of a patent on other areas of public policy at the stage of exercise of rights. There is also no basis for this argument, he said.

Another argument is that for exceptions to be workable in an internationally harmonized approach, the grounds under which an exception may operate would usually need to be clearly defined to create sufficient certainty for a harmonized approach to be adopted. Musungu said that the proponents of the proposals were never given the opportunity to present the proposals exhaustively. There may be a need to separate and formulate specific language for exceptions for patentability and exceptions to patent rights. Only after an exhaustive discussion and revisions of the proposed provisions can there be a conclusion on whether the provisions are clearly defined.

There is thus no basis in the arguments to exclude exceptions from the SPLT, concluded Musungu.

The first task in addressing exceptions in the SPLT is to understand the objectives and scope of the treaty. He outlined three methods of addressing exceptions in the SPLT. It could be by "silence" (which he said was not a good choice), by enumerating the exceptions and defining each exception, or by incorporating a "general saving clause."

Two other speakers who made very pointed comments on the SPLT were Narendra Zaveri, an advocate from India who spoke on "Effective mechanism to challenge the validity of patents", and Prof Frederick Abbott from the Florida University College of Law, who spoke on "Contractual licence and transfer of technology".

Zaveri said that three safeguards – pre- and post-grant opposition to patents as well as "no presumption of validity"– have to be effectively provided for in the SPLT, in view of the grave consequences for other stakeholders from questionable patent grants, the need to balance the rights and obligations of all stakeholders, and the inherent problems and limitations of the patent system.

He also said that a global patent system with weak standards of patentability would have disastrous consequences especially for developing countries. He gave the case of AIDS drug zidovudine, the anti-viral effects of which had been known since 1975 but which was patented by Burroughs Wellcome in the US and several other countries merely on the basis of its new use for treating AIDS. The price of the drug was prohibitive, making it inaccessible to the many millions of people in need of it. Pre-grant opposition could have prevented the questionable grant.

He said there is also the problem of "me too" drugs, and gave many examples of patents being granted on laughable claims with insignificant improvements, such as patents for food slices and method for making the same; filled potato product; extruded potato casing; preservation of exposed cut fresh fruit; French-fry potato with improved functionality and process for preparing; drops of honey; ice-cream with fat containing coating; composite ice-cream cone, food slices and method and apparatus.

He said that the grant of frivolous/questionable patents deprives other stakeholders of their legitimate right with no reciprocal benefit, and that the facility of acquiring global patents at least cost will provide a strong inducement for such frivolous claims. Thus pre- and post-grant opposition and no presumption of validity have to be provided to discourage the trend towards questionable claims and patent grants.

Addressing the inherent limitations of the SPLT, he said that unlike national patent offices under national laws, the SPLT will not have the jurisdiction or powers to require oaths and declarations/disclosures or enforce them, or the powers to punish claimants making false, fraudulent, frivolous, repetitive and excessive patent claims.

Also, as a result of the SPLT, national authorities will not be able to have the benefit of independent search and examinations by several national patent offices, or the benefit of review by way of appeal against decisions of national patent offices, or the power to limit the scope of adverse impact on other stakeholders by excluding some patentable subjects (such as business methods, methods for treatment, etc.).

He added that the US patent office has a workforce of 6,939 employees, including 3,538 patent examiners and about 4,000 contract employees. Despite its vast

resources, the US patent office also faces inherent problems in weeding out questionable claims and ensuring the validity of patent grants.

Prof Abbott spoke about the benefits of patent licensing, stating that it may facilitate access to and use of patented technologies and products. He also added that anti-competitive licensing is generally an accepted practice among states, giving examples of developed countries where it is practised. He referred to the TRIPS Agreement which recognizes that intellectual property rights may be abused and which authorizes members to regulate anti-competitive licensing practices.

He added that rules regarding anti-competitive aspects of patent licensing are within the reasonable potential scope of an SPLT. Such rules, he said, could take a positive form, prescribing certain types of conduct or establishing presumptions regarding certain types of conduct as "anti-competitive". It could also take a negative form, making clear that governments are permitted to regulate anti-competitive licensing practices notwithstanding positive obligations regarding the grant of patents. Rules also could include an illustrative list of potentially anti-competitive licensing practices, he added. Alternatively, he said, a combination approach could be used.

He also said that approaches to regulation of competition tend to vary over time within the same jurisdiction as industrial policy considerations shift, and this may argue in favour of preserving regulatory flexibility. Further, he said that industrial policy considerations of developed and developing countries with respect to the application of competition law to patent licensing may differ. Each developing country is also at a different stage which may also need differing industrial policy interests. Thus, he argued that taking a negative approach would permit the maintenance of regulatory flexibility.

# 3 Patents on Genes, Lifeforms and Medicines

THE final day of the WIPO open forum saw a heated exchange on the impact of patents on access to medicines, as well as an interesting debate on whether genes and lifeforms should be patented.

Nobel laureate Sir John Sulston, who is credited with the discovery of the human genome, gave his view that gene patenting should not be allowed, and that patents had been found to have a hindering effect on upstream science, especially on gene-based diagnostic tests.

The highlight in another session on patents and health was a heated exchange between the leading representative of the multinational drug companies and the former chairman of the US generic drug producers association, on whether patents hinder access to medicines and whether compulsory licensing results in health benefits.

**Biotech patents**

In a session on "Biotechnological inventions, patenting of genes and lifeforms and the impact of patenting on upstream science", Prof Joseph Strauss of the Max Planck Institute for Intellectual Property said there was no empirical evidence on serious negative impacts on upstream science, despite the large number of patents that have been granted on genes. He also said that without patents on biotech products, many biotech companies could not have provided medicines.

Nancy Linck from the Biotechnology Industry Organization said the US patent system is a "strong enduring system that can be improved but is certainly not broken". She added that having disclosure of the source of origin (of genetic

* This chapter first appeared as an article in the *South-North Development Monitor* (*SUNS*), No. 5980, 7 March 2006.

resources) in the patent system would be devastating especially for the small biotech companies.

She faulted the developing countries which do not have national access-and-benefit-sharing regimes in place, as this resulted in a situation where it is not clear who to reward when the genetic material is taken. She also said that the US would not sign on to any initiative that incorporates disclosure requirements.

Several of the previous speakers' arguments were rebutted by Sulston, who is Vice Chair of the Human Genetics Commission. He said that although IP expansion has been breathtaking in the last 30 years, with clear beneficiaries, the value for society as a whole is less certain, as exploration and innovation are threatened by the culture of exclusive rights.

He said that lifeforms are not patentable since they occur in nature and there is no inventive step involved. A modified lifeform is patentable, but only as far as the actual modification is concerned and if it involves an inventive step. In future when new lifeforms will be synthesized from scratch, such lifeforms will be inventions and therefore patentable. Before that point it will be commonplace to modify lifeforms so extensively that their origins are unclear.

He added that conflicts arise because under the current system of exclusive rights, possession of a patent confers too much power. Therefore, stricter controls need to be instituted on its use and until that is done, it is better to retain a precautionary position on claims.

On the issue of patenting of genes, he said that genes are discoveries (which are not patentable), and the inventive step consists of their isolation from nature. However, even the isolation has been obvious for many years. He noted that there has been a corresponding shift to claims through functionality (of the genes), but this constitutes discovery. So logically gene patenting should not be allowed at all, he said.

Sulston also said he was assured 15 years ago that strong gene patents would be essential to ensure that companies' efforts are spread out rather than focussing on a few easy targets. But the pharmaceutical scene is now awash with "lookalike" drugs, an outcome that has nothing to do with patents and everything to do with markets.

Stressing that patenting has an impact on upstream science, he referred to a comprehensive survey, combined with review material, published by the National

Research Committee (NRC) of the US, which concluded that there is some inhibition on research caused by third-party patents. In most fields a minority of researchers declare significant impediment. The exception is in the area of gene-based diagnostic tests, where a majority had experienced interference.

Another finding was that only 7% of researchers were motivated by patents while the majority were motivated by scientific importance (97%), personal interest (95%) and availability of funding (80%).

Making the point that patents can be an obstacle, he gave his own personal experience as a researcher, when the supplier of the machines tried to keep the emerging data encrypted so that they are tied to the software throughout the analysis. He said that negotiation did not work so they decrypted the output file from the machine.

Surveys concluding that all is well are not necessarily a vindication of the system. This often only means that people are getting around or ignoring the obstacles put in their way by patents. Tightening the system will be destructive of science.

The NRC, he said, concluded that patents already have a small negative effect on upstream research, and that this is likely to increase. To offset this trend, it recommends measures to maintain the vigour of public research.

At question time, Joshua Sarnoff from American University asked Linck how fair it is to patent genetic materials when there is uncertainty as to whom to reward. He added that the disclosure requirement is designed to remove the uncertainties. Responding, Linck reiterated that having disclosure requirements within the patent system is not the way to go, adding that such requirements are difficult to satisfy.

Another participant said there was a need to ensure that the patent system is made more equitable, and including the disclosure requirements would make it more so.

To a question as to whether the problems of bad patents can be resolved so long as patent offices have an economic interest in granting the patents, Sulston and Strauss both agreed that the system in patent offices has to be changed.

But when Strauss commented that scientists are not well rewarded and the IP system can provide sufficient rewards, Sulston rebutted him, saying that there are many rewards for scientists, including the joy of simply doing the research. He also added that when traditional knowledge is used in a profit-making manner, it is an injustice.

**Access to medicines**

At another session on "Patents and public health, including second use patents", following the panel presentations, there was a heated exchange between one of the speakers, Eric Noehrenberg, who represents the global drug industry, and William F Haddad, former chairman of the US generic trade association.

The other speaker on that panel, James Love, Director of the Consumer Project on Technology, said medicines are costly and unaffordable to many. The pharmaceutical companies seek maximum profit and use the patent system to raise prices. Using patents is a costly way to finance R&D, particularly for products that are new and better than existing products.

Thus, he proposed to separate the market for innovation from the market for products. He supported a bill in the US Congress (the Medical Innovation Prize Act of 2005) which provides generic producers non-voluntary authorizations to use any and all patents (and *sui generis* IP, such as rights in registration data) relevant to the manufacture and sale of all prescription medicines in the US market.

The bill provides for remuneration to the developers of new medicines through a medical innovation prize fund worth more than the current royalties from patents. This way, he said, the patent system would remain intact through product development and market approval, while at the same time there is no market exclusivity, thus allowing generic companies to compete freely.

He said that the prize payments would be awarded for the first 10 years that a product is on the market, based upon evidence of the incremental health benefits of the product. There would also be funding for global public-health priorities and for neglected diseases affecting the poor in developing countries.

He highlighted the benefits of competitive and decentralized sources of funds for R&D, diversity of approaches to R&D, and open source projects.

He noted a new paradigm emerging on a global framework for health R&D, in which every country is required to support medical R&D, the obligation would depend on the level of development, and purchases of medicines, public sector research, prize funds and so on would be allowed, to the degree that they stimulate R&D.

He added that the Executive Board of the World Health Organization (WHO) had agreed to forward to the World Health Assembly for debate a resolution on a new

"global framework on essential health research and development". This resolution is widely supported by many NGOs, scientists and governments.

Noehrenberg challenged Love, saying that there is no consensus on the WHO resolution and many parts are bracketed (indicating lack of agreement). To this, Love said that in any negotiation process, brackets are frequently found in a draft before it is finalized.

Noehrenberg, representing the International Federation of Pharmaceutical Manufacturers and Associations, remarked that "parallel trade" was bad for poor countries, and that compulsory licences do not result in health benefits.

He said the recent WTO amendment to the TRIPS Agreement to waive the limitation on exports of generic products to countries with insufficient manufacturing capacity was a solution that is easy to use. (This amendment has been criticized by health activists for being difficult to invoke and thus hampering access to affordable medicines in poor countries.)

Noehrenberg's basic premise was that the patent system works to bring about R&D and medicines into the market, and there should not be attempts to use the system's flexibilities (such as compulsory licensing) as this would remove the companies' incentives to innovate. He also claimed that these flexibilities in trade agreements were put there to facilitate "industrial policy" and not "health policy."

At question time, many participants challenged Noehrenberg's presentation, especially on his position that the use of flexibilities was not for health purposes.

Haddad asked Noehrenberg: "What planet have you been living on the last few years? Your statement is not only false but also misleading."

"I came to hear an intellectual debate," he said. Instead, what he heard was the same argument of the big drug companies made 30 years ago. "What I saw there was my country [referring to the US] demanding and threatening to go along with what PhRMA [the association of multinational drug corporations] wanted."

First there was the TRIPS Agreement, he said, and then "TRIPS-plus" policies (which go beyond the standards demanded by the TRIPS Agreement). And while this is going on, two-thirds of the world's population are being denied access to medicines, although affordable generic versions are available. He called Noehrenberg's presentation "rehashed trash" that lacked any intellectual content.

Another participant who appeared to be angered by Noehrenberg's presentation said that the forum was convened to discuss harmonization, but in the presentation, the flexibilities of the international trade agreements were not recognized (by the big drug companies).

She asked how many more resolutions it will take for the flexibilities that have been endorsed internationally to be respected, since along every step of the way, these flexibilities are being trampled on.

A Brazilian delegate asked Noehrenberg whether his constituents can state what industrial policy is and what health policy is. He asked whether Noehrenberg was advocating leaving out provisions relating to flexibilities in any future SPLT initiative and how this would relate legally to the flexibilities in the TRIPS Agreement and in the Paris Convention.

Noehrenberg insisted that he was presenting an academic argument. He agreed that there were flexibilities but the reality was that they do not have public-health benefits. To a question asking if he could provide examples of his claim that there was diversion of lower-priced medicines in developing countries to developed countries, he said that he could give examples of such diversion taking place in Senegal and Uganda. Haddad responded that the cases of diversion were simply untrue.

Love also replied to Noehrenberg's remarks on compulsory licensing, citing cases where compulsory licences are being used for health purposes. For example, many countries, including the US, have indicated that compulsory licences will be issued for the avian-flu drug Tamiflu, where the patent is a barrier.

**Software patents**

There were also other panels including on "Software patents", "Patents and standards", "Grace period" and "Scope of the patent system and alternative models to promote innovation".

The main issue in the panel on software patents was whether such patents should be granted at all. The US does grant such patents while in Europe debate is ongoing on this matter. This issue was also discussed in the panel on "Patents and standards".

Speakers such as Rishab Aiyer Ghosh, Senior Researcher at United Nations University-MERIT, and Jules Theeuwes from the University of Amsterdam, and some participants, felt that more work was needed to understand the issue, especially whether patenting would hinder the development of innovative products, before patents are granted for software products.

Views were also expressed that there are some features of software that make it different from other products, so it should be treated differently in relation to intellectual property rights. A participant said that this is a "vague area"; even in US patent offices there are divergences in perspective on this issue.

The panellists who appeared to be in favour of software patents were Jonathan Zuck, President of the Association for Competitive Technology, and Benoit Mueller from the Business Software Alliance (BSA).

Love said that there is a debate in the US on whether the software-patent system is too strong and there are also problems in managing disclosure. He added that the TRIPS Agreement does not allow discrimination between products in the application of the rules. He also asked whether it is a mistake to have a "one-size-fits-all" idea in the system.

# ANNEX

# The Impact on Patentability Criteria

*by Martin Khor*

DEVELOPING countries risk losing their present flexibility to decide on the standards for granting patents if developed countries' proposals for the SPLT are adopted.

This warning was given by an expert on intellectual property law in a paper distributed at the WIPO open forum.

Professor Carlos Correa of the University of Buenos Aires, who is a renowned authority on intellectual property and development issues, said the developed countries had proposed a uniform definition to key aspects determining the scope of patentability for the SPLT, which is being negotiated in WIPO.

Under the TRIPS Agreement of the WTO, member states are allowed to adopt their own definitions on all the concepts proposed for harmonization in the SPLT (i.e., definition of prior art, grace period, novelty and inventive step). Thus, the TRIPS Agreement provides the WTO members with flexibility to design their patent regimes.

However, if the developed countries' proposals for the SPLT are adopted, the harmonization of patent standards would eliminate the room that countries have retained to decide what an "invention" is and how the patentability standards are determined.

Correa was a speaker at the three-day WIPO open forum. His paper, "An Agenda for Patent Reform and Harmonization for Developing Countries", is available on the WIPO website, together with the papers of other speakers.

---

* This annex first appeared as an article in the *South-North Development Monitor* (*SUNS*), No. 5977, 2 March 2006.

Correa's paper gives an account of the patent harmonization process in WIPO (of which the SPLT negotiations are a major part) and analyzes its implications for developing countries.

According to the paper, the patent system contains serious distortions and there is a need for a "deep re-examination" of how it operates in different countries. Correa warned that the patent harmonization process under WIPO overlooks the problems of the system, nor is it intended to adapt the system to the needs of the developing countries.

"The harmonization process poses a significant challenge and creates a number of risks for developing countries," Correa said, adding that there are no convincing reasons for the developing countries to support the process if it proceeds further on the basis of the proposals of the major developed countries.

Correa also warned that it would be a great disservice to developing countries if they were induced through WIPO processes to import features of a patent regime that is growingly seen as malfunctioning in developed countries and often stifling rather than promoting innovation.

**WIPO Patent Agenda**

The paper recalled that in 2001, WIPO's Director-General Dr Kamil Idris launched a "Patent Agenda" whose main emphasis has been to facilitate the acquisition of patent protection in foreign countries by making the system more user-friendly, cost-effective and secure.

The main purpose of the Patent Agenda as set out by the WIPO Director-General is, therefore, to create mechanisms whereby inventors and industry have access to national, regional and international patent protection systems that enable them to obtain, maintain and enforce their patents globally.

"Development objectives are completely absent from the initiative," said Correa. "No assessment was provided about the benefits and costs of the proposed harmonization, particularly as it would eliminate the room that countries have retained to decide what an 'invention' is and how the patentability standards are determined.

"The proposed Agenda failed to acknowledge the major problems that the patent system currently [faces], as a result of the application of lax patentability criteria, the asymmetries in the ability to use it due to high enforcement costs, and the

disadvantages of patent policy harmonization for different levels of economic and technological development."

One component of the Patent Agenda is the development of an SPLT. As originally conceived in 2000, the SPLT was to have a wide agenda of issues. But due to resistance from developing countries and disagreement among developed countries on some provisions, the developed countries opted for a more gradual approach.

The US, Japan and the EU suggested (in what is known as the trilateral approach) that immediate discussions be limited to a narrow but important set of four issues: definition of prior art; grace period; novelty; and non-obviousness/inventive step.

"The issues suggested for this initial phase of harmonization are crucial. If agreed upon, they would provide a uniform definition to key aspects determining the scope of patentability," said Correa.

In order to push forward this proposal, WIPO's Director-General convened "informal consultations" concerning future sessions of the Standing Committee on the Law of Patents (SCP) in Casablanca in February 2005. Widely criticized for lack of transparency and the attempt to give undue weight to the outcome of the meeting, this process was unable to move the negotiations further. At the WIPO General Assembly held in September 2005, a compromise was reached to continue work at the SCP.

**Expanding patentability**

Correa said that the "trilateral proposal" aims at addressing key issues concerning the patentability standards. These concepts determine the extent of knowledge that may be detracted from the public domain and subject to exclusive rights for a minimum 20-year period. The TRIPS Agreement does allow members to adopt their own definitions on all these concepts, thereby providing members flexibility to design their patent regimes.

The paper examines the proposals on the four issues. On the first issue of prior art, the eventual harmonization of this concept would require agreement on a number of issues on which national laws differ, notably: non-written disclosures; secret prior commercial use or the offer for sale without disclosure; disclosures in prior patent applications; determination of the date of availability to the public; availability to the public; and indigenous/traditional knowledge.

On the issue of grace period, the application of a grace period (admitted in the US and in many other countries) has raised a significant controversy between the US and European countries, where such period is not provided for.

"It expands the scope for patenting, as inventions disclosed during that period would be eligible for protection, notwithstanding that they would have been deemed in the prior art in accordance with the general rule on novelty."

On the third issue of novelty, Correa said that the definition of "novelty" is crucial. Since the TRIPS Agreement allows members to adopt their own concept, the US, for instance, has been able to maintain its relative novelty standard with regard to the place where disclosures have taken place.

Novelty results from the comparison between the existing prior art at the date of filing (or the date of priority) and the claimed invention. In practice, the concept of novelty is narrowly construed by patent offices, requiring in some cases an almost "photographic" disclosure of the invention in a single prior document in order to consider that novelty does not exist.

On the fourth issue of non-obviousness/inventive step, Correa said defining this is one of the most critical aspects of a patent regime, as it determines the level of technical contribution required to obtain protection. As the TRIPS Agreement does not define this concept, member countries are free to determine whether they want a system under which a myriad of minor, incremental developments are patentable, or one aimed at rewarding substantive departures from the prior art.

The draft SPLT regulations proposed a low standard for determining inventive step. The claimed invention would be assessed against the general knowledge of an ordinary skilled person, and not against specialized knowledge in a particular field of technology.

"Developing countries will be made a great disservice if they were induced, through the WIPO patent harmonization process, technical assistance or other means, to import features of a patent regime that is growingly seen as malfunctioning in developed countries, and often stifling rather than promoting innovation," said Correa.

The decline in the patentability standards is one of the factors behind what has been described as the "intense pathology of the current [patent] system" in the US.

"The best policy for developing countries would rather be to establish high standards of inventive step, in order to avoid 'ever-greening' and other patenting strategies aimed at blocking genuine competition and follow-on innovation," said Correa.

["Ever-greening" consists of the patenting of minor changes to or versions of existing products (e.g., formulations, dosage forms, polymorphs, salts, etc.) in order to extend the life of the original patent over an active ingredient.]

For instance, the recent reform (2005) of the Indian patent law has incorporated an anti-ever-greening provision, which tightens the inventive-step requirement as applied to new forms or modifications of existing pharmaceutical products.

Correa said that developed countries are likely to pursue negotiations on a 'light' SPLT on the basis of the trilateral proposal.

"Quite clearly, it is not in the interest of developing countries to seek either a 'light' SPLT or a more comprehensive SPLT, since they have little to gain from a broader harmonization of substantive patent law," he said. "Developing countries should resist any attempt to limit their capacity to prevent the patenting of developments that do not constitute a real technical contribution to the state of the art."

If such countries wished to promote 'minor' innovations, the appropriate policy would not be to lower the patentability requirements, as is often argued, but to establish utility models (or "petty patents") that confer less extensive rights than patents or to explore other options, such as the recognition of a remuneration right rather than exclusionary rights.

In brief, developing countries should endeavour to keep the existing policy space to determine the level of the "inventive step".

If negotiations on the prior art and novelty concepts were pursued, developing countries should aim at the recognition of a universal novelty standard that does not discriminate on the basis of the place where non-written disclosures took place. Such a standard could prevent a significant part of the misappropriation of genetic resources and indigenous/traditional knowledge that currently occurs.

However, the change of the novelty standard may not be sufficient to prevent biopiracy if the evidentiary requirements for non-written disclosures made abroad are too complex or stringent, thus making the proof of the existence of prior art too

difficult or impossible. If this were the case, there would be little gain for developing countries.

In addition, the circumstances under which traditional knowledge may be deemed part of the prior art should be explored systematically and incorporated into the discussion. Developing countries should also incorporate into any possible negotiating text an obligation to disclose the origin of genetic materials and associated indigenous/traditional knowledge claimed in patent applications, as demanded by such countries within both the WTO and WIPO.

In addition to the disclosure-of-origin obligation, developing countries may seek to incorporate safeguards and other provisions that ensure sufficient flexibilities and a pro-development approach. In fact, those countries had already suggested in the SPLT process a number of such provisions, such as exception, public-interest exceptions and compliance with applicable law on other matters.

Correa suggested that other provisions may be worked on, including: (i) requirement of industrial applicability (as opposed to utility) based on a distinct technical effect of the invention; (ii) best mode as a uniform requirement; (iii) principles and objectives; (iv) transfer of technology; and (v) measures against anti-competitive practices.

**Risks of harmonization**

The paper concludes that "a deep re-examination of the patent system and how it operates in different contexts is called for. The system presents a number of serious distortions that affect its potential role in promoting innovation, particularly in developing countries.

"The harmonization process conducted for almost two decades under WIPO's auspices overlooks the problems and asymmetries of the system, and essentially aims at reducing the operational costs for users at a global scale. That process is certainly not intended to address the system's current shortcomings, nor adapting it to the needs of developing countries."

Correa added that the harmonization process poses a significant challenge and creates a number of risks for developing countries. While there are no convincing reasons for such countries to support the process, if it proceeds further on the basis of the trilateral or other proposals, three main issues should be considered.

Firstly, what objectives should developing countries pursue in responding to the harmonization demands of developed countries?

Developing countries should aim at the recognition of a universal novelty requirement and of a disclosure-of-origin obligation. They should also seek, inter alia, to clarify the treatment of indigenous/traditional knowledge as part of prior art. The ability to determine the required level of inventive step should not be negotiable; in particular, no proposals should be admitted that allow for a low inventive-step standard for the granting of patents. Developing countries should consider means alternative to patents to promote minor innovations, if suitable to their development needs.

Secondly, how feasible and practical do these proposals have to be in order to gain support from other stakeholders and to be successfully carried forward in international fora? Although developing countries should seek the elaboration of a scientifically based development assessment on the general implications of the proposed harmonization process, they should also elaborate concrete proposals on the issues put on the table by developed countries, as well as those that are of interest to developing countries, such as those mentioned above.

Thirdly, which could be the areas of the respective reform processes where coalitions could be built between developing and developed partners?

There are specific areas in which agreements with some developed countries may be reached. Thus, European countries are likely to support demands for a truly universal novelty requirement, while the US may support the consideration of prior patent applications as part of the prior art for both novelty and inventive step. Developing countries negotiating strategies should try to ably capitalize on the divergences that exist between developed countries in order to advance their own agenda in the process.

## Titles in the Intellectual Property Rights Series

1 Rethinking IPRs and the TRIPS Agreement *by Martin Khor (24 pages)*
2 TRIPS, Drugs and Public Health: Issues & Proposals *by TWN (52 pages)*
3 IPRs and Economic Development - Historical Lessons & Emerging Issues *by Ha-Joon Chang (40 pages)*
4 Patents and Development: Lessons Learnt from the Economic History of Switzerland *by Richard Gerster (32 pages)*
5 Biodiversity, Traditional Knowledge and Rights of Indigenous Peoples *by Victoria Tauli-Corpuz (48 pages)*
6 Compulsory Licensing: Models for State Practices in Developing Countries, Access to Medicine and Compliance with the WTO TRIPS Accord *by James Love (32 pages)*
7 Intellectual Property, Competition and Development *by Martin Khor (44 pages)*
8 Imports by and Exports to Countries with Insufficient or No Manufacturing Capacities in the Pharmaceutical Sector: Measures Required by the WTO Decision of 30 August 2003 in Relation to the TRIPS Agreement and Public Health *by TWN (40 pages)*
9 Malaysia's Experience in Increasing Access to Antiretroviral Drugs: Exercising the 'Government Use' Option *by Chee Yoke Ling (32 pages)*
10 Patents, Compulsory Licences and Access to Medicines: Some Recent Experiences *by Martin Khor (28 pages)*
11 The Substantive Patent Law Treaty: The Dangers of Global Patent Policy Harmonization *by Sangeeta Shashikant (40 pages)*

# THE SUBSTANTIVE PATENT LAW TREATY: THE DANGERS OF GLOBAL PATENT POLICY HARMONIZATION

Negotiations at the World Intellectual Property Organization (WIPO) to draw up a Substantive Patent Law Treaty (SPLT) have long been bogged down by differences among WIPO member states over the scope and orientation of the agreement. As part of efforts to break the negotiating deadlock, WIPO convened an open forum in Geneva on 1-3 March 2006 to discuss the major issues which lie at the heart of the debate surrounding the SPLT.

While the forum did not lead to a resolution of the impasse, the discussions that took place there shed light on the import and potential impacts of a treaty which would harmonize patent norms the world over.

In this compilation of articles on the WIPO forum, originally written for the *South-North Development Monitor* (*SUNS*), Sangeeta Shashikant reports that many of the participating experts cautioned against global harmonization of patent laws based on the loose patentability criteria and strict protection standards of the developed countries. If effected under an SPLT, such a move, it is feared, would "export a dysfunctional system to the rest of the world". These and other issues raised in the forum should be borne in mind in dealing with any attempts to revive the SPLT negotiations or to harmonize national patent regimes through other means.

**SANGEETA SHASHIKANT** *is a Legal Adviser to the Third World Network as well as the Coordinator of the TWN office in Geneva.*

**TWN INTELLECTUAL PROPERTY RIGHTS SERIES**

is a series of papers published by the Third World Network to provide a critical analysis of intellectual property rights protection from a Third World perspective. A particular focus is given to the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and its implications for developing countries.

ISBN 978-967-5412-01-1