Commentary

Competition, Microsoft and the Old Lady at a Busy street - Helen Disney & Meir P. Pugatch*

Fans of the 'Benny Hill Show' are probably familiar with the concept of two or three 'gentlemen' trying to help an old lady cross a busy street, without ever asking her if this is actually her intention. When she objects, they force her to cross the street, extremely pleased to do their good deed for the day. And the old lady is left helpless, as all she wanted is to do was to rest before going in the opposite direction.

Likewise, it would be nice every once in a while to try and understand what the public wants before acting on their behalf. But do we? The European Commission, at least, seems to think it knows exactly what the public wants and needs. Which may explain why the ongoing arm-wrestle between the Commission and Microsoft seems so peculiar from an ordinary consumer's point of view.

In an age of catchy rhetoric, however, every power struggle is said to be taking place 'on behalf of consumers'. The latest legal exchanges between Microsoft and the Commission, surely meet this description. After all, what consumer wouldn't be interested in the thousands of pages of 'consumer friendly' debates on interoperability, source code, technical specifications,, internal architecture, functionality…the list goes on.

When Commissioner Neelie Kroes argued that she had "given Microsoft every opportunity to comply with its obligations", one would be tempted to ask which opportunities and, more importantly, which obligations are we talking about?

The European Commission recently argued that "one of the remedies imposed by the decision was for Microsoft to disclose complete and accurate interface documentation which would allow non-Microsoft work group servers to achieve full interoperability with Windows PCs and servers". For the Commission there are two major obligations with which Microsoft should comply: to give up its intellectual property – patents or any other type of proprietary technologies and know-how - and to hand this proprietary information (so-called interoperability information) to its competitors more or less on a silver platter.

But are we sure that sacrificing one company's intellectual property (be it Microsoft or any other company, perhaps even a more 'European' one) for another's commercial interest is ultimately good for consumers?

In fact, the debate over interoperability is secondary to a much more fundamental issue: the European Commission's decision to sacrifice one principle – the protection of intellectual property rights – over another principle – competition. Is that bad? Ultimately, everything boils down the question of monopoly – or more accurately, the tension between a 'bad monopoly' and 'good monopoly'.

A monopoly is a market condition in which there is only one provider of a certain article or a service. Economic theory concludes that a monopoly will sell a lower quantity of goods or services at a higher price than other firms would under purely competitive

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conditions. In other words, economists tell us that monopoly is usually bad for consumers. Since government authorities are alert to market monopolies, and in many cases justifiably so, they put in place legal and regulatory mechanisms (antitrust) aimed at increasing competition in the market.

However, while antitrust mechanisms may well be appropriate for combating anti-competitive and monopolistic practices in general, the use of these tools in the case of proprietary knowledge-based products is highly problematic. This is because the establishment of property rights in knowledge-products (such as software, medicines, processors) is based on a very different type of monopoly – intellectual property rights (what we may call a 'good monopoly').

Patents, copyrights, trademarks, trade secrets and other forms of intellectual property rights establish (time-delimited) exclusive ownership of varying types of knowledge. The monopoly deriving from intellectual property rights provides a powerful incentive for innovation by allowing inventors - both firms and individuals - to secure commercial returns for their work, thereby increasing their incentive to invest in future inventive activities. True, the market exclusivity that derives from the intellectual property system can sometimes restrict the rapid dissemination of existing knowledge products. The system of intellectual property rights has, therefore, a built-in tradeoff: the incentive to innovate and to create new knowledge for the future, in exchange for a temporary monopoly on this knowledge at present.

Intellectual property rights are probably the most unique form of monopoly legally protected by the regulator. As such, one should always strive to maintain a proper balance between the protection of intellectual property rights on one hand and competition-based rules, especially antitrust, on the other.
European practices in this area, are based on Article 82 of the EC Treaty, which prohibits companies from using their dominant (monopolistic) position in an abusive and non-competitive manner.

Arguably, in recent years the European Commission has been following a more active policy, which goes beyond the McGill Principle of 1995 (where it was decided that intellectual property rights were abused in such a way that prevented the introduction of a completely new product to the market). In the case of Microsoft, the European Commission has essentially forced it to release its intellectual property rights to its competitors, who were not seeking to design a new product or technology but are actually looking to provide *the same products* to consumers.

The issue here is not about sacrificing intellectual property rights for the noble cause of providing new products to consumers (that otherwise would not have been developed) but about the profits of competing companies.

Invoking anti-trust rules with regard to intellectual property rights should be limited to extreme cases, wherein such rights' existence blocks the market's ability to experiment with new ground-breaking technologies. Nevertheless, the European Commission is so entangled in its power games with Microsoft that it seems to be treating this entire policy dimension as merely a technical issue. Nothing could be further from the truth.

By adopting a hawkish position on the use of antitrust remedies over the protection of intellectual property rights, the European Commission is making a policy choice on behalf of

all the consumers in Europe. And, as with all policy choices, one must face the consequences.

Views

Technology Transfer in Europe – a Cause for Hope or a Cause for Concern? Cathy Garner*

Europe still falls short in turning Research and Development (R&D) results into commercial opportunities. This is the implication behind the recent proposal to create a European Institute of Technology (EIT)[1] and therefore surely points the blame towards those who are responsible for that translation. Since Europe is strong in fundamental research the problem must lie with those who "move" or transfer that technology to industry. Technology transfer in Europe is therefore a cause for concern. So might this article conclude if the issue were quite so simple. Unfortunately it is not.

Europe's competitive future is not going to be solved by improving the intermediation between publicly funded R&D and industry without many other interventions on both the demand and supply sides. It also requires a long-term culture change which alters not only the European attitude to risk but also addresses some of the structural weaknesses, which this author believes are in reality the causes of concern in developing commercial opportunities from the research base.

Technology transfer competencies in Europe have probably increased substantially in the last decade. The evidence is not actually available to substantiate such a claim. However, it is certainly the case that there are many more people involved in technology and knowledge transfer in universities and research institutes than ever before. Likewise there has been considerable investment in the delivery of training courses and the production of good practice guidelines, best practice toolkits and knowledge exchange and research about the subject of technology transfer. [2] In terms of the creation of a cadre of professionals capable of undertaking the processes of technology transfer it is probably fair to say that the movement has been in a positive direction. Why then the concern?

Concerns are not new, evidence of falling productivity in Europe in the 1990s[3] prompted the development of the Lisbon Agenda which set out to establish the EU as "the most dynamic and competitive knowledge-based economy in the world... by 2010." Central to that agenda was a commitment to increase investment in R&D with an ultimate aim of increasing the creation and diffusion of scientific, technological and intellectual capital. However, more than half –way to the Lisbon Agenda target, numerous high-level reviews and summits have concluded that on average Europe will not only fail to meet the aims of the Lisbon agenda but has lost ground to both the USA and to Asia.[4]

Is this a failure of technology transfer? Maybe, the hundreds of new technology transfer managers who have been employed across Europe to emulate the successes of the Bayh-Dole programme have not been as

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[1] Implementing the renewed partnership for growth and jobs, Developing a knowledge flagship: the European Institute of Technology, Commission of the European Communities, COM (2006) 77 final.

[2] Praxis, ProTon, ASTP, AUTM UNICO, AURIL.

[3] Kok Report "Facing the Challenge, The Lisbon Strategy for growth and employment, EC 2004.

[4] Ibid; Aho Group Report " Creating an Innovative Europe" EU, January 2006.

successful as was hoped – but it is actually too early to say. The major push to develop technology transfer came at the end of the 1990s – just as the stock market collapsed; the dotcom bubble burst, telecoms and silicon went through a downturn and venture capital investment retreated. This was a rather different environment and a rather shorter timescale than the 20-25 years of opportunity in the USA under Bayh-Dole. Evidence from the USA would suggest that it has taken 25 years for technology transfer to become established and be successful.

Should Europe therefore just be patient and all will come right? Once again, it is not that simple. The world is very different in 2006 than in 1980. We live in a fast-moving globally connected knowledge-based economy. We do not have 25 years to solve our competitiveness, to realise the fruits of R&D, to raise our productivity through innovation and the establishment of a few high-growth companies like Microsoft, Hewlett Packard or Cisco Systems. Europe needs to release its competitive edge now.

No amount of improvement in technology transfer can release Europe's innovation without interventions on both the supply and demand sides. I would argue that interventions should not be about new structures such as the EIT but rather about incentives and changes of approach. This assertion is based on the following observations.

First, there is new evidence which suggests that the European Paradox (Europe is good at research but poor at its commercialisation) may be wrongly focusing attention. In a recent article Dosi et al.[5] show that there is no generalised European leadership in all science. Europe tends to be less strong in biotechnology, ICT and the 'newer' knowledge based industries and stronger in low and medium technology areas. The European assumption of strength in R&D needs to be qualified by sector and therefore there should not be an expectation of universal technology transfer.

Second, strength in innovation is frequently measured in terms of patents filed. Patent filing comparisons with the USA and Japan show the European countries lagging far behind. However patent filing is NOT an indication of patent use – the huge growth in filing of patents in Japan has not been accompanied by a similar growth in patent licensing. What is important is industry use of inventions not the process of filing patents. A focus on increasing the number of patent filings will not necessarily increase either innovation or competitiveness.

Third, the very term 'technology transfer' implies a linear, one-way movement of technology from the research base to business and industry. The commercialisation of product is however more complex and crucially depends on the ability of firms to absorb new technologies and processes. The absorptive capacity of the business base is itself vital for the success of technology transfer. Whilst both the total expenditure on R&D and the research activity of large companies in Europe and the USA are broadly comparable, small and medium sized Enterprises (SMEs) in Europe undertake 7-8 times less research than their US counterparts. The difference between US and European SMEs is fundamental to the nature of the ability of such firms to absorb new technologies and to drive the development of innovative processes and products.

[5] Dosi, G.,Llerena, P. and Labini, M. "Evaluating and Comparing the innovation performance of the United States and the European Union", Trendchart Policy Workshop, 2005.

Research on European firms suggests areas where attention and incentives might be focused:

First, a significantly higher proportion of the chief executives or managing directors in the USA have degrees than in the UK (80% cf 52%).[6]

Second, firms in the US were also more likely to invest in product-design and in developing skills for production. Some 75% of large firms in the USA which have been founded since 1980 began as small enterprises. By contrast 80% of such firms in Europe are the result of mergers and acquisitions[7] indicating a very different trajectory for growth.

Third, firms in the USA use technology to drive their productivity much more in the USA than in Europe. It was therefore less the development of new products which drove growth in the late 1990s in the USA than the use of ICT to cut costs and drive efficiency.

While we might therefore conclude from a generalised understanding that Europe is less successful in commercialising from its research base than other countries and that ineffectual technology transfer could be to blame for a lack-lustre performance in innovation, the complexities of the real situation suggest otherwise.

Simplistic solutions or meaningless structural changes in technology transfer will do little to achieve the Lisbon agenda. Real change will come from a much more detailed and comprehensive understanding of the differences that prevail in the European system in comparison to that of the USA and Asia and the implementation of interventions that therefore offer an opportunity to make a real improvement.

What of the future? A number of emerging agendas give hope that Europe can stimulate an increased rate of innovation. The Aho report, however, points out bluntly that: "Europe must break out of structures and expectations established in the post-WWW2 era…This society, averse to risk and reluctant to change … is unsustainable in the fact of rising competition from other parts of the world"[8] The report proposes some radical changes which could stimulate activity on the demand-side of the market and provide supply-side incentives through public procurement – a tool that has proved positive and well founded in the USA through the SBIR and ATP programmes[9].

These actions complement the changing model which is emerging in those firms which already undertake R&D. Companies such as Procter and Gamble (P&G) are changing they way that they develop new products. They are moving away from direct licensing in of technologies (the model favoured under Bayh-Dole) and creating networks of innovators around the world.

For technology transfer in Europe, this means that the emphasis should not be in honing Bayh-Dole type licensing skills but rather in developing a class of skilled relationship managers who understand sufficient about the needs of universities and companies to be able to span the boundaries and to keep research and other relationships working well with those companies which already have the capacity to innovate. It is likely that 'softer' knowledge transfer mechanisms will be more encouraging of collaboration

[6] Cosh, A.,Hughes, A. and Lester, R. "International Innovation Benchmarking and Business-University Linkage", unpublished presentation CMI/MIT 2005.

[7] EARTO Discussion paper "Towards a Dedicated European Research Programme for SME's", undated.

[8] Aho Report

[9] Aho report

with research institutions than the hard transactional deal-focused approach of the late 1990s.

My hope is that technology transfer in Europe may have a greater chance for success under an 'open innovation' model than trying to emulate an approach which is both outdated and less appropriate for the prevailing approaches of the past. This hope is encouraged by the fact that the emergence of new models of innovation has already been recognised by a leading technology transfer organisation in Europe.[10]

Topic of the Month

Private Copies: One (Triple) Test to Rule Them All – Benjamin May*

Are anti-copy systems on discs and DVDs illegal? Not necessarily, answered the French Supreme Court on February 28, 2006, after applying the three step test.

Although the question itself and the absence of a clear-cut answer by the court may sound scary to the culture industry, one must recall that several member states acknowledge the 'private copy' system, i.e. a system under which the buyer of a disc or DVD may copy it freely for use in a private circle.

This is where the three step test is supposed to bring a balance between copyright and the rights of consumers.

1. The triple test in the EU Copyright Directive (EUCD): how to conciliate copyright and *droit d'auteur*[11]?

Basically, the three step test is a set of limitations over exceptions to the authors' exclusive rights. Following the work of the 1967 Stockholm Revision Conference, Article 9.2 of the Berne Convention first applied the test to the right of reproduction. Since then, the test has been extended to all exclusive rights and transplanted into the TRIPs Agreement (Article 13), and article 5.5 of the EUCD of May 22, 2001.

The triple-test admits limitations to copyright provided that such limitations:

I. Concern certain special cases;
II. do not conflict with a normal exploitation of the work;
III. do not unreasonably prejudice the legitimate interests of the right holder.

Admittedly, the three step test is inspired by an economic approach of copyright derived from the Anglo-Saxon system, which conflicts with the conception of continental *droit d'auteur*. In the copyright approach, it expects the courts to analyse on a case-by-case basis what constitutes 'fair use' of the rights. In the *droit d'auteur* culture, the Parliament has jurisdiction over a limited list of exceptions to the rights holders.

The Directive tries to conciliate the continental *droit d'auteur* together with the three step test. Article 5 provides for a limited list of exceptions (e.g. private copying, short quotation, etc.) which may be admitted under the condition they pass the three step test. The list of exceptions is however not compulsory and there is no obligation for the member states to

[10] ProTon Europe

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[11] "*Droit d'auteur*" in French, "*Derechos de autor*" in Spanish, "*Diritto d'autore*" in Italian, are the continental European equivalent of the Anglo-Saxon "*copyright*". For the purpose of this article, we oppose "*droit d'auteur*" to "*copyright*" when we want to stress differences between the two systems.

expressly refer to the test in their implementation.

This certainly explains why the test enjoyed different fortunes in the implementation of the Directive: the test is not expressly imported in national German, Danish, Italian and Dutch laws; Greece and Spain decided on the contrary to refer to it. In France, the Parliament voted a draft law on March 21, 2006 (still to be examined by the Senate), which provides expressly for two steps of the test – the 'special case' step being oddly omitted.

The most spectacular consequence of this poor level of harmonisation concerns the private copying exception.

2. The triple test in practice: how to conciliate copyright and private copy?

Admitting private copying without restriction would lead to uncontrolled spread of copies competing with 'normal' exploitation of the works, thus threatening the cultural industries. This is where the triple test is supposed to provide safeguards.

Some claimed however that anti-copy systems conflicted with the 'right' of private copy, therefore were to be forbidden. The '*Mulholland Drive* case' in France offered a good perspective on the chaos.

The facts in brief: an anti-copy system prevented a consumer from making a copy of a legally bought DVD of *Mulholland Drive*. Arguing that he had a so-called 'right to make private copies', the consumer sued the film producer and distributor.

In this landmark case, the French Supreme Court did not rule in favour of either party. It simply cancelled the judgement of the Appeal court (which had accepted the principle of 'private copying' without limitations, thus declared illegal anti-copy systems) on the ground that it did not apply the triple test. It is now up to a second Appeal court to handle the case and to decide whether, after applying the triple test, anti-copy systems shall be held illegal.

What is at stake in the French Supreme Court ruling is that for the first time, it expressly refers to the triple test, although not providing guidelines on how to apply it. Also, the Court confirmed that private copy was an exception rather than a 'right' and that such exception was to be confined into economic considerations and risks on the industry in the digital environment – i.e. the three steps of the test.

There are few precedents which could help courts to interpret the test. The main sources of information hitherto come from WIPO's studies[12] related to copyright in the information age. So far, only one case actually required an interpretation of the test in respect of the TRIPs Agreement[13].

European countries have legislated on this in very disparate ways. Some of them did not take into account the new digital environment and maintained unchanged their rules relating to private copy (Italy). Other countries such as Germany and Austria firmly restrained the scope of this exception and legalised anti-copy systems. The UK sticks to its copyright system letting the judge to decide for the fairness of the private copying exception.

[12] Limitations and exceptions under the three step test (R. Knights, August 29, 2000); WIPO study on limitations and exceptions on copyright and related right in the digital environment (S. Ricketson, April 5, 2003)
[13] A WTO dispute settlement panel has tried a case involving the EU and the United States over an exception to copyright in US law (WTO panel report June 15, 2000 WT/DS160/R).

One does not need to be a cynic to say that the implementation of the Directive in France led to extreme confusion. After a heated discussion among MPs, the draft law glumly proclaims "the right to benefit from the private copying exception" (right to exception?) and concomitantly legitimates the 'TPM' (technical protection measures) that obstruct prohibited uses.

It is difficult to foresee a happy future for the culture industry in Europe without anti-copy systems. The challenge is now to reach a level of harmonisation between the member states. No doubt the Directive will need serious updating.

Expert's Corner

Innovations, Patent Extensions and Combination (Pharmaceutical) Products - Manuel Campolini*

SPC (Supplementary Protection Certificate) is an IP right which allows the extension – up to 5 years - of the patent protection for a pharmaceutical product in Europe. It is an important legal tool that promotes biomedical research in the European Union. Many other countries (US, Japan, Australia, Switzerland) also have an equivalent mechanism in place.

An SPC can only be granted on the basis of an existing and valid patent!

In most cases, pharmaceutical products include one active substance to treat a disease. However, there are an increasing number of pharmaceutical products that combine two – or more – active ingredients, each of them having its own therapeutic effect. Their combination could result in an improved or even completely new therapeutic effect. These 'cocktail drugs', which often require extensive research and clinical trials, are routinely defined as 'combination products'. Some combination products are already available to patients, while other are currently in development and clinical trials.

Provided that the protection criteria are met, a combination product can benefit from patent protection and SPC. Also, the European Commission has recently confirmed that the pre-clinical and clinical data specifically collected to demonstrate the safety and efficacy of a new combination product should enjoy the full 10-years period of data and market exclusivity provided in Europe (the so called 8+2+1 formula).

However, a new and very important issue was recently raised in the EU context: could a new formulation resulting from the combination of an off-patent active ingredient, and a patented substance that has no therapeutic effect on its own (excipient), benefit from an SPC?

The Massachusetts Institute of Technology (MIT) is the holder of a European patent covering a substance called polifeprosan, (developed to provide a biodegradable matrix for use in biomedical applications, in particular for the controlled release of active substances *in vivo*). Polifeprosan is not an active substance and could be defined as an excipient.

Gliadel 7.7mg Implant is a medicinal product that integrates this MIT technology. It is a new formulation of the off-patent active ingredient carmustine, combined with polifeprosan, which is intended to treat recurrent brain cancers. The combination of polifeprosan with carmustine allows the controlled

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release of this latter active ingredient at higher but still constant doses. Gliadel therefore substantially improves the therapeutic effect of carmustine, and the life expectancy of patients.

On the basis of its patent, the MIT applied to the UK, French and German Patent Offices for an SPC for Gliadel. The German Patent Office considered that an SPC could not be granted for Gliadel. In its opinion, the combination of carmustine and polifeprosan could not be considered as a combination product within the meaning of the SPC Regulation 1768/92 because polifeprosan is not an active substance having its own therapeutic effects. MIT lodged an appeal against this decision and finally, the competent German Court asked the European Court of Justice (ECJ) for a preliminary ruling (Case C-431/04 MIT).

The Advocate General Léger has now rendered an opinion. He refers to the objectives of Regulation 1768/92, which require sufficient protection to be granted to innovations that also provide an increased therapeutic efficacy. He says that "the combination at stake represents a major innovation, resulting from long, costly research, which the regulation is precisely seeking to protect". The absence of an SPC "would be likely to discourage research centres located in the Member States from investing in the development of medicinal combinations such as the one at stake".

Based on these policy considerations, the Advocate General considers that Regulation 1768/92 "does not preclude the granting of an [SPC]" for the benefit of such a combination, provided that the pharmaceutical product is subject to a marketing authorisation, benefits from a basic patent and constitutes a therapeutic innovation whose development is encouraged by Regulation 1768/92.

As regards the condition of 'therapeutic innovation', the Advocate General indicated on one hand that an SPC 'cannot be granted every time the characteristics of a medicinal combination are slightly modified'. On the other hand, the Advocate General also included in his opinion a contradictory statement, that "it is … the necessity of the excipient to the therapeutic efficacy of the active ingredient that must be the determining factor in ascertaining whether a combination of these two substances is covered by 'combination of active ingredients of a medicinal product'." This latter technical criterion appears more appropriate and logical than the one based on a so-called therapeutic innovation.

The decision of the European Court of Justice is expected in the coming weeks and is likely to impact on investments in biopharmaceutical research conducted in Europe.