Both provisions are well within the parameters of the TRIPS Agreement. Brazil came under tremendous pressure from the United States — which filed a complaint to the WTO which it later withdrew — first to drop the law and later not to use it. Although Brazil was able to successfully stand up to that pressure, smaller countries may have found the pressure too great and given in. Brazil has, however, not so far issued a compulsory licence to produce second-line ARVs, placing a potential strain on national AIDS funds, 't Hoen says.

> "Following the Doha Declaration, countries can legally set patents aside, but countries are hesitant to do so because they are afraid of provoking the anger of the United States. The political pressure is enormous."
>
> *Ellen 't Hoen, Director of Policy and Advocacy at Médecins Sans Frontières.*

Although existing provisions of the TRIPS Agreement permit the granting of compulsory licences to enable generic production of medicines, countries without domestic manufacturing capacity cannot use this flexibility. This is because TRIPS requires production under compulsory licence to be predominantly for the supply of the domestic market. In 2003, the WTO waived this export restriction and the decision is in the process of being made permanent. Under this waiver, countries that do not have their own drug manufacturing capability can issue a compulsory licence so that another country or company in another country can manufacture generic drugs for them.

However, organizations such as MSF have criticized the import mechanism for being unnecessarily cumbersome as it is based on a drug-by-drug, country-by-country and case-by-case decision-making process.

Under the waiver, potential exporting countries must amend their national laws to enable the production and export of generic medicines under compulsory licence. Canada, India, China and Norway have done this while the European Union is considering draft legislation. But so far not a single product has been delivered to a patient under these new rules and no single country has even notified the WTO of its intention to use the system as an importer. This may be because it is too complex and burdensome.

WTO Members recently agreed to convert this system into an amendment of the TRIPS Agreement. The amendment is expected to come into force in 2007, if two-thirds of WTO Members ratify it.

Oh says: "Perhaps countries don't fully understand the system yet. Also at the moment manufacturers in India are still producing drugs that are not under patent. But in two to three years time, most new drugs will come under patent. When this happens, the system may be critical in determining whether or not countries can have access to generic medicines." ■

Jacqui Wise, *Cape Town*

Rich and poor countries divided on patent treaty

Developing countries fear that a proposed treaty to harmonize patent laws globally could have a devastating impact on their access to essential medicines, diagnostics and vaccines. A passionate and fractious debate around the proposed treaty underscores the vital role of trade and intellectual property for public health.

Indian HIV/AIDS activists and an international lawyers' group lodged an objection in late March 2006 to a patent application for an AIDS drug filed by a multinational company in India, arguing the patent would restrict access to this medicine. The case illustrates the impact that global harmonization of patent law could have on public health in developing countries, as it could remove the legal basis for such objections in future.

Last year, India, an important global provider of cheap generic medicines to other developing nations, adopted a new law on patents to bring the country in line with the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

Under the new law, the Indian Government retained the right of its people or companies to oppose new applications for patents in India prior to approval by national patent offices. Now, groups fighting to improve access to medicines say proposals for global patent harmonization could strip national patent offices of this and other responsibilities.

The TRIPS Agreement established minimum standards for patents in WTO member states, but left room for each country to decide which patents to grant. In addition, TRIPS provided flexibilities, which were reinforced in the 2001 WTO Doha Ministerial Declaration, so that countries could escape some provisions in a public health emergency. Countries have barely used these flexibilities (see story on pp. 342–343) and now the work of another Geneva-based international body — the UN World Intellectual Property Organization (WIPO) threatens to eliminate them entirely.

Some TRIPS provisions were first proposed when WIPO started working on global patent harmonization in the 1980s. In 2000, some procedures for patent filing worldwide were streamlined under the WIPO Patent Law Treaty. Since then, the European Union, Japan and the United States have pushed for further harmonization by reviving WIPO's efforts to harmonize substantive aspects of patent processing, i.e. aspects that go beyond procedure. But most of WIPO's 183 members stand firmly opposed to this.

The primary vehicle for harmonization at WIPO is the proposed Substantive Patent Law Treaty (SPLT), which is being negotiated by the WIPO Standing Committee on the Law of Patents. But since it was first proposed in 2001, the SPLT has snagged year after year, partly because its chief promoters, the European Union, Japan and the United States — the "trilateral" countries — cannot agree, but also because developing countries see little advantage in proceeding with it.

Developing countries fear that the proposed treaty would mean less autonomy in national decision-making with regard to patents, loss of TRIPS flexibilities, and higher prices for medicines.

"Quite clearly, it is not in the interests 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," said Professor Carlos Correa, Director of the Centre for Interdisciplinary Studies on Industrial Property and Economics Law at the University of Buenos Aires.

Correa and Sisule Musungu, Acting Coordinator of the Programme on Innovation, Access to Knowledge and Intellectual Property at the Geneva-based South Centre, argue that harmonization will lead to a situation where the United States' definition of patent law is imposed on all countries. They have called for an assessment — governmental or independent — of the impact patent harmonization would have on developing countries.

Trilateral industry groups, meanwhile, are stepping up the pressure on WIPO to make progress towards harmonization. Phil Thorpe, Deputy Director of the United Kingdom Patent Office, warned that developing countries may lose influence in the debate if that debate moves outside WIPO, as some have suggested it should.

The trilateral proposal calls for discussions on four issues: the uses of a given innovation prior to patent application; possible patent protection when details about an invention have been disclosed before approval; how a product or an idea adds something new; and whether an innovation represents a step forward.

In addition, key developing countries have sought to include in these discussions talks on genetic resources, especially a requirement that the origin of the resources be disclosed in patent applications, and on protection of traditional knowledge (see story below).

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The impact of the proposed treaty on patent harmonization will depend on how it defines what may or may not be patented, or patentability, according to Professor Brook K. Baker of the Northeastern University School of Law. Baker said that developed countries with strong innovative pharmaceutical industries have increased the scope of what can be patented, broadening the definition of, for example, what is new. This has led to a "growing insistence on patents for new uses, new formulations, new combinations, and for minor, therapeutically *de minimus* changes in chemical structures," he said, referring to minimal changes that some argue should not be covered by separate patents at all.

Protecting traditional knowledge: the San and hoodia

The holders of traditional knowledge often face a dilemma. How can they benefit from their own traditional knowledge if they don't patent it?

Intellectual property rights are often regarded as incompatible with traditional knowledge because patents are based on innovations or discoveries and held exclusively, while traditional knowledge is collectively owned and based on prior use.

In 2003, the San indigenous people (Bushmen) and South Africa's state research institute the Council for Scientific and Industrial Research (CSIR) reached an agreement to share any royalties from potential sales of drugs or other products derived from the hoodia plant, *Hoodia gordonii*, which has long been known to the San as an appetite suppressor.

It was one of the first agreements to give the holders of traditional knowledge a share of the potential profits of products derived from that knowledge. A few years earlier the plant's active ingredient had been patented by CSIR and licensed for further development to a British company which in turn sold additional licences to Pfizer and later to food multinational Unilever. The San also signed a profit-sharing agreement with the South African Hoodia Growers (Pty) Ltd in February 2006.

The appetite suppressant was to be commercialized into a food supplement and/or prescription medicine, with considerable financial potential, but so far no products have been launched under the profit-sharing agreement. Recently lawyers representing the San filed complaints to the governments of Switzerland and Germany about hoodia products produced outside the agreement that were being sold in those countries. They said these sales were in contravention of international agreements on biodiversity. In a letter sent in March 2006, they asked that the obligations of the Biodiversity Convention be honoured and that countries take steps to stop the sale of unauthorized hoodia products.

The San live in a region that cuts a swathe across Angola, Botswana, Namibia and South Africa. They are one of southern Africa's most marginalized groups.

South Photographs/G. Williams

Petrus Vaalbooi, Chairperson of the South African San Council, sampling a piece of a hoodia plant in the Brosdoring area in the San communal land of the Kalahari Desert in South Africa, 2004.

Baker said that new chemical entities represented the only area where harmonization of patentability could have a positive impact on access to medicines, but that the standards of patentability currently under discussion in treaty negotiations "would have a negative impact on public health, because they would expand the scope and extend the time period of patent protections on pharmaceutical products". He added: "The predictable consequence is that prices will be higher and access lessened."

The March 2006 objection to the Indian patent filing was that there was nothing new in GlaxoSmithKline's fixed-dose combination of two existing HIV/AIDS drugs, zidovudine/lamivudine or AZT/3TC (Combivir), for which it was seeking a patent. Their argument: that the combination of two existing drugs — of which there are generic versions — is not an invention.

Ellen 't Hoen, Director of Policy and Advocacy at Médecins Sans Frontières, drew a link between the Indian case and the proposed treaty, as it shows the diversity in what may or may not be patented today. "If WIPO gets its way with harmonization there will be no diversity, meaning that a mistake in one patent office will not be corrected in another."

She gave the example of the way strict patentability requirements in Indian law allowed the Indian Patent Office to reject a patent application from Novartis for the anti-cancer drug Gleevec earlier this year, even though that patent had been granted in other countries. Following, opposition to the patent from a cancer patient association and generic companies, the Indian Patent Office rejected the application on the grounds that a new form of a known substance is not an invention.

But Louise Dunn, a spokesperson at GlaxoSmithKline, argued that the situation in India is evidence that patents are not a root cause for the lack of access to medicines.

"The root cause of developing countries' inability to address their health-care problems does not lie with the patenting system but with a lack of funding, a lack of political will, and inadequate health-care infrastructure," Dunn said, citing a common industry argument for inadequate access to medicines in developing countries.

The proposed treaty and its potential impact on public health remain highly controversial. A WIPO open forum on the proposed treaty in March 2006 showed that differences go deep and passions run high. Industry assertions similar to Dunn's were vigorously opposed at the forum, a meeting intended to feed the WIPO negotiating process.

Eric Noehrenberg, Director of International Trade and Market Policy at the International Federation of Pharmaceutical Manufacturers & Associations, told the WIPO forum that research and development-based industry is developing the best treatments for neglected diseases, that patents are not blocking access to essential medicines in poor countries, that compulsory licences are harmful to countries, and that the debate over flexibilities in international agreements is an "industrial policy" debate not a health policy debate. He said industry had endeavoured to provide much-needed medicines to poor countries, but has been blocked by the governments of those countries.

> "If WIPO gets its way with harmonization there will be no diversity, meaning that a mistake in one patent office will not be corrected in another."
>
> *Ellen 't Hoen of Médecins Sans Frontières.*

William Haddad, US generics industry leader and Chief Executive Officer of Biogenerics, called Noehrenberg's remarks "false and misleading".

"These are real crises, not patent pricing arguments," Haddad, a former US congressional aide, said: "We need real arguments". ■

William New,[a] *Geneva*

Meeting the need for treatment: the initiatives

How do you stimulate research and development (R&D) for new drugs, vaccines and diagnostics, for which there will never be a lucrative market?

Many diseases prevail because drugs are old and ineffective, or simply do not exist. Tuberculosis (TB) is a major killer in poor countries, but no new anti-TB drug has been developed since the 1960s. There are rare, often life-threatening diseases, defined in Europe as affecting fewer than one in 2000 people, for which more "orphan drugs" need to be developed. There are diseases that are highly prevalent, such as HIV/AIDS in southern Africa, but while new, effective medicines exist, millions of people and their governments cannot afford them or they are not available at all. Neglected tropical diseases, such as malaria, affect millions of people, but most are too poor to constitute a market that is lucrative enough to justify drug research and development (R&D) in industry terms.

Over the last decade, the world has recognized the problem and started to spend more on health research and product development for these diseases. There has been a flurry of initiatives to address the lack of treatment for people in developing and developed countries. Many of these are outlined by WHO's Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH), an independent panel of experts, in their final report: *Public Health, Innovation and Intellectual Property Rights* which was published on 3 April 2006 (see p. 351). For example, public–private partnerships have become a leading force in the development of drugs for neglected diseases; 46 such projects were in the pipeline in 2005, according to a Wellcome Trust report. The generic drugs industry provides cheap copies of brand-name

[a] William New is Editor-in-Chief of *Intellectual Property Watch*, a Geneva-based newsletter.