



## Know IP - Stockholm Network Monthly Bulletin on IPRS

### **European patenting of software-based inventions - Helen Disney & Meir P. Pugatch\***

After more than three years of deliberations, the EU is getting closer to allowing the patenting of software-based inventions.

The EU Competitiveness Council recently adopted a common position supporting the European Commission's directive on the patenting of computer-implemented inventions. This decision, though still awaiting a painful as well as uncertain approval by the European Parliament, takes the EU one step closer to America's technology-friendly Intellectual Property model. It is also possible that, perhaps for the first time, the EU's IP goals will be aligned with the Lisbon Strategy - aiming to make the EU the world's most competitive economy by 2010 - a goal which has yet to produce the anticipated outcomes.

Over the past few months, tons of words have been spilled over the damaging/beneficial effects of patenting computer and software-based technologies and on its implications for the European software industry. This debate, however, between supporters of Open Source and the Code nation, seems to produce more heat than substance.

A more detailed and less passionate analysis of the Commission's proposal of February 2002 suggests two things:

First, **the proposed directive is essentially about harmonization** - aiming to level the playing field of the EU patent system both at the regional and the national levels. Contrary to what has been perceived or portrayed

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in the media, the patenting of software-based inventions is common in Europe (though certainly less so than in the US). The European Patent Office (EPO) as well as national patent offices are allowed to grant patents to computer and software-implemented inventions. The major problem today is the significant gap within Europe concerning the interpretation and application of the conditions of patentability of these technologies (an invention may be patentable provided it is new, involves an inventive step and capable of industrial application). True, the proposed directive aims to harmonise European legislation in such a way that the patenting of computer and software-based inventions will be made both easier and wider in Europe. However, this upward harmonization reflects the EU's ambitions to maintain and improve its innovative position in the world.

Secondly, **the proposed directive does not aim to patent software, but rather to allow the patentability of computer and software-based inventions.** The term '*software patent*', which has now become the standard jargon, is completely mistaken. Rather, the Commission proposes to harmonize the patentability of a "computer-implemented invention", defined as any invention implemented on a computer or similar apparatus which is realised by a computer programme. **The main focus here is on the technical contribution to the state of the art of such inventions.** In other words, these inventions would be patentable subject to strict criteria that emphasise the added value of the invention.

The latest report of the High Level Group, chaired by Wim Kok, dated November 2004, on the Lisbon Agenda suggests that the EU has yet to achieve its intellectual property goals. The report states that "*the time has come for the Council to adopt the Community patent or drop it. Agreement should be reached on this*



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fundamentally important piece of legislation before or at the 2005 Spring European Council". The report adds: "most urgently, the EU should adopt the pending proposal on the patenting of computer-implemented inventions and, of course, the Community patent".

The EU must go ahead with proposed legislation if it wants be loyal to its own objectives.

### **EU, Australia and USA claim victory in a recent WTO GIs dispute - Christoph Spennemann\***

After the release on 15 March of a WTO panel report<sup>1</sup> opposing the EU as defendant against Australia and the USA as claimants, all three parties to the dispute have praised the WTO ruling as a confirmation of their respective positions.

The dispute concerned Australian and US claims about alleged inconsistencies of the EU's domestic system for the protection of geographical indications (GIs) for agricultural products and foodstuffs<sup>2</sup> with the WTO's Agreement on Trade-

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<sup>1</sup> *European Communities - Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs*, WT/DS174/R of 15 March 2005 (US complaint) and WT/DS290/R of 15 March 2005 (Australian complaint). Both complaints were essentially based on the same claims.

<sup>2</sup> EC Council Regulation (EEC) No. 2081/92 of 14 July 1992 as amended, Official Journal of the European Communities L 208 of 24 July 1992, p. 1 *et seq.* This regulation currently protects geographical names of over 600 agricultural products and foodstuffs, such as cheeses, fruits, meat and fish.

Related Aspects of Intellectual Property Rights (TRIPs Agreement).

GIs provide protection for names of products that derive their quality, reputation or other typical characteristics from their geographical origin. They may be protected through the ordinary trademark system, such as in the USA, or through a specific *sui generis* system, such as in the EU. T

The claims raised by Australia and the USA concerned mainly the TRIPs Agreement rules on national treatment and on the relationship between trademarks and GIs.<sup>3</sup>

### **The panel confirmed an infringement by the EU regulation of the national treatment obligation, but rejected an infringement of the TRIPs trademark provisions.**

As to national treatment, the TRIPs Agreement in its Article 3 requires each WTO Member to accord to the nationals of other Members treatment no less favourable than it accords to its own nationals with regard to the protection of intellectual property. Under the relevant EU regulation, geographical names of agricultural products or foodstuffs from non-EU countries may be registered as European GIs only if the third country provides protection equivalent to that available in the EU. This condition, which amounts to a material reciprocity requirement, in the view of the Panel sets up an "extra hurdle" for the registration of third-country GIs and thus constitutes less favourable treatment of third-country producers *vis-à-vis* EU-based producers.

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<sup>3</sup> Note that the complaints were also based on a number of other claims, in particular with respect to the TRIPs disciplines on most-favoured-nation treatment and minimum standards of GI protection. However, the Panel either rejected these claims or refused to examine them, exercising *judicial economy*.



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The Panel also found such "extra hurdles" for third-country producers with respect to the EU's procedures for application for GI registration, objection to such registration and the establishment of inspection structures for monitoring the quality of GI-protected goods. The requirement for the producer's home country government to participate in these procedures puts third-country producers at a disadvantage with respect to their EU counterparts, as non-EU governments have no obligation to actually establish comparable procedures, while EU-based producers under domestic law have the right to claim such action by their governments.

With respect to trademarks, the complainants considered the 1992 EU regulation to infringe the exclusive rights of trademark holders as provided under Article 16.1 of the TRIPS Agreement. According to this provision, the trademark owner essentially has the right to prevent others from using signs similar to or identical with his own sign, where such use would result in a likelihood of confusion. In the case of trademarks applied for or registered in good faith prior to the registration (or application for registration) of a similar GI, domestic EU law provides for the coexistence of the trademark and GI, except for cases where the trademark has a particular reputation or has been protected for some time. The issue at stake was whether providing for coexistence of both rights instead of according *priority* to the trademark would infringe the exclusive rights of the trademark holder under Article 16 of the TRIPS Agreement. As GIs are not particularly exempted under Article 16.1, the Panel found that the exclusive right of trademark holders may also be exercised against third party use of similar GIs. The EU system of coexistence of prior trademarks and similar GIs therefore infringes Article 16.1 of the TRIPS Agreement. However,

the Panel considered the EU system justified under the trademark exception clause of Article 17 of the TRIPS Agreement. In this context, the Panel observed that under the 1992 regulation, the regime of coexistence does not apply to *all* signs similar to the protected trademark. For instance, use of any non-registered linguistic versions of the protected GI may be prevented, provided there is likelihood of consumer confusion. The Panel, while stressing the need to construe Article 17 narrowly, considered this provision less restrictive than other exceptions under TRIPS in the areas of copyright, industrial designs and patent law.

**As a result of this judgment, the EU will have to facilitate the possibilities for third-country producers to register their products as European GIs.** This concerns in particular the equivalence requirement as discussed above.

On the other hand, the Panel endorsed the current EU system of coexistence of prior trademarks and similar GIs.

As neither Australia nor the USA have ever submitted an application for GI protection under the EU's 1992 regulation, the commercial impact of the ruling has been described as insignificant. On the other hand, the past inaction on the part of third-country producers may well be explained by the "extra hurdles" they have had to face under the relevant legislation.



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### **IP, Generics, and ARV Treatment – Ken Shadlen\***

An increasing number of people living with HIV/AIDS in the developing world are receiving treatment with antiretroviral drugs (ARVs). The WHO is working towards the goal of three million people receiving treatment by the end of 2005, with an eye towards further scaling up in the years to come. The emerging consensus is that expanding treatment is essential and feasible, and that with the mobilization of sufficient resources an ever-increasing number of people can receive ARV treatment.

This note addresses, briefly, the concern that as the demand for treatment increases, the world's ability to respond effectively may be limited. What has worked so far may not continue to work: more of the same may not be enough. This has to do with how contemporary changes in the global political economy of intellectual property (IP) may affect the future availability of affordable ARVs.

Pharmaceutical patents remain rare in most developing countries. The "least developed countries" have until 2016 to issue pharmaceutical patents; where patents are available, originator firms often chose not to bother patenting their drugs in a given country; and even where patents are available and sought, drugs that were already on the market prior to a country changing its patent laws typically cannot be patented. Thus, quite a number of drugs that are patented throughout the OECD are not patented in many of the least developing countries.

The limited extent of pharmaceutical patents in the developing world does

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not mean that patents are unimportant, but it does mean that we need to reconsider how patents can affect access to medicines. We ought not look not at IP and patenting across the board. After all, few developing countries have the economic and technological capacity to produce their own ARVs, regardless of the patent situation; they import their ARVs. Our attention should be directed toward IP in the more advanced developing (and also developed) countries with sophisticated pharmaceutical sectors – the exporters.

It is for this reason that so much attention has been paid to India's amended Patent Act, which now offers product patents on pharmaceuticals. Prior to 2005, India was the last country with an advanced pharmaceutical sector not to offer drug patents. Indian firms had served as the principal suppliers of affordable antiretrovirals (ARVs) to developing countries. Of the roughly 700,000 people in the developing world receiving antiretroviral therapy, for example, it is estimated that more than half of those are treated with generic ARVs produced in India. Furthermore, the subsequent competition encouraged brand-name producers to lower the prices of their patented drugs as well. Thus, India's IP system had contributed to the growth of a pharmaceutical sector whose active presence in the global ARV market greatly increases the feasibility of extending treatment to people living with HIV/AIDS in poor countries, directly, through the supply of affordable ARVs, and indirectly, by placing pressure on brand-name firms.

What happens now, as we move towards a world of full pharmaceutical patentability, i.e. where all new drugs can (and almost certainly will) be patented in all countries with production capacity?

WTO regulations allow generic drugs produced under compulsory license to



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be exported to countries with public health needs that their domestic manufacturing base cannot meet. A temporary waiver allowing this was agreed in August 2003, and a number of export-capable countries have since revised their patent laws. Canada was the first, the European Union is in the process of doing so, and India's amended Patent Act also permits compulsory licensing for export. But as numerous observers have cautioned, the waiver permitted by the WTO and the subsequent clauses introduced in national legislation are extraordinarily complex and are likely to be difficult to use in practice. Time will tell, though the challenges do appear daunting.

It would seem that the most critical issue is not the actual legality of exporting ARVs, but how changes in the global IP system may fundamentally transform the supply of subsequent generations of such drugs. In a nutshell, there may be few incentives for potential exporters to bother investing in the production of new ARVs.

Exporting generic drugs to poor countries is a low-margin activity. To the extent that IP rules raise the transaction costs to producing and exporting generics, they may encourage pharmaceutical firms in India (and elsewhere) to abandon this line of business. Note, for example, that India's generic exports mean much more to the world than they do to Indian pharmaceutical firms: while Indian generics account for roughly fifty percent of ARVs used in developing countries, that is roughly four to ten times the importance of these exports to the firms themselves, in terms of total sales. Or to put it another way, the developing world importers rely on Indian exporters much more than the exporters rely on demand throughout the developing world.

The new incentives faced by India's pharmaceutical firms may encourage

them to dedicate fewer and fewer resources toward producing and distributing generic ARVs in the years to come. Indian firms do lots of things besides producing generic ARVs for the developing world, and the asymmetry in this relationship is bound to intensify over time as the firms diversify in response to the new IP environment. Indeed, engendering such diversification away from production of specialised generics and towards off-patent generics and, ideally (but probably less likely) new innovative medicines are among the central objectives of the amended Patent Act. What this means for treatment, however, is that when new ARVs are introduced in coming years, drugs that will be essential as ARV resistance develops, there may be few firms that are legally, financially, and technically capable of producing generic versions for export. Developing countries and international organisations may demand these drugs, but one major source of supply may cease to exist.

Efforts to scale-up treatment of people with HIV/AIDS should not be affected immediately by India's amended Patent Act and the effective universality of pharmaceutical patenting. Indian firms can continue to produce and export the ARVs that are currently used throughout the developing world (this was a point of concern among many but was clarified in the final revisions to the amended Patent Act in March 2005). The dangers lie just over the horizon, for it will be much more difficult for Indian firms to produce and export generic versions of subsequent generations of ARVs; and few firms will retain economic and political stakes in doing so. This, in turn, could have serious ripple effects, for in the absence of competition from generics, brand-name firms face fewer incentives to lower their prices. The need for expanding the availability of affordable ARVs has never been greater, nor has the international



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community's commitment to doing so, but the challenges to widened and sustained treatment are significantly more complex than commonly believed.

### **Singapore's Commitment to a Stronger IP Regime: Are there lessons for other developing countries - Julius Sen\***

On January 15<sup>th</sup>, Singapore and the US signed a Free Trade Agreement that was and remains easily one of the most comprehensive FTAs of recent years, and represents in many respects the template for other FTAs negotiated by the US thereafter.

Its specific provisions relating to these rights, set out in chapter 16 of the agreement, push the process of deepening and widening IP commitments, at least insofar as Singapore is concerned, beyond TRIPS mandated levels.

Certainly for a developing country, this represents a major commitment to a knowledge-based development model.

The significance of this development has to be understood from three additional perspectives.

Firstly, Singapore really only started to develop its IP regime from the mid 1990s onwards and has effectively put in place a complete IP apparatus that now incorporates legal, institutional, organisational, and operational features comparable with some of the best in the developed world. It has therefore moved dramatically and credibly from a weak to a very strong IP regime in a very short period of time.

Secondly, the negotiations straddled the events of September 11<sup>th</sup>, 2001, and were seen by both sides as

emblematic of a larger political expression of solidarity. For Singapore it represented a statement of friendship and continued trust at a difficult time for the US, while for the US it represented a vital gesture from a troubled region at a troubled time.

And finally, from a US perspective it represented a major shift away from the multilateral process – an approach that America has rather badly threatened to pursue at various times.

But setting aside the political symbolism of the US-Singapore FTA for a moment, and focusing specifically on its provisions relating to intellectual property protection, the question remains of whether this gradual raising of IP standards and hardening of enforcement measures to significantly TRIPS plus levels will in fact achieve what the two governments hope and say it will. More particularly, will it achieve what the Singaporean side wants it to achieve in terms of acting as a stimulus to investment research, economic growth, thus creating the foundation for a knowledge-based economy?

It is clear, that Singapore considers IPRs as a strategic tool for increasing its competitive position in the global arena. However, while it would obviously be premature to assess results of Singapore's IP regime so soon into the process of implementation, it may perhaps be worth identifying certain yardsticks by which we could assess results in the years to come.

To be sure, this assessment would relate to the IP regime generally – that is for the TRIPS and TRIPS-plus level of commitments as they relate to Singapore – and would thus help provide some answers to a question that is of concern to many developing countries. The question is, does a stronger IP regime actually generate economic growth? And if so would it be equally true to say: the stronger the better? In this case the logic for

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Singapore's commitment to a TRIPS plus regime would be sound and consistent with its objectives.

Alternatively, is there an optimal level of IP protection that is appropriate, below which it would not work and above which it would be counterproductive, and what would this optimal level be (measured in economic terms)?

These are obviously a hugely complex set of issues to consider, but with reference to Singapore's specific situation arising out of its WTO and US-SFTA commitments in the IP sector and their choice of policies in pursuit and support of these commitments, some sort of assessment should be possible.

Firstly, is an assessment of aggregate costs of benefit to Singapore; that is how much has it actually cost Singapore to establish and enforce its IP regime, and how much economic activity does it generate?

Second is an assessment of the global business investment climate relating directly to research, and whether the policy framework provided by Singapore would work in attracting significant investment commitments from them in key areas?

Third is a comparative analysis – between Singapore and other (countries) seeking to compete in the global market

The significance of such findings would be enormously important not only for Singapore and other (countries), but also for international business interests and investors looking seriously at the research market. It would also answer many of the riddles posed by the incorporation of IP-related measures into trade agreements.