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Commentary

A Sisyphean tale of the European Community Patent? - Helen Disney & Meir P. Pugatch*

Anyone browsing through the website of the European Commission's Directorates General of Internal Market would be impressed by the wealth of information and data on the proposed Council Regulation on the Community Patent, (http://europa.eu.int/comm/internal_market/en/indprop/patent/index.htm).

The website has it all: Minutes, Q&As, draft proposals and revised drafts, press releases, green papers, and research papers. (If and when the EU finally adopts a Single Community Patent Regulation, DG Internal Market will have a particularly good reason to celebrate.)

Yet, a closer look at the website suggests that the Commission's first Green Paper on this issue dates as far back as 1997. More than 8 years have passed and the signs are definitely not encouraging. At this pace, the Lisbon Agenda's 10-year blueprint (2000-2010) would long be gone before a single Community Patent would be in place.

The European Commission has some very powerful reasons to insist on having a Community Patent.

First, it will save money - a lot of money. Today, patent protection in just eight European countries costs about €50,000, around five times as much as in the US or Japan. The Commission estimates that a Community Patent could cut these costs by half to about €25,000 for 25 Member States

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(although this would still be more than the US or Japan).

Secondly, a Community Patent would accelerate the pace of patent harmonisation within the Single Market. It would create, *inter alia*, a centralised fast-track system for patent applications (very much like the European Agency for Evaluation of Medicinal Products - EMEA).

Thirdly, a Community Patent could greatly improve the ability of SMEs to protect and exploit their patents cost-effectively.

And, last but not least, the creation of a central (and specialised) Community Patent Court will increase business transparency and certainty in the European patent system, particularly in the long run.

Yet, this is all very much in theory. For one, the Commission had to make some significant political compromises in the course of its considerable efforts to persuade the relevant institutional actors to reach a consensus on the subject. These in turn led to some serious problems with the current proposal.

Translation is one aspect that could undermine the entire economic rationale of the proposed Community Patent. The requirement to translate all patent claims into all EU languages creates excessive and burdensome costs, especially on SMEs.

The business community is also very concerned about the level of expertise and the detailed operability of the Community Patent Court.

Despite these efforts, the Competitive Council failed to agree on the proposed regulation on a Community Patent in March 2004, dealing a painful blow to the entire process. Unable (or unwilling) to hide his disappointment, then Commissioner Bolkestein argued that "I am



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disappointed that more than two years after the deadline was set by the Lisbon Council, and a whole year after the Council agreed the main principles, today's Council has still proved incapable of agreeing this crucially important initiative. European industry desperately needs access to pan-European patent protection at reasonable cost with minimum red-tape and maximum legal certainty"

A Community Patent is long overdue. Despite the failure of the Competitive Council to agree on the proposed Regulation in March 2004, the European Commission should not abandon its struggle. We can only hope that these will not become Sisyphian efforts.

Topic of the Month

The Entrepreneurial Function in Integrating New Knowledge for the New Technology-Based Firm - Geoff Gregson*

The shift towards knowledge-based industries identifies the critical role of new technology-based firms (NTBFs) in generating intellectual property (IP), transferring it to the market and contributing to regional and national economic prosperity.

NTBFs can be described as new firms established for the purpose of commercialising IP from new technologies for economic gain. The centrality of new knowledge in the NTBF as a source of economic gain and competitiveness also places the intellectual property system at centre stage of the knowledge economy. It is argued that the knowledge economy has affected how NTBFs generate new knowledge, with accelerated innovation and commercialisation of

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knowledge-based IP challenging an economic, social and legal system previously developed for industrial rather than knowledge-based exploitation of IP.

The 'entrepreneurial function' can be described as the capability to identify and integrate new novel combinations of technical knowledge with commercial knowledge that allow the NTBF to gain a market foothold and eventually generate profitable returns.

However, high failure rates of NTBFs have been identified with too much attention paid to technical knowledge, over-reliance on intellectual property rights (IPRs), inappropriate or weak business knowledge and poor understanding of the market. Although the IPR system creates a mechanism to resolve the 'appropriability' problem of new knowledge and its transferability to the market, early-stage IP may be 'premature' to benefit from an IPR.

In some cases, the cost of protecting its IP may be prohibitive for the NTBF. Since most NTBFs do not achieve an early 'home-run' high valuation from their IP, early survival and success in attracting private investment often depends on how well the entrepreneurial function integrates technical and commercial knowledge and develops new firm competencies.

The entrepreneurial function is necessary for sensing the market opportunity appropriate to the technology and IP, integrating relevant technical and commercial knowledge and generating new firm competencies.

As the NTBF develops, the entrepreneurial function may well develop *routines* from complementary knowledge that can be bundled as firm operations, such as product design, customer service and quality control, and generate more formal



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organisational structures, processes and incentives to manage and effectively utilise a growing knowledge base. If knowledge and the experiences generated within the firm remain personal and are not somehow shared, then the firm can at best expect to achieve a constant return to scale.

The entrepreneurial function includes the organisational 'amplification' of various sources of knowledge for internal and external use¹. The importance of the external environment to generating new knowledge and IP by the NTBF is suggested in regional and national systems of innovation perspectives, which emphasise how new capabilities of the firm will be affected by the level of engagement with local supporting institutions, business and industry networks, customers and competitors.

Successful NTBFs go beyond the 'basic' entrepreneurial function to reconfigure knowledge assets and generate new competencies and complementary assets to achieve a more sustainable presence and competitive advantage in the market. The notion of 'dynamic capabilities' suggests that entrepreneurs in successful NTBFs establish a framework from which new dynamic capabilities can be created and developed, allowing the firm to respond quickly and flexibly to changing conditions².

The notion of dynamic capabilities places emphasis on ongoing reconsideration and re-evaluation of NTBF competencies, as they accumulate over time and the need

to strategically adapt and reconfigure knowledge assets to match requirements of a changing internal and external environment³. The entrepreneur must consider, for example, changing market conditions that affect new knowledge acquisition, valuation of IP, pricing of products, market segmentation strategies and growth opportunities. The entrepreneur must also consider the effects of *untraded interdependencies* that take the form of conventions, informal rules, habits and routines being developed within the NTBF and between the NTBF and its external environment.

More research is needed to understand the underlying processes and decision-making activities that contribute to the success or failure of IP exploitation and knowledge management in the NTBF.

This includes the processes by which the entrepreneur identifies, secures and integrates new sources of 'appropriate' technical and commercial knowledge, how the external environment influences dynamic capabilities of the NTBF and the impact of the relevant IPR system on decisions to invent, disclose, commercialise, design-around and invest in IP and new knowledge assets.

¹ Nonaka, I. and Takeuchi, H. (1995) *The Knowledge-creating Company*. New York: Oxford University Press.

² Teece, D.J. (1998) "Capturing Value from Knowledge Assets: The New Economy, Markets for Know-How and Intangible Assets." *California Management Review* 40 (3): 55-79.

³ Teece (1998), Teece, D., Pisano, G. and Shuen, A. (1997) "Dynamic Capabilities and Strategic Management." *Strategic Management Journal* 18: 509-33.



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Book Review

Resource Book on TRIPs and Development, UNCTAD-ICTSD Project of IPRs and Sustainable Development (CUP: November 2004)

The inclusion of an agreement on trade related aspects of intellectual property rights (TRIPs) under the auspices of the World Trade Organisation was one of the most innovative and controversial elements of the multilateral trading system.

The TRIPs agreement represents a significant increase in the global level of intellectual property protection and is considered to be a 'revolution' in international intellectual property law

Nevertheless, the process of implementing the TRIPs agreement by developing countries and least developed countries is far from simple, particularly in the area of pharmaceuticals.

The debate over TRIPs implementation have become increasingly emotional, encompassing legal, commercial and social issues and even questions of ethics and morality.

It is in this context that the Resource Book on TRIPs and Development (Resource Book) is crucially important to those dealing with trade policies of intellectual property: academics, practitioners and especially policy-makers. More than anything, the Resource Book is a practical guide to the TRIPs Agreement.

Bringing contributions from experts in the field of IPRs, under the skillful guidance of UNCTAD-ICTSD Project on IPRS and Sustainable Development, the Resource Book provides background and technical information with two broad objectives in mind. First, to facilitate an informed participation by developing countries in the

ongoing negotiations on IPRs. Second, to assist countries (and especially developing countries) in the implementation and adoption of IPRs policies in the broad context of growth and development.

The main strength of the Resource Book is its wide intellectual appeal. Researchers will find the book to be an invaluable resource for any academic research (including the ability to use primary resources). To those interested in the legal aspects of TRIPs, the Resource Book provides a considerable amount of legal interpretation of TRIPs provisions, as well as linkage to jurisprudence.

Policy makers will find the book to be a practical manual for IP negotiations. To students, the book provides an easy entry point to the world of IPRs.

In terms of methodology, the Resource Book follows the structure of the TRIPs Agreement: (nature of obligations, principles and objectives, substantive rights, IPRs & competition, enforcement, dispute settlement, transitional arrangements).

In each part the Resource Book provides: a substantive analysis and interpretation of TRIPs provisions; in-depth information on the agreement's negotiating history; a summary of relevant jurisprudence cases; an analysis of the relationship between TRIPs provisions and other IP instruments, at the multilateral, regional and bilateral levels; and a summary of the latest IP developments associated with the TRIPs regime.

Of particular importance are the comments and analysis on the broader economic and social implications of the various TRIPs provisions. These allow the reader not only to understand the various elements of TRIPs at the technical level, but also to be able to place them in a broader policy context. Indeed, a must read book!



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Experts' Corner

Pharmaceuticals and IPRs in the EU: Evidence from Jurisprudence - Manuel Campolini*

The explosion of R&D expenditure coupled with the difficulty of launching new blockbuster products, is posing innovative pharmaceutical companies operating in Europe with new and additional challenges.

National authorities continue to implement cost containment plans—and to promote accelerated generic entry to reduce healthcare expenditures. However, as far as parallel trade is concerned, there have been some developments that are encouraging for the pharmaceutical industry.

European policy makers are relatively well aware of the crucial need for Europe to remain an attractive home for innovation, including in the sector of bioscience. In this difficult and mixed environment IP plays a crucial role.

Patent and Supplementary Protection Certificates (SPCs) - SPC is the European form of patent term restoration, which aims at compensating the time lost - between 8 to 12 years - between a patent being filed and the effective marketing of the medicinal product. SPCs combined with patent protection cannot exceed a maximum of 15 years from "the date of first authorisation to place the product on the market" in any member of the EU/EEA.

In Case C-127/00 Hassle, the European Court of Justice (ECJ) specified that

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this refers to the marketing approval granted by the registration authorities and not to the authorisation required under national legislation on pricing and reimbursement, which takes place later on. Should the ECJ have retained this last option, the effective protection of pharmaceutical products would have been substantially increased in many cases. In the Novartis case C-207/03, the question was to determine whether a Swiss approval, which automatically allows the sale of the product in Lichtenstein, could trigger the start of the 15 year period. Lichtenstein is a member of the EEA but Switzerland is not. Pharmaceutical products can be marketed in Lichtenstein when they benefit from a Lichtenstein approval based on a prior EU approval or from a Swiss marketing approval. The ECJ has recently decided that a Swiss approval recognised in Lichtenstein triggers the 15 year period, which is likely to have a negative impact in a number of cases, since Swiss approval is often granted before the first approval in EU/EEA member states. It results from the ECJ decision in case C-31/03, Pharmacia Italia that the granting of a first marketing approval for a veterinary product might trigger the start of the SPC in relation to a pharmaceutical product for human use.

Patents and commercial testing (Bolar)

- The recent introduction of EU legislation which permits a third party to conduct commercial tests and experiments on a patented medicine for the purpose of introducing a generic substitute (so called Bolar-type provisions) has also been the focal point of opposition between the innovative and the generic industries.

In 1997, the ECJ preliminary ruling in the case Generics v Smith Kline French Laboratories (C-316/95) considered the prohibition by national patent laws of the submission of samples for registration purposes before patent expiry compatible with EU law. In case



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of violation, the ECJ indicated that prohibition of marketing of the generic product for a period of up to fourteen months after patent expiry was acceptable. In 2004, the EU introduced a Bolar-type provision, which mainly reflects the evolution of case law trends in the various EU member states.

However, beyond the conduct by generic companies of bio-equivalence studies in the EU before patent/SPC expiry that are now expressly allowed, the EU provision also allows the conduct of any tests and clinical trials for registration purposes. These tests could be related to the development and the registration of a new indication, for instance, but also to the registration of a so-called bio-similar product, i.e. the registration of a generic copy of a biotech product, which requires much more data than a bio-equivalence study.

Data Exclusivity and related issues - A pharmaceutical company which wants to market a new medical product must submit a dossier of pre-clinical and clinical data which demonstrates the quality, safety and efficacy of its products to the regulator. These data are costly to generate and time consuming. Data Exclusivity is an IPR mandated by TRIPS Article 39.3. It relates to the period of time after which a generic company can register its copy product on the basis of an abridged application i.e. without submitting these data but by relying on the originator's registration dossier. Data Exclusivity is extremely important when there is no patent available or the existing patent is weak. In the EU, this period was previously 6 or 10 years after the first marketing approval of the originator's product in any EU member state.

In the landmark Generics case (C-368/96), the ECJ decided that 10/6 years after the first marketing approval

of the original product, generic products that are essentially similar could refer to the data supporting any further improvement (new indications, doses etc.) registered by the innovator later on. These data do not benefit from a protection on their own. The criteria of essential similarity were defined as follows: same active "principle"; same pharmaceutical form and bioequivalence.

In the Novartis case (C-106/01) similar questions emerged in relation to products that were not essentially similar. The ECJ basically ruled that the additional data to register an improved product that was not bioequivalent to another product of the same originator that uses the same active ingredient likewise did not benefit from any protection on their own.

The ECJ has also considered that after the expiry of the Data Exclusivity term, a generic product that is not bioequivalent to the reference one, due to the fact that it is administered by a different route or in different doses, could be approved on the basis of bridging data and no full dossier is required. In the APS case (C-36/03), the ECJ ruled that a generic abridged application can refer to an originator's product that is approved for less than [6 or] 10 years, provided that this latter is a new pharmaceutical form of another product of the same originator that has been approved for at least [6 or] 10 years.

The new EU pharmaceutical legislation adopted last year has largely confirmed and sometimes expanded the previous case law. It has, however, harmonised the data exclusivity period with an eight + two year system that could be extended to 11 years in the case of the registration by the innovator after the first marketing approval of a new important indication. The extension of the protection to 11 years addresses, at



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least in part, the problem underlined in the Generics case C-368/96.

Parallel trade - Huge pricing differences between the EU member states, due to the intervention of national authorities and price controls, have boosted parallel trade in pharmaceutical products.

Articles 28 and 30 of the Treaty of Rome generally prohibit national measures, which would impede the free movement of goods, including parallel trade. However, the Treaty allows member states to take measures to prevent parallel trade if they are justified "on grounds of the protection of health or the protection of industrial and commercial property".

With respect to patent law, as a tool to prevent parallel trade, the last important ECJ decision dates from 1996. The outcome was rather unsatisfactory from the innovative industry's standpoint, as the ECJ narrowly interpreted national derogation to the principle of free movement of patented products.

Concerning trademark rights, the ECJ has progressively refined its case law. Basically, the parallel trader can repackage, re-affix or replace the trademark of the originator's product when it is "objectively necessary", for example to comply with local rules.

The question of how and under what conditions a pharmaceutical company behaves in a way that prevents parallel trade but remains in conformity with the European competition rules emerged in the *Bayer-Adalat* cases. Bayer's stated objective was to prevent parallel trade. The Commission failed in its attempt to demonstrate that Bayer's unilateral conduct was an agreement imposed on the parallel traders that was contrary to Article 81 of the Treaty of Rome. Among others things, the ECJ

makes a distinction between an agreement prohibited by Article 81.1 and Bayer's unilateral policy brought into effect without the assistance or tacit acquiescence of the wholesalers, which was not contrary to EU competition law.

(Regarding unilateral conduct, the pending *Syfait v GSK* case, aims at determining whether a pharmaceutical company, which is in a dominant position with respect to a specific product, violates Article 82 of the Treaty by refusing to meet wholesalers' orders in full, to limit parallel trade.) In his recent opinion, the Advocate General considers that such refusal may be acceptable, particularly in the context of the unique characteristics of the pharmaceutical industry, i.e. the pervasive and diverse States' intervention in the pricing of pharmaceutical products, the negative consequences of parallel trade for pharmaceutical innovation and the absence of benefit for consumers. If confirmed by the Court, this would be a very positive signal given to the pharmaceutical industry in general and to innovation in particular.

Useful Reports, Articles and Links

United States Trade Representative (USTR) issues its Annual 301 Review

The United States Trade Representative (USTR) has issued its new "301 annual review" for 2005. The Report identifies **Priority Foreign Countries** - countries, which, according to the USTR, do not provide an adequate level of IP protection or enforcement.

The Report also places countries in two more categories: **Priority Watch List** - countries that do not provide an adequate level of IPR protection or enforcement, or market access for



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persons relying on IP protection, and **Watch List** - of countries with less severe IP inadequacies.

Section 301, particularly after its amendment by the Omnibus Trade and Competitiveness Act of 1988, allows the US to impose unilateral sanctions against countries that maintain acts, policies and practices in the field of intellectual property that violate or deny such rights from U.S. companies, or deny benefits under trade agreements, or that are unjustifiable, unreasonable or discriminatory in a manner that restricts U.S. commerce in the field of intellectual property.

The process of imposing sanctions against countries that were placed in the category of Priority Foreign Country is rather complicated, and is far from being automatic. The USTR, before retaliating against such a foreign country, is required to launch an investigation within 30 days in order to study the case or cases leading to that identification. WTO considerations and the dispute settlement procedures in particular, are also taken into account, before retaliation can occur.

Link to the report:
http://www.ustr.gov/Document_Library/Reports_Publications/2005/2005_Special_301/Section_Index.html

New IP Blog by the Intellectual Property Institute - www.IPBlog.org

The Intellectual Property Institute (IPI) has created a new IPBlog, covering news, notes and opinions on Intellectual property policies.

The purpose of the blog is to cover developments in intellectual property protection from a property-rights, pro-market orientation.

The IPI notes: " It is also our observation that intellectual property protection is

today under siege as never before. Hopefully, this blog will be a valued resource, making arguments in favour of intellectual property protection, and drawing attention to important work being done in this area".

April 2005 - the European Commission has released its new proposal for the European Research Framework Programme (FP7) for 2007-2013

On 6 April, the European Commission adopted a proposal for a new EU programme for Research.

The proposal provides new impetus to increase Europe's growth and competitiveness, recognising that knowledge is Europe's greatest resource.

According to the new proposal, FP7 will differ from the existing programme (FP6) by aiming to: (1) make FP7 simpler (a much needed change, but this remains to be seen) (2) become more flexible and adaptable to the needs of industry (3) establish for the first time a "European Research Council" (4) International co-operation will be integrated into all four programmes (very important to researchers from non-member and/or associated countries) (5) Developing of "regions of knowledge", bringing together research partners, and most importantly (6) Risk-Sharing Finance Facility", aimed at fostering private investment in research by improving access to European Investment Bank loans for large European research actions.

It is not clear yet what are the changes, if any, to the IP clauses of the different programmes of FP7

<http://europa.eu.int/rapid/pressReleasesAction.do?reference=MEMO/05/114&format=HTML&aged=0&language=EN&guiLanguage=en>