



Know IP - Stockholm Network Monthly Bulletin on IPRS

Commentary

Turn of the Tide or Big Pharmas Strike Back - Helen Disney & Meir P. Pugatch*

In the pharmaceutical industry, we are told, there are several undeniable truths, which transcend time and space. To mention a few: Research-based pharmaceutical companies are big (hence big pharmas) while generic pharmaceutical companies are small. Big pharmas are multinational in nature while generic companies are quite local. Big pharmas rely on exclusivity while generic companies do not. Innovative drugs are expensive, while their generic substitutes are not.

These in turn have led to some well known personifications of both research-based companies (the bad guys) and generic-based companies (the good guys).

But to the dismay of those who still wish to stick to the old "historical truths" about the pharmaceutical industry, things have changed in the last decade, quite dramatically! Indeed, one can even argue that the traditional business model of the industry has been turned on its head.

And the change, this time, is more significant in the generic end of the industry. For a start, generic companies are no longer local. In fact they are quite multinational; take for example, Teva, Ranbaxy and Dr. Reddy. Teva now has manufacturing facilities (not to mention a commercial presence) in the US, Canada, the EU and soon in Asia. And, like the big pharmas the bulk of the sales of the new multinational generic companies come from the most competitive

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market in the globe – the US. More than 60% of Teva's sales of \$US 5.25 billion in 2005 originated from the US and Canada (an additional 30% came from Europe).

But more importantly, and quite paradoxically, while becoming much more proactive in challenging the market exclusivity of research-based companies, multinational generic companies tend today to rely heavily on their own market exclusivity – the US-based 180 days of market exclusivity to be exact.

In the US, the Federal Food Drug and Cosmetic Act grants 180 days of marketing exclusivity to the first generic applicant who, in the course of submitting an abbreviated new drug application (i.e. generic application) to the Federal Drug Authority, is able to challenge the validity of the patent of the original drug. This arrangement is part of the Hatch-Waxman Amendments to the Drug Price Competition and Patent Term Restoration Act of 1984.¹

The 180 days of marketing exclusivity have become one of the most commercially significant periods for generic companies operating in the US. As noted by Teva: "(the) selling process of generic drugs typically decline, sometimes dramatically, as additional companies receive approvals for a given product and competition intensifies. **To the extent that we succeed in being the first to market a generic version of a significant product, and particularly if**

¹ For an overview of the 180-days exclusivity clause see: U.S. Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER). *Guidance for Industry 180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act, Procedural Guidance 5* (CDER: 1998), <http://www.fda.gov/cder/guidance/2576f.nl.pdf>;



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we obtain the 180-day period of market exclusivity provided under the Hatch-Waxman Act, our sales, profit and profitability can be substantially increased in the period following the introduction of such product and prior to a competitor's introduction of the equivalent product or the launch of an authorised generic"¹.

But the 180-days exclusivity period is currently being challenged. The war over the price of medicines and over their respective exclusivity has now moved into the generic playground. And big pharmas have decided (some would argue belatedly) to strike back.

It started with the so called 'authorised generics' phenomenon – that is a strategy by research-based companies (Pfizer, Merck and Eli Lilly) aimed at targeting the substantial prospective profits of a generic company that has been granted 180 days marketing exclusivity, by granting another 'friendly' generic company a license to produce a generic substitute for the original drug.

But now, things have moved to the next level. This month Merck signed an agreement with one of the leading US-based insurance providers (United Health) to provide one of its flagship medicines, Zocor (the anti-cholesterol blockbuster), which is about to lose its patent, at a price significantly lower than its first prospective generic substitute, Teva's Simvastatin. De facto, the 70 million US consumers insured by United Health would be able to buy Zocor at 10\$ a pack (compared with 25\$ before).

But if the battle between big pharmas and big generics leads to significant

price reductions for consumers, shouldn't we all rejoice? "No", says Senator Charles Schumer. The opposite is true.

Indeed, in his June 20th press release Senator Schumer called on the Federal Trade Commission to "Investigate anti-competitive arrangements that could devastate the market for all generic drugs", as well as asking health insurers not to accept the (Merck) deal.²

It is worth quoting some of the more sophisticated elements of his statement. First, the Senator argues that "this could close the door on future generics" and that "it's a desperate move to keep prices high and generics out of the market."

Secondly, he argues that "the big pharmaceutical companies are trying to deny tens of millions of families and seniors the cheaper generic drugs that they rely on so desperately".

And finally, and most importantly, Senator Schumer **explains that the deal is "intentionally designed to interfere with the 180-day exclusivity period that the first generic drug on the market relies on to recoup the costs of ensuring timely patent challenges and market entry."**

Exclusivity is needed to recoup costs on investments? Didn't we hear similar statements from big pharmas?

But we are probably wrong and the Senator is probably right. The facts are not important. What is important is to make sure that the old historical divisions will remain in place. Otherwise who will we have to blame?

¹. Teva 2005 Annual Report, page. 6
<http://www.tevapharm.com/pdf/12909ACL.PDF>

². Schumer reveals Merck offering payoffs to discourage health plans from using generic version of Zocor (20 June 2006),
http://www.senate.gov/~schumer/SchumerWebsite/pressroom/press_releases/2006/PR207.Zocor%20Generic%20Version.062006.html



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Topic of the Month

National IP Policy Making - Myth and Reality - Michael Blakeney*

A consequence of the broad impacts of IP is that a number of international and trans-national organisations and agencies are concerning themselves with this subject. Also involved are the national government ministries which typically liaise with those organisations.

An obvious consequence of the involvement of so many international organisations in the formulation of IP policy is the difficulty of securing consistency of approach in relation to common subjects. The diversity of organisations in different locations lends itself to this inconsistency.

For example, at the same time (November 2001) that the WTO was engaged in the Doha Trade Ministers' meeting, the UN Food and Agriculture Organisation (FAO), together with The Consultative Group on International Agricultural Research (CGIAR), was formulating a Treaty on Access to Genetic Resources for Food and Agriculture, the UN Conference of the Parties (COP) and the UN Environment Program (UNEP) were examining modalities governing access to genetic resources and benefit-sharing and WIPO was examining the same subject in the context of the negotiation of its Substantive Patent Law Treaty. Providing country representatives for all of these fora concerned with IP is a challenge for all countries. Invariably, for poorer countries which are distant from the places where the negotiations are

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occurring, the national representation may be undertaken by the local diplomatic representative.

National IP Policy in the UK

(a) The Patent Office

The difficulty of securing consistency in IP policy formulation at the international level is exacerbated by the difficulty of securing consistency in IP policy formulation at the national level. An illustration of these difficulties is provided by the UK. In the UK, a number of ministries and agencies have concerned themselves with IP policy. Additionally, the UK as an EU member is subject to the direction of the various Directorates General of the European Commission which have also assumed an IP policy role.

The website of the UK Patent Office¹ declares that: "The Patent Office is responsible for developing and carrying out UK policy on all aspects of intellectual property. The Intellectual Property & Innovation Directorate (IPID) deals with the policy for patents, copyright (and related rights), trade marks, designs and geographical indications of origin, and co-ordinates on issues affecting both copyright and industrial property matters."

Cognisant of the fact that Patent Office officials, who typically come from science or engineering backgrounds, cannot possibly represent the diversity of interests embraced by IP, the Office has established an Intellectual Property Advisory Committee (IPAC) as a "body formed to give high level independent advice to Government on intellectual property issues."

The first impression that one has is that the IPAC is a useful corrective to the

¹. <http://www.patent.gov.uk>



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potential technocratic narrowness of the Patent Office as an IP policy formulator. However, a review of the activities of IPAC identified a number of inadequacies in its contribution to policy formulation. Among the conclusions reached in the review were that IPAC had not adequately fulfilled its role and has largely disappointed the expectations of both its members and other stakeholders. This was attributable to a lack of clarity about IPAC's role and a lack of appreciation in Government departments about how IPAC might help them.

(b) Treasury-Gowers Review 2006

Given the amount of experience of the Patent Office in IP policy formulation and the effort which has been devoted to sorting out the advisory role of IPAC, it came as something of a surprise when the Chancellor of the Exchequer announced at the end of 2005, the appointment of Mr Andrew Gowers to conduct a review of IP in the UK.

On 23 February 2006 Mr Gowers wrote to "key contacts across a range of industry sectors, including scientific, high-tech, manufacturing, media and creative industries, as well as public sector and third sector bodies, relevant industry associations, inventors' bodies, consumer groups, experts in corporate finance and venture capital, the legal profession, and leading economists and other academics in the field" to submit "evidence" to the Review team. This paper observed that while it has been suggested that the present UK system strikes broadly the right balance between consumers and rights-holders, it also appears that there are a variety of practical issues with the existing framework. The scope of the review was identified as examining all elements of the IP system, to ensure that it delivers incentives while minimising inefficiency.

An obvious question about the Gowers Review is how it fits in with the existing UK IP policy arrangements, co-ordinated by the Patent Office. Obviously there is an overlap with the IP policy activities of the Patent Office. Indeed the letter of invitation inviting submissions to the Gowers Review acknowledges that "The Patent Office is currently consulting on two specific intellectual property issues: the inventive step requirement in UK patent law and practice; and the way UK trade mark applications are examined on the basis of their potential conflict with earlier trade marks."

By some alchemy which was not readily apparent, the Treasury has identified a number of "Friends of the Review", who have been invited to contribute their views on an informal basis. A number of UK academics were asked to make such contributions and this precipitated an open letter from over 40 academics, which questioned the time frame for the review, its scope, expertise and transparency.

(c) Department for International Development (DfID)- Commission on Intellectual Property Rights (CIPR)

A significant recent event in IP policy formulation by the UK Government was the establishment of the Commission on Intellectual Property Rights, which was set up on the initiative of Clare Short, the then Secretary of State for International Development "to look at how intellectual property rights might work better for poor people and developing countries."¹ The first Commission meeting was in London on the 8th-9th May 2001, and the final report was published on 12th September 2002.²

¹. <http://www.iprcommission.org/ome.html>

². *Integrating Intellectual Property Rights and Development Policy, Report of the Commission on Intellectual Property Rights,*



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According to the final report, the idea of the Commission on Intellectual Property Rights originated in the UK Government's White Paper on International Development Eliminating World Poverty: Making Globalisation Work for the Poor published in December 2000 (paragraphs 142-149). The aim was "...to look at the ways that intellectual property rules need to develop in the future in order to take greater account of the interests of developing countries and poor people."

The final report of the commission containing comprehensive analysis of the evidence and policy recommendations was published on 12th September 2002 and presented at a conference which it organised in Geneva. The Commission has since been disbanded and Clare Short has departed from the front line of UK politics. However, the enduring influence of the report is probably reflected in the adoption by WIPO of a development agenda and the agitation of developing countries within the TRIPS Council to 'operationalise' the development objectives of the TRIPS Agreement.

Policy Implications of the UK IP Policy Experience

Some conclusions which can be drawn from the UK experience in IP policy formulation are:

- The importance of inter-ministerial co-ordination
- Securing expert advice
- Identification and representation of stakeholder interests
- Access to stakeholder inputs – commerce and industry, Government, NGOs and civil society, IP professionals, universities, public

http://www.iprcommission.org/papers/world/final_report/

- Transparency of any policy review process.

IP Policy Formulation in the EU

The UK as a Member State of the EU is of course subject to the IP policy initiatives of the European Parliament and the European Commission. The European Commission is organised into 36 Directorates-General (DGs) and 'services' (such as the Legal Service). Each DG is responsible for a particular policy area and is headed by a Director-General who is answerable to one of the commissioners. It is the DGs that actually devise and draft the Commission's legislative proposals and technical co-operation activities. A number of the Directorates General of the European Commission are concerned with the intellectual property policy formulation and the foremost among these are: Internal Market and Services, Trade, Enterprise, Research, Information Society, Taxation and Customs Union and DG Enlargement.

(a) DG Internal Market and Services

The Internal Market DG focuses in particular on the 'knowledge-based' aspects of the Single Market. Its work is partly concerned with traditional instruments regulating the market, such as harmonising the laws of the Member States relating to industrial property rights to avoid barriers to trade. The aim is also to create unitary systems for the protection of such rights with Community-wide effect through the filing of one single application for protection (Community trade marks, designs and patents). The Internal Market DG is also increasingly concerned with ensuring that the Single Market functions properly in the Information Society and the fight against counterfeiting. DG Internal Market and Services as of November 2004 has the political responsibility for implementing the Lisbon Agenda to promote the European knowledge



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economy. In January 2005 the Commissioner announced a review of how copyright and related rights are being commercially exploited. On 16 January 2006 DG Internal Market and Trade launched a public consultation "on how future action in patent policy to create an EU-wide system of protection can best take account of stakeholders' needs". Interested stakeholders, including industry and individuals, were encouraged to reply to a questionnaire by 31 March 2006.¹ The feedback obtained from stakeholders formed the basis of a hearing, which the Commission organised in Brussels on 12 June 2006.

(b) DG Trade

DG Trade has responsibility, among other things, for devising and monitoring internal or external intellectual property policies in accordance with the trade policies of the EU. A key policy of the EU is to secure a better recognition and enforcement of intellectual property rights. DG Trade recently announced the *EU Strategy for Enforcement of IPR in Third Countries*. The Strategy seeks to: (i) identify priority countries: EU action will focus on the most problematic countries in terms of IPR violations (ii) awareness raising about the impact of counterfeiting; (iii) political dialogue, incentives and technical co-operation: ensuring that technical assistance provided to third countries focuses on IPR enforcement; provision of technical assistance; (iv) create of public-private partnerships.

Enterprise

The main objective of DG Enterprise is to assist potential and current contractors taking part in European Community funded research and technological development projects on intellectual property rights (IPR)

¹http://europa.eu.int/comm/internal_market/indprop/patent/consultation_en.htm

issues. The IPR-Helpdesk advises also on Community diffusion and protection rules and other issues relating to IPR in international research projects. Another more global objective of the action is to raise awareness of the European research community on IPR issues, emphasising their European dimension.

(c) Other DGs

DG Research promotes the research base for EU innovation.

The mission of DG Information Society is to support innovation and competitiveness in Europe through excellence in ICT research and development. It is concerned with the eEurope 2005 initiative, which seeks to promote the development of the underlying information society infrastructure and stimulate the supply of advanced services, notably via the public sector (eGovernment, eHealth and eLearning, as well as Digital Rights Management).

The role of DG Taxation and Customs Union (TAXUD) is to maintain and defend the Customs Union and to ensure the uniform application of the nomenclature and origin rules. With the border control obligations mandated by the TRIPS Agreement and by the EU Border Control Regulation, TAXUD plays an active role in assisting national Customs authorities to implement this legislation.

DG Enlargement is concerned with supervising the accession of new Member States. As part of the accession process applicant states contractually undertake to comply with the European IP *acquis communautaire*. This involves: (i) the introduction of compliant IP legislation; (ii) the establishment of appropriate administrative organs; (iii) the training of government officials, judges and lawyers; and (iv) IP awareness-raising in industry and among the public. These



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activities have the potential for a significant impact upon the IP policies which will be pursued by new EU states.

The Office for Harmonisation in the Internal Market (OHIM) has the task of registering Community Trade Marks and Community Designs. In this regard it has an indirect effect upon the EU's IP policy. Its registration policies can be questioned by the European Trade Marks and Designs Courts, which are actually national courts exercising a European jurisdiction. Of much greater significance in this regard, is the European Court of Justice, which deals with questions referred to it from the national courts.

EU IP Policy co-ordination

Formally, EU IP policy co-ordination could be achieved through the EU Parliament and Council of Ministers, through direct legislation (Regulations) or through indirect legislation (Directives). The existence of the various DGs with overlapping IP policies is probably an indication of the failure to achieve this. Informally some co-ordination could be achieved through the European Court of Justice.

Conclusion

The multi-faceted nature of IP and its diverse applications have resulted in a multiplicity of international, national and regional entities which involve themselves in IP policy formulation.

This makes consistency or effectiveness in policy formulation difficult to achieve. Co-ordination of national IP policy formulation by a body representative of the various stakeholders would seem to be a logical solution.

However, as the UK experience has illustrated, where the Patent Office was identified as such a body, it has

proven possible for powerful government Ministers to ignore its co-ordinating role and to duplicate its policy function.

A similar picture is identified in the EU where the various Directorates General compete with each other for the IP turf.

A number of developing countries have sought to centralise IP administration, such as Indonesia (Directorate General of Intellectual Property), Thailand (Department of Intellectual Property). This would seem to be a logical solution, but it may have to accommodate the vagaries of political influence.

Experts' Corner

Research Use of Patent Inventions: Experiences of the Swiss Patent Law Revision - Nikolaus Thumm*

Economists and lawyers believe that strong patent rights are beneficial for economic development. Over the last decade, however, some critical voices have expressed a concern that excessively strong and broad patent rights build up barriers to follow-up research and thus hinder innovation rather than promote it.

This question is of particular relevance for biotechnological inventions. It was one of the questions posed at the beginning of the patent law reform in Switzerland and it has been followed up very carefully over the last years.

Problems with too many patents

Patents are designed as an incentive

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mechanism for the creation of new, economically valuable knowledge and as a knowledge-dissemination mechanism helping to distribute innovations. Yet the significant increase of patent applications over the last decade, especially with new technologies, gave rise to fears that too much patenting could potentially block scientific development and build up barriers for research on patented inventions.

Concerns arose in particular about the following problems. First, the anti-commons problem describes a situation where the necessary knowledge to conduct further research is covered by a large number of patents from different firms (Heller/Eisenberg, 1998)¹. Second, patent thickets create a similar situation, where to actually commercialise a new technology, a company must hack its way through a dense web of overlapping intellectual property rights (Shapiro 2001)². In both situations transaction costs for contacting and coordinating all the different possible licenses were described as prohibitively high which results in licensing agreements not being concluded. Finally, both licensor and licensee could be hindered in pursuing their research and development in the patented technological field. Because of the huge number of patents being issued nowadays and the tendency to apply for multiple patents to cover one invention, hold-up problems are arising where a single product can potentially infringe many different patent rights. The stacking of royalties also can have

¹. Heller, M., Eisenberg, R., (1998). Can patents deter innovation? The anticommons in biomedical research. *Science* 280, 698–701

². Shapiro, C., (2001). Navigating the Patent Thicket. *Innovation Policy and the Economy*, <http://faculty.haas.berkeley.edu/shapiro/thicket.pdf>

an adverse effect on further investment in research and development.

These potentially problematic situations are one reason why the Swiss Federal Council requested the Swiss Federal Institute of Intellectual Property to investigate these problems in detail over the course of the patent law reform in Switzerland. In 2003, the institute provided two questionnaires, addressed to private and public biotechnology entities in Switzerland. A focus of this study was on the question of access to patented inventions in biotechnology and in particular on the access to genetic inventions.

The investigation (cf. Thumm, 2003)³ did not find a break-down or systematic abuse of the existing patent system for biotechnological inventions. The findings, however, confirmed that patents in their existing form are an important factor for innovation and that they provide an essential incentive for biotechnological inventions. The empirical investigations confirm that the concepts of anti-commons, patent thickets and royalty stacking are of practical relevance, even though their economic dimension and consequences are not very high. Respondents to the questionnaires perceived the phenomena of overly strong dependencies among patents, patents blocking entire technological fields and problems with overlapping patents only to a moderate degree (cf. Thumm, 2005)⁴.

³.Thumm, N., (2003). Research and Patenting in Biotechnology; A Survey in Switzerland. Swiss Federal Institute of Intellectual Property; <http://www.ige.ch/E/jurinfo/documents/j1005e.pdf>

⁴. Thumm, N. (2005) 'Patents for genetic inventions: a tool to promote technological advance or a limitation to upstream inventions', *Technovation, The International Journal of Technological Innovation and Entrepreneurship*, Vol 25/12 pp. 1410-1417



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A new statutory research exemption for Switzerland

In response to these findings, as a precautionary measure and in order to serve the interests of researchers in Switzerland, a new statutory research exemption has been included into the Swiss draft version of the new patent law.¹ It has been common praxis that acts of research did not constitute infringements of rights of patent holders. However, there has never been a court decision on the issue in Switzerland. The new formulation in Art 9 1. b of the revised version of the patent law foresees that the research on the object of the invention is exempted, even if it is commercially oriented. The general purpose of the regulation is to serve research and innovation and avoid negative influences of patenting on basic research.

The new research exemption furthermore includes clinical trials proving the effectiveness and effects of protected substances in drugs on humans. This includes trials with the purpose of getting approval with the responsible agencies of certain drugs. The commercial orientation of these activities does not prohibit the research. The production and storage of a patented substance is allowed as long as it serves the purpose of clinical trials and the drug approval in Switzerland. Whenever the production goes beyond a level that would be justified for clinical trials or drug approval, this is not covered any more under the research exemption. Nor is production and storage of substances before the expiry of the patent (stockpiling) allowed under the research exemption.

The exemption only covers research on the patented invention, where the

¹ Swiss patent law revision, information under <http://www.ige.ch/E/jurinfo/i100.shtm#a03>

patented invention is the object of the research. Not covered is the use of patented inventions as an instrument or tool of research (research tools).

However, in order to avoid monopolistic use of research tools and to provide access to patented research tools Art 9a gives the right of a non-exclusive license for patented inventions. Furthermore, this right to a legal license provides with a tool to avoid the abusive use of Material Transfer Agreements wherever they limit the access to and the use of biological material (reach through license).

Conclusion

Good intellectual property policy is not the same as maximal intellectual property rights. Too many patents or too strong patents may sometimes lead to hold-up situations, royalty stacking and other problems. In such cases the societal benefit of patents for innovation and economic growth is greatly reduced. To a certain degree, the provision of good quality patents can help to solve some of these problems. A correct and rigorous application of patentability criteria can help to reduce these risks and increases the quality of patents. Promoting collaborative mechanisms, such as patent pools, cross-licensing and patent consortia are another way to help patent owners to facilitate the exchange of patent rights.

The patent system as it stands today does not need overall re-organisation but rather continued fine-tuning on the basis of existing regulations. Finding the right balance between the interests of different stakeholders involved and the overall benefit for society is a difficult task. To provide a clearly defined and broad statutory research exemption is one way to clarify the situation in cases where access to patented inventions for pure research purposes is problematic.



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News Flashes

Top Stories in the World of IP and Competition – Anne Jensen*

Developing Countries Propose TRIPS Amendment

Earlier this month eight of the world's largest developing countries, including Brazil, India and China, proposed an amendment to the TRIPS Agreement that would require disclosure of origin of biological resources and traditional knowledge in patent applications.

For more information see www.ip-watch.org/weblog

Scandinavian Countries Threaten Apple

Apple Computer's successful iTunes online music store faced more problems earlier this month when consumer organisations in Norway, Sweden and Denmark issued a joint statement urging Apple to make downloaded songs usable on all digital music players or face exclusion from their markets.

For more information see www.ft.com/home/uk

Bill Gates Steps Down

Earlier this month Bill Gates, co-founder and president of Microsoft, and the world's richest man, unexpectedly announced that he will step down from his position at Microsoft to focus on his philanthropic work at the Bill and Melinda Gates Foundation.

For more information see www.guardian.co.uk

EU Proposes New Anti-trust Guidelines

Companies under investigation for anti-competitive behaviour could be

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fined 30% of their annual turnover under new European Union guidelines announced by Neelie Kroes, competition commissioner, earlier this month.

For more information see www.ft.com/home/uk

WIPO Development Agenda Struggles

As the members of the Provisional Committee on Proposals Related to a WIPO Development Agenda (PCDA) started their meeting in late June, it is becoming evident that the proposed development-oriented reform of WIPO is running into some difficulties due to divisions between the parties.

For more information see www.ip-watch.org

News and Events

Amigo Society Debate on IPRs and Competition Rules- 27th June, Brussels

On the 27th June 2006 the Stockholm Network and the Ludwig von Mises Institute Europe co-hosted an **Amigo Society Debate** at Hotel Amigo, Brussels, on the topic of intellectual property rights (IPRs) and competition rules in Europe.

Chaired by **Dr Meir Perez Pugatch**, Head of the Stockholm Network Intellectual Property and Competition Programme, the central theme of the debate was:

Intellectual Property Rights vs. Anti-trust: Is there a Sensible Middle Ground?

It is often stated that there is an inherent tension between supporting intellectual property rights on the one hand and using anti-trust rules on the other hand. And while anti-trust mechanisms may well be appropriate for combating anti-competitive and monopolistic practices in general, the use of these tools in the case of



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proprietary knowledge-based products is highly complex.

Speaking on these highly controversial issues were **Dr Duncan Curley**, who is Partner at the Intellectual Property Media and Technology division at McDermott Will & Emery UK LLP, and **Manuel Campolini**, who is Partner at Janson-Baugniet.

Dr Curley addressed the policy tension between IPRs and competition rules in the information technology sector, and argued that in recent years, the European Commission has taken a more interventionist stance in cases where it believes IPRs are being "abused". The classic example of this more hawkish approach to competition rules is the high-profile case where the European Commission decided Microsoft had violated Art 82 of the EC Treaty by refusing to supply interoperability information to its competitor, Sun Microsystems. The decision, which meant Microsoft was required to license its IP, including 3 patents, to its competitor, was highly controversial and is currently on appeal to the Court of First Instance.

Campolini then went on to discuss the tension between IPRs and anti-trust rules in another sector that relies profoundly on its IP; pharmaceuticals. This sector differs from most other sectors in 3 main ways, Campolini argued; it is regulated by price controls, it invests heavily in research and development (R&D) and it depends on enforceable IPRs.

As in the information technology sector, the EU competition authorities have also intervened. A prominent example illustrated by Campolini, was when the Commission fined AstraZeneca for abusing its dominant position and breaching Art 82 of the EC Treaty. The Commission argued that AstraZeneca's product Losec had a dominant position in the market, which was due to the company having misled several national patent offices. AstraZeneca announced later that it would not accept the €60 million fine, and appealed the decision.

Both the cases mentioned at the seminar, including other cases involving IPRs and anti-trust, have been controversial. It is therefore worth mentioning that an Article 82 policy review is underway, which outcome is likely to have huge consequences for anti-trust practices in the European Union. The Stockholm Network will continue to report on developments in this area over the coming months.