



Know IP - Stockholm Network Monthly Bulletin on IPRS

Commentary

Two Perspectives on IPRs and Multilateralism - Helen Disney & Meir P. Pugatch*

"Complacency and neglect led to the wrecking of the world trade talks, and the consequences could be disastrous" proclaimed *The Economist* (29 July 2006), when describing the final collapse on July 23rd of the WTO summit between six of its key members Australia, Brazil, the European Union, India, Japan and the United States.

Everyone seems to agree that the WTO is in a coma, and along with it the entire multilateral trading framework. The situation of the TRIPS Agreement, one of the WTO's more innovative and, yes, controversial elements is no different.

Yet this does not mean that the international regulation of IP systems world-wide is in deep freeze. Far from it. We have reported previously that the international regulation of IPRs is particularly fierce.¹ New IP issues are constantly being introduced and debated. But these are all taking place in bilateral negotiations, and mostly with the US and the EU as leaders. Which brings us to ask the following question – what will become of TRIPS? We present two perspectives.

The Doomsday Perspective: TRIPS, a failed test of history

Are intellectual property rights trade-related?

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1. Pugatch M.P. "the International Regulation of IPRs in a TRIPs and TRIPs plus World", *Journal of World Investment and Trade*, vol. 6:3 (July 2005), pp. 430-465

This question, although settled theoretically (they are!), still generates debate and controversy. The inclusion of the Agreement on Trade Related Aspects of Intellectual Property Rights) in the WTO, while effectively weakening the negotiating scope of the World Intellectual Property Organisation (WIPO), was doomed to fail.

Developed countries backed by IP holders, were overconfident and even naïve in thinking that a minimum standard, rule-based agreement such as TRIPS would be capable of levelling the IP playing field in developing countries.

They failed to predict the level of resistance by developing countries. Nor did they foresee that TRIPS would become a political scape-goat, not least for those countries that are unable or unwilling to deal with the most basic and fundamental health issues (which should come before any discussion on the linkage between patents and prices of medicines).

Developing countries were even more naïve in thinking that they could shape a more 'flexible' international IP framework (so called TRIPS flexibilities).

But the more developing countries insisted on a loose and non-obligatory interpretation of their TRIPS obligations, the more they found themselves dealing with much higher, precise and non-compromising IP demands at the bilateral level, *vis-à-vis* free trade agreements.

Thus, the multilateral level is, and should be, forsaken. Bilateral methods will prevail and the international IP system will be polarised – between those countries with very high IP standards and those countries with very low and even non-existing IP regimes.



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The Optimistic Perspective: TRIPS, the only hope for a North-South consensus?

Back to the basics. A multilateral framework provides the best chance for a win-win trading agenda. In it, IPRs are but one subject among many. Accordingly, IP issues can be negotiated either horizontally (i.e. linked to other trade issues), or vertically (IP issues from one field are negotiated in conjunction with IP issues from other fields), or both. That is the real greatness of the multilateral trading system and that is why, when results are secured, they are much more far-reaching as well as beneficial.

The claim that developing countries were ignorant of IPRs, or just bullied into committing to TRIPS is both factually incorrect and to some extent vain. Developing countries, such as Brazil, India and Argentina expressed their reservations about the TRIPS agreement as early as 1984. But they nevertheless agreed to commit to the 1991 Duncel Draft and to TRIPS because it was in their national interest to do so.¹

It is no secret that even some of the traditionally most sceptical developing countries, such as India, have experienced significant entrepreneurial developments which highlight the importance of IPRs to their economy. India's music, film and IT industries are probably the most vivid example of the benefits of copyright protection. Moreover, to the dismay of those who believe that IPRs should remain a North-North issue, many developing countries, including China, Singapore, Israel, Korea, Thailand, Chile, and the Czech Republic, consider IPRs to be an increasingly

important dimension in their tool-box of economic policies. Their use of IPRs is as affected by domestic considerations as it is by external pressures.

Therefore, the multilateral framework is the only way in which all countries, developed and developing, can cope together with the external and domestic pressures, as well as the static and dynamic challenges, in an age in which the knowledge economy is becoming more and more dominant.

Present realities and wishful thinking

TRIPS is not going to move forward, certainly not in the near future. This has nothing to do with the current disputes and disagreements that characterise the multilateral IP agenda. Rather, it has everything to do with the fact that the WTO is probably at its weakest moment.

Thus, from a realistic point of view, it seems that the bilateral track is going to be the primary tool through which the international regulation of IPRs is going to progress. Countries should be aware of this fact and prepare accordingly.

It would, however, be good, at least in our view, to wish that a sudden revival in the multilateral framework would also trigger a renewed interest in TRIPS. But should an opportunity of this kind presents itself, one can only hope that the lessons of the past be learned, and that a pragmatic and a no-nonsense approach will set the tone for future IP negotiations. But then again, we are realists after all.

¹. Stewart, P. T. ed. *GATT Uruguay Round - A Negotiating History (1986-1992)* (Boston: Kluwer, 1993), vol.3



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Topic of the Month

The Importance of Technology Transfer in Developing Countries - Jon Sandelin*

"A good idea not put into use is wasted." Such was the belief of the famous American inventor Thomas Edison, and he was right. Good ideas can come from anywhere and in any field. Agriculture, mining, manufacturing and so on can all benefit from new ideas. Frequently it is the result of seeking a better, more effective or efficient way to do something or achieve an objective. The process of taking a good idea and putting it into use is called technology transfer or technology commercialisation. It is important for all economies, but especially developing economies, to convert good ideas resulting from study or research or just plain intuition into new products and services. This provides for economic growth and job creation.

For technology transfer to be successful, there must be a process that is widely known and where policies and procedures are well documented and readily available. There are reference manuals that provide both descriptions of policies and procedures and with many sample documents. Two such reference manuals are the Association of University Technology Managers "Technology Transfer Practice Manual" (www.autm.net) and "Operations Manual for a Technology Transfer Organization" (www.techingroup.com).

The process includes an evaluation procedure to determine if the new idea has commercial merit, obtaining intellectual property protection if

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needed to protect risk, capital investment to develop the idea into products or services, a search process to find the person or company that will convert the idea into commercial products or services, a negotiation process to develop any legal documents (e.g., a license agreement to the intellectual property rights), and a monitoring system to ensure progress is made towards converting the idea into products or services.

Another factor in successful technology transfer is the active involvement of the creators of the idea in the technology transfer process. This involves expending time and energy and thus there must be a rationale, such as financial incentives, for them to agree to participate in the process. For the evaluation phase, the creators are expected to provide a detailed written description of the idea and how far developed it is. If a patent is to be sought to protect the idea, the creators are expected to work closely with a patent attorney in drafting the patent application and in subsequent patent prosecution. In the search phase, the creators are asked to identify people or companies they believe should be interested in their idea, and to host visits of potential developers of the idea. At Stanford University where I have worked most of my life, getting the support of busy professors is not easy. Thus we publicise the benefits of participating in the technology transfer process such as direct and indirect financial support. Creators receive one-third of net royalty income from the licensing of their idea, without a cap, so a few have received millions of dollars in added compensation. Licensed companies also sometimes provide research funding to the lab of the creators, ask the creators to serve as paid consultants or serve (for compensation) on advisory boards, and sometimes will hire graduating students.



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The technology transfer process is also aided if the suppliers and consumers of new ideas are already connected and in communication. For universities or government research laboratories, it is helpful if consulting work, industrial affiliate programs, interdisciplinary research work involving industry, and attendance at conferences where both academic and industry scientists are participating bring the academic people in direct contact with their industry colleagues. This exchange of information and viewpoints by itself can lead to important technology transfer.

If a developing country is just starting to consider strengthening its technology transfer processes, it should focus initially on universities and research laboratories where the generation of new knowledge is a mission of the institution. There should be an office with at least one person who can accept and evaluate new ideas (normally called invention disclosures) and who is authorised to seek intellectual property protection for ideas with good potential. This person will also be authorised to search for potential licensees and to negotiate agreements. There should also be an office (which could be within the same office) where research or collaboration agreements can be prepared with industry and where industry knows it can go if it is seeking a collaboration in a certain area. In certain cases, such as when just starting and the number of invention disclosures is low, one office may be tasked with accepting invention disclosures from a number of universities and research laboratories. An assessment should be made in each research institution as to areas of particular strength at that institution, especially as seen by industry, as these are areas with the best potential for generating ideas of interest to companies or to investors in start-up companies.

Technology transfer is important and if done correctly will, in the long term, lead to economic growth and job creation. But it requires committed funding, a long-term viewpoint, and much patience. Although a small number of ideas (e.g., computer software based products) can move quickly from the idea stage to the marketplace, others may take 10 to 15 years to reach large-scale usage. Committed long-term funding is needed to cover the costs of technology transfer offices, but also obtaining intellectual property protection and where necessary to develop ideas into working prototypes. Companies or investors will normally not spend any time evaluating an idea that is not proven to work.

It is also important to recognise that expensive patents may not be needed for successful technology transfer. At Stanford University, of the top 50 income earning ideas in the history of the Office of Technology Licensing, 30% were not patented. Two were Material Transfer Agreements where there was no intellectual property at all, and most of the rest were computer software-based products protected by copyright and sometimes supplemented by trademark protection.

For developing countries, where to start or what to do to move things forward? My suggestion is to think about this in the context of starting a new business. This requires preparing a business plan that identifies objectives, outlines the resources needed over a number of years, and defines an implementation plan. Then investors must be found. The most likely source of funding is regional and/or national governments, as these have the capacity for long-term funding and should have the foresight to see the value in regional economic development and improving standards of living. But the experience in the United States documents the reality



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that results will not occur in the short term, but will take many years. However, there is a body of knowledge and experience in places like the US and Europe that can provide guidelines and guidance to developing nations that can avoid mistakes and missteps. In the US the Association of University Technology Managers (AUTM) has a special very low cost membership option for people in developing countries that makes the resources of AUTM available. In Europe, organisations such as ProTon-Europe, the Association of Science and Technology Professionals (ASTP), and the Stockholm Network are sources of useful information on technology transfer practices and policies.

Experts' Corner

Anti-trust and Patent Settlement Investigations - Joseph P. Cook and David Monk*

On June 26, 2006, the US Supreme Court denied a request by the US Federal Trade Commission (FTC) to review a case against drug companies involved in the settlements of patent infringement suits.² The underlying patent suits, brought by Schering-Plough against two generic firms, Upsher-Smith and ESI Lederle, involved Schering's potassium chloride product, K-Dur. The basic facts in these patent suits are not unusual. Neither, perhaps, is the basic structure of the settlements between the parties. However, concerns at the FTC have led to investigations of several settlements of patent infringement suits.

In general, these patent settlement cases begin with a branded drug

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¹. *FTC V. Schering-Plough Corp*, 528 U.S. No. 05-273 (June 26, 2006) (cert. denied).

manufacturer filing suit against generic manufacturers that are seeking FDA approval to market a generic version of the branded drug. The generic manufacturers argue that no valid patents are infringed by their entry, and, therefore, they should be granted FDA approval before the expiration of the patent(s).

Generally, the FTC is concerned by settlements that include a negotiated entry date that is before the expiration of the patent, but not immediately, and an ancillary agreement by the branded manufacturer to pay the generic manufacturer some amount of money. The FTC is concerned that such settlement agreements are likely to have anticompetitive effects.

Many of these investigations have resulted in consent agreements with the FTC. In May 2000, Abbott Labs settled with the FTC over the drug Hytrin.³ In May 2001, Hoescht Marion Roussel settled with the FTC over the drug Cardizem CD.⁴ In April 2003, Bristol-Myers Squibb, settled with the FTC over three different drugs, BuSpar, Taxol and Platinol.⁵

The K-Dur case was different and perhaps not least of all because it was litigated to the fullest extent. The FTC filed suit on April 2, 2001, alleging that the parties' agreements to settle these suits, which included an agreed date of entry somewhere midway between the time of the dispute and the expiration of the patent, "were agreements not to compete that unreasonably restrained commerce."⁶

². "Overview of FTC Antitrust Actions in Pharmaceutical Services and Product," Health Care Services and Products Division, Bureau of Competition, Federal Trade Commission, April 2006, pp. 8-9.

⁴. *Ibid*, p. 8.

⁵. *Ibid*, p. 3.

⁶. "FTC Charges Schering-Plough over Allegedly Anticompetitive Agreements with Two Other Drug Manufacturers: Complaint



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The case went to trial and was heard by an administrative law judge (ALJ) at the FTC, who found in favour of the pharmaceutical companies. The ALJ determined that the FTC staff's claims required "a presumption that [the patent] was not valid or that Upsher-Smith's and ESI's products did not infringe [the patent]."¹ The court found that there was "no basis in law or fact to make that presumption."² Moreover, the court also found that the FTC staff had not met its burden of "proving the relevant product market or that Schering had maintained an illegal monopoly".³

A refusal to accept presumptions of validity and non-infringement meant that, at least according to the ALJ, such cases would require the FTC staff to try to prove such assertions and look at the merits of the underlying patent litigation.⁴ The Commissioners would

Alleges Illegal Payments to Delay Entry of Generic Products into the U.S. Market," US Federal Trade Commission, Press Release (April 2, 2001); In the Matter of Schering-Plough Corp., Upsher-Smith Corp., and American Home Products Corp., US Federal Trade Commission, Initial Decision, June 27, 2002, p. 2.

¹ Ibid., p. 4.

² Ibid., p. 4.

³ Ibid., p. 4.

⁴ Two recent court decisions help illustrate the unsurprising fact that a presumption that a branded manufacturer's patent is invalid will not always be consistent with the results of court rulings. On August 1, 2006, a U.S. District Court ruled in favor of Daiichi Pharmaceutical, finding its patent for Floxin Otic was not invalid; on August 2, 2006, the U.S. Court of Appeals for the Federal Circuit upheld an earlier decision affirming the validity of one of the patents on Pfizer's drug Lipitor. Daiichi Pharmaceutical Co., LTC and Daiichi Pharmaceutical Corporation v. Apotex, Inc. and Apotex Corp, Civ. No. 03-937, United States District Court for the District of New Jersey, Opinion, August 1, 2006. Pfizer, Inc, Pfizer Ireland Pharmaceuticals, Warner-Lambert Company, Warner Lambert Company LLC, and Warner Lambert Export, LTD v Ranbaxy Laboratories Limited

disagree with the ALJ on this point when the case was brought to them on appeal by the FTC staff. The Commission found that the ALJ had erred in finding that the underlying patent litigation had to be examined in order to determine whether the agreements were anticompetitive. More particularly, the Commission found that the payments from the patent holder to the alleged infringers that were included in those agreements "were likely to have anticompetitive effects because they delayed generic entry beyond the dates that would have been agreed upon in the absence of the payments."⁵

The Commission also found that the method of evaluating the likelihood of anticompetitive effects argued for by the ALJ, including the definition of a relevant market, was "not the most appropriate way to proceed... where more direct evidence of competitive effects is available."⁶

The defendants then appealed the case to the 11th Circuit Court of Appeals, which set aside the Commission's opinion.⁷ The 11th Circuit seemed to interpret the Commission as having effectively adopted a per se prohibition on "settlements under which the generic receives anything of value and agrees to defer its own research, development, production or sales activities."⁸ The 11th Circuit stated that "the proper analysis of antitrust

and Ranbaxy Pharmaceuticals, Incorporated, No. 06-1179 United States Court of Appeals for the Federal Circuit, decided August 2, 2006.

⁵ In the Matter of Schering-Plough Corp. et al. US Federal Trade Commission, Opinion of the Commission, December 8, 2003, pp. 6-7.

⁶ Ibid., p. 8.

⁷ Schering-Plough Corp. v. FTC, http://www.ca11.uscourts.gov/opinions/op_s/200410688.pdf (402 F.3d 1056 (11th Cir. 2005)).

⁸ Ibid., p. 11.



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liability requires an examination of: (1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceeded that scope; and (3) the resulting anticompetitive effects."¹

The 11th Circuit then went on to find "the terms of the settlement to be within the patent's exclusionary power."² In the end, the court based its decision, at least in part, on policy, saying that "[g]iven the costs of lawsuits to the parties, the public problems associated with overcrowded court dockets, and the correlative public and private benefits of settlements, we fear and reject a rule of law that would automatically invalidate any agreement where a patent-holding pharmaceutical manufacturer settles an infringement case by negotiating the generic's entry date, and, in an ancillary transaction, pays for other products licensed by the generic."³

As noted at the outset, the Supreme Court has refused to review this decision by the 11th Circuit. In so doing, it has let stand an opinion that is a rejection of a presumption against patent holders who may elect to settle infringement suits with negotiated entry dates and ancillary payments. Prior to its refusal to hear this case, the Supreme Court held in *Independent Ink* that there would no longer be a presumption of market power for patents in antitrust cases.⁴

Perhaps taken together these decisions reflect a desire by the Supreme Court to move away from overly simplistic rules that side-step a more careful analysis of all the relevant facts and circumstances—particularly in the intersection of the law and

¹. *Ibid.*, p. 11.

². *Ibid.*, p. 34.

³. *Ibid.*, p. 43.

⁴. *Illinois Tool Works, Inc. et al. v. Independent Ink, Inc.*, 547 U.S. ____ (2006).

policies of intellectual property and antitrust.

Notwithstanding the fact that the decisions of the 11th Circuit and Supreme Court did not go their way, the FTC is continuing its fight. Mylan Laboratories revealed in its July SEC quarterly filings that the FTC has sent a letter requesting information concerning a patent settlement related to modafinil.⁵ In addition, a revised patent settlement between Sanofi-Aventis and Bristol-Myers Squibb with Apotex concerning the blood thinner Plavix has failed to receive the necessary approval; moreover, the US Department of Justice has opened a criminal investigation.⁶

News Flashes

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

1) Kazaa, the world's biggest name in online music sharing, is to go legitimate by paying \$115m (£61m) compensation to the entertainment industry for aiding millions of illegal downloads over the past five years.

To read more go to *The Guardian*, www.guardian.co.uk

2) In a self-regulatory approach to software development, Microsoft has laid out a set of broad principles it said it would adhere to in the development of Windows in order to head off the risk of anti-trust action over its forthcoming Windows Vista operating system.

⁵. Mylan Laboratories Inc, Form 10-Q (July 28, 2006), p. 21.

⁶. "PLAVIX® Litigation Settlement Fails To Receive Antitrust Clearance From States Attorneys General" Bristol-Myers Squibb, Press Release (July 28, 2006).

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To read more go to *The Financial Times*, www.ft.com

3) Founder of the open source software Linux, Linus Torvalds, has expressed concern about the second draft of the General Public License (GPL) version 3. The initial draft prohibited any use of DRM technology: a move labelled "insane" by Torvalds. While the second draft incorporates DRM measures, critics still claim it fails to address important problems.

To read more go to www.linuxtoday.com

4) In a submission to the UK Treasury Gowers Review, the Creative Economy Forum, a part of the Royal Society of Arts, has called for the establishment of a new body to regulate intellectual property: the Office for Intellectual Property (OfIP). The OfIP would be a governmental structure that would replace the Patent Office and have explicit public responsibilities.

To read more go to www.adelphicharter.org

5) After the indefinite suspension of the WTO Doha Round of trade talks, many developing countries fear that the discussion on the relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD) will not go forward.

To read more go to *Intellectual Property Watch*, www.ip-watch.org

News and Events

Future Patent Policy in Europe- Public Hearing- Brussels, 12th July 2006

On 16 January this year the European Commission, DG Internal Market (DG MARKT), launched a consultation on future patent policy in Europe. The aim was to collect stakeholders' views on

the current patent system in Europe and how it could be improved.

The deadline for submitting replies was 12th April and when the public hearing took place in Brussels on 12th July, *Know IP* was there. Although DG MARKT was competing with wonderful weather that day, several hundred IP-interested people had found their way to the meeting, which lasted a good nine hours.

Chairing the event was Jacqueline Minor, Director, Knowledge Based Economy, DG MARKT. Minor introduced the hearing by declaring the consultation a success on the basis of the impressive number of 2515 replies they had received.

As a natural consequence of the issues at hand, certain countries and industries represented the majority of the submissions to the consultation. DG MARKT registered, for example, that 667 of the submissions were from individuals and companies in Germany, while new Member States such as Malta and Estonia had only submitted one response each to the consultation. Furthermore, companies were the most active stakeholders and represented 40% of the replies, followed by the open source & software developers' community, which counted 24% of all replies. Unsurprisingly, the IT sector was by far the most active industry, followed by the pharmaceutical industry. It is worth noting however, that the IT sector accounted for more than seven times as many responses as the pharmaceutical industry (http://ec.europa.eu/internal_market).

More than 40 attendees had been invited beforehand to speak for 5 minutes each on the issues most important to the group they represented. While these speakers represented companies and organisations which are influenced very differently by European patent



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policies, it became evident during the hearing that there was a certain consensus among them on which policies would best benefit Europe.

The need for increased patent harmonisation in Europe was emphasised by a majority of the speakers. Since the parties have failed to agree on the establishment of a Community Patent, despite more than 50 years of negotiations, the second-best alternative is the London Agreement. If ratified, the Agreement could cut patenting costs in Europe by 50% by easing the current translation requirements. Some speakers took this proposal even further by suggesting that a patent application in English only would be sufficient, based on the fact that English is already the *lingua franca* in science and technology.

Another widely raised concern was litigation. While industry and patent attorneys alike seemed to favour the European Patent Litigation Agreement (EPLA), there was great disparity on the exact details of the system such as the character of the EPLA court. Especially the SME community stressed the need for a local court of first instance, in order to secure proximity and accessibility of justice. To secure uniform interpretation of the law, on the other hand, both small and big industry supported a centralised Community and/or EPLA appeal court.

From an attendee's point of view it would therefore seem that most stakeholders agreed on what needed to be done to improve the current patent system in Europe and to increase the continent's competitiveness *vis-à-vis* its key competitors. This was at least the conclusion until the floor was opened up to interventions and a couple of representatives from the open source & software developer's community suggested their views had purposely been ignored throughout the whole consultation. This claim was rejected by the Chair, who argued that all stakeholders had been given a voice throughout the exchange.

Although *Know IP* doesn't necessarily see eye-to-eye with the views of the open source community, it was certainly refreshing to hear at least one dissenting voice during the nine-hour long consultation. If the consultation did represent all stakeholders' views and everyone agrees that Europe needs a Community Patent, that the London Agreement should be signed and the whole process of applying for and defending a patent should be less complicated and costly, why is this not happening already?