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## **Intellectual Property vs. Anti-Trust Rules: Is There a Middle Ground?**

### **Meir Pugatch, Chair:**

We are grateful to have such a big audience today, despite the World Cup! You may have seen today's newspaper headlines about Microsoft facing a daily fine of € 2 million, so we are at least engaging in an interesting topic, although perhaps not as interesting as the Brazil-Ghana match.

If we discuss competition from an economic point of view, competition rules aim at reducing economic inefficiencies and market failures, to increase productivity and employment, and third to reduce prices. Intellectual property rights (IPRs) on the other hand are a very particular form of monopoly, for the fact of granting ownership to ideas and knowledge has a very complex nature. First, knowledge is not a scarce resource: the more we use it, the more we get. So why grant property rights on knowledge if it multiplies through using it? The basic theory of IP rights is that there is an incentive for knowledge creation and creativity; in this sense, it acts like competition rules. The downside of IPRs, we are told that it restricts access to knowledge products. Therefore, there is a very delicate balance between the monopoly of IP and the competition rules which are supposed to negate monopolies.

My questions to the panel are: do you think the European Commission's interpretation of IPRs and competition rules has evolved, and if so how and why? Secondly, does the Commission's interpretation and implementation of competition rules take place across the board? In other words, is it treating different areas of technology, such as pharmaceuticals in the same way as software? Take for instance the issue of incremental (or "follow-on") innovation: in terms of software, follow-on innovation is mostly celebrated for competition, whereas new pharmaceutical products are usually described as "me-too" drugs. What is the proper approach? And finally, is there a middle ground and may we expect an EU policy to address this?

### **Duncan Curley:**

This debate is very timely in the context of the Lisbon objectives, i.e. the goal to become the world's leading knowledge economy by 2010. This was set in 2000 in Lisbon; as we are now in 2006, let us say that progress has been a little slow.

There can be no debate that there is strong need for IP protection in Europe. Patents protect inventions with industrial applicability, whereas copyright protects creative expression. They are exclusionary monopoly rights

People generally think of competition law in the sense of attacking monopolies, i.e. competition is there to reduce prices and facilitate consumer choice. Some therefore sense a clash between competition laws (intended to open up markets) and IPRs which may lead to higher prices. Recent statements from the European Commission have stressed the complementarity of the two, particularly in fostering innovation. (Monti quote)

Articles 81 and 82 of the EC Treaty are the legal instruments used by the European Commission to facilitate the market economy in Europe. A key component of policy-making these days is of course the Lisbon Agenda: Ms. Kroes, Commissioner for Competition Policy, said in a speech in Paris last week that she is committed to ensuring that competition policy plays its part in fulfilling the Lisbon Agenda.

How does the rhetoric measure up to the reality of the case law? First, let us look at the two main limbs, articles 81 and 82. The first prohibits cartels, but you have to remember that it goes beyond this: it can also impact on many kinds of contractual agreements, such as exclusive distribution, R&D agreements and IP license and technology transfer agreements. In 2004, the Commission radically updated its competition policy in terms of IP license agreements. It brought in a new technology transfer block exemption, intended to give much greater freedom to companies licensing their IP. The new rules on application of article 81 were firmly in accord with the Lisbon objectives, at least according to the Commission.

Article 82 is aimed at a quite different kind of mischief. It is used to regulate unilateral conduct of larger market players. Cases under article 82 are rare, and those involving intellectual property rights even more rare. It is aimed at dominant firms, with strong market position or near monopoly, which can act independently from the other players. Lack of competition can lessen the incentive for a dominant firm to increase its performance in terms of cost reduction and innovation. Article 82 b is the specific provision saying that, in certain circumstances, dominant firms may not restrict access to their technology. This raises the question at the focus of today's debates: to what extent must dominant firms open their doors and license their IP if asked by their competitors? The European Commission will intervene in some circumstances, and the key issue is of course for companies, what are these circumstances?

## **Case law**

The Magill case involved a comprehensive television guide in Ireland which would include all TV programmes for all channels. But the TV broadcasters all had their own listings and asserted their copyrights in order to sue Mr. Magill for infringement, and thus prevented his TV guide from being published. The European Court of Justice then held that “exceptional circumstances” warranted a compulsory licensing of the copyrights belonging to the broadcasters. The key point was that Mr. Magill was offering a brand new product not yet on the market, there was proven customer demand, but this was frustrated by the copyrights held by the broadcasters.

In the mid-1990s, access to IP was limited to exceptional circumstances. Since then, access to technology has become more important and IPRs have become part of the daily business environment. The European Commission has arguably therefore become more interventionist when it believes that IPRs are not exercised in a fair way.

### The IMS Health case

IMS Health is a big provider of pharmaceutical data which owns a copyrighted database containing sales data for the German market. A small company called NDC wanted to get into this market for selling these data with a very similar database. IMS sued NDC for copyright infringement and NDC then turned to the European Commission. The Commission granted a decision forcing IMS to grant a copyright license to allow NDC to get into the market. The Court of First Instance subsequently annulled this decision and later the case went to the Court of Justice. What is important to note is that NDC was proposing to launch a product very similar to the IMS Health product, so the case is not comparable to the Magill case which involved a brand new product.

### The Microsoft decision

I am not going to focus on the aspect of the bundling of the MediaPlayer to the Windows operating system; but on the work group server, or interoperability aspect which is the most relevant to the IP/antitrust debate. We are all familiar with the MS Windows operating system which is simply a software which controls the functioning of computer hardware. A server on the other hand is essentially a powerful computer whose main role is to organise and manage network communications between different PCs. Work group servers are smaller and handle certain services (e.g. file and print) for computers which are linked together. Microsoft has a very strong market position for PC operating systems: the MS Windows has a market share of more than 90% and has been described as ubiquitous.

The case was launched because Sun Microsystems wanted to offer its own work group server operating system which would be compatible with the Windows PC operating

system. In order to do so, Sun needed information on the MS work group system to ensure interoperability. Microsoft refused to supply this technical information. In its March 2004 decision, the Commission then ordered Microsoft to provide the information to let Sun develop products which could interact with the Windows OS on a “reasonable and non discriminatory basis”. By doing so, the Commission tried to open up the market for work group server operating systems by allowing competitors such as Sun into the market.

But what about the IP rights? Microsoft claimed that, to comply with the decision, it would have to grant an IP license in order for companies like Sun to practise the information lawfully. In fairness, the Commission did not shy away from the far-reaching nature of its order. In paragraph 546 of the decision, it stated that *“It cannot be excluded that ordering Microsoft to disclose [its] specifications and allow [...] use of them by third parties restricts the exercise of Microsoft’s intellectual property rights”*.

Microsoft claimed, I think correctly, that the Commission’s disclosure order was unprecedented and that this would have adverse effects on its own incentives to innovate and develop new products. The Commission – and this is the most interesting aspect of the decision – then turned Microsoft’s argument back on the company and said that it was stifling innovation in the work group server market, since all the players were trying to gravitate towards the Microsoft standard. The Commission stated that *““The major objective justification put forward by Microsoft relates to Microsoft’s intellectual property over Windows. However, a detailed examination of the disclosure at stake leads to the conclusion that, on balance, **the possible negative impact of an order to supply on Microsoft’s incentives to innovate is outweighed by its positive impact on the level of innovation in the whole industry**)...”* (paragraph 783)

And this is confirmed further on in the same paragraph: *“[T]he need to protect Microsoft’s incentives to innovate cannot constitute an objective justification that would offset the exceptional [Magill-type] circumstances identified”*, in particular Microsoft’s very large market share.

So the Commission’s argument proceeds on the basis that, if Microsoft were allowed to continue its behaviour, innovation would be stifled in the work group server operating systems market. But the decision does not properly address the wider effects which may erode IP protection for dominant firms. And this is a serious issue. According to Chris Parker, Director of Law and Corporate Affairs at Microsoft, *“A crucial part of this case rests on the rights of companies to invest in research and development, innovate, produce new products to meet customer demand and then retain the right to earn a return on that investment.”* In other words, IP law would ordinarily let Microsoft the right to retain any profit on licensing, or indeed not to license at all; the Commission takes away that choice.

Has the Commission gotten its balancing act right? According to a Report prepared by the Economic Advisory Group for Competition Policy, as part of the European Commission’s recent review of policy under Article 82 (July 2005):

*“...even if a refusal to deal harms consumers in the short-run, it may be socially beneficial in the long-run. If the bottleneck is the result of investment or innovation activities of the dominant firm **then forcing the firm to give its competitors access to the bottleneck is an expropriation of the returns of the firm’s efforts. This may discourage this and other firms from investing in the future, and it may reduce incentives to innovate. Tolerating a (temporary) monopoly may be the best way to promote investment and innovation incentives...**”*

According to Microsoft, the European Commission has...“[committed]...*the biggest encroachment on intellectual property in European competition law history*”“...opened the vaults of a bank” to hand money out to passers-by. (Microsoft’s Counsel, Ian Forrester QC, before the Court of First Instance, April 2006).

An Article 82 policy review is underway. The Microsoft decision is on appeal to the Court of First Instance. Watch this space.

### **Manuel Campolini:**

Before going into private practice, I worked at the European Federation of Pharmaceutical Industries and Associations (EFPIA).

I would like to start by describing the pharmaceutical industry and then move towards the competition issues. What is distinctive for this industry is the size of R&D investment: approx. \$ 800 million is needed to develop a new product (this includes failures), although this figure is sometimes challenged. The industry very much depends on a very small number of “block-buster” products (sales of more than \$ 1 billion). Second, the pharmaceutical industry, unlike other businesses, is subject to price controls at least in Europe. Third, it depends heavily on the effectiveness of the IP system: when you apply for a patent for a new pharmaceutical product, you do so everywhere in the world. Finally and importantly, the customer wants the best product: if you have cancer, AIDS or hepatitis, you are ready to fight to get the latest products (but not necessarily to get the latest version of Windows).

This means that these are not products like any others, to use a very French expression. In Belgium recently, the new breast cancer drug Herceptin (Hoffman-La Roche) was not yet on the market because of reimbursement procedures, but public pressure was so high that the authorities had to put it on the market months before normal approval.

What are the key issues?

- 1) Strong product competition through innovation. This is related to new research and development, but also incremental R & D: sometimes products are new, but sometimes they are the result of product line extension. You may find within the same category highly valuable products and others with less value. At the same time, a “me-too” product with a small incremental improvement can bring a great

therapeutic value. An example: a molecule has been found to radically improve the successful treatment of hepatitis C.

- 2) Parallel trade. This is the product of European price controls: a product x in Greece may be bought at a low price and imported to the UK where the price is much higher.
- 3) Generic competition. This is directly linked to IPRs, since generics depend on patent expiry.

Article 81 deals with concerted practices.

In October 2000, the European Court of Justice delivered its judgment on the case where Bayer had imposed supply restrictions in order to prevent parallel imports. The ECJ established that these restrictions did not contravene European competition rules as long as these were not adopted pursuant to a concurrence of wills between the manufacturer and domestic suppliers and did not amount to an abuse of dominant position. The case dates back to 1991 when Bayer was first accused of limiting supplies of its anti-hypertensive drug Adalat in France and Spain. As prices for Adalat were lower in the latter countries, demand trebled suddenly which resulted in considerable parallel trade from France and Spain to the UK. Bayer reacted by introducing a policy of supplies corresponding to market needs, and cut the supply into the UK. The European Commission responded by claiming this policy reflected a tacit agreement between Bayer and its wholesalers.

The European Commission first fined Bayer €3 million for infringement of EU competition rules. This was later overruled by the Court of First Instance, which dismissed the contention of an export ban as unfounded; no such evidence could be found, nor of any intention by wholesalers to adopt Bayer's antiparallel trade policy.

Bayer's position was crystal clear: its policy aimed at preventing parallel trade. Finally, the Court observed that "[n]or, finally, can the Commission rely in support of its argument upon its conviction, which is, moreover, devoid of all foundation, that parallel imports will in the long term bring about the harmonisation of the price of medicinal products". The Commission appealed to the ECJ and lost.

The second case is similar and deals with Article 82 (abuse of dominant position): Syfait vs. GSK. It relates to a patented product. GSK refused to meet the wholesaler demand in full in order to avoid parallel trade. The Advocate General Jacobs said that, a refusal to supply may be acceptable because of the characteristics of the pharmaceutical industry, i.e. government price controls of the products, the consequences for innovation and the absence of benefit for the consumers. The issue has recently been raised again before the European Court of Justice.

In 2005, Astra-Zeneca was condemned for abuse of dominant position in a case directly linked to IPRs and competition:

- 1) “giving misleading information to several national patent offices, resulting in gaining extended patent protection for Losec through so-called SPCs”.
- 2) “misusing rules and procedures applied by national medicines agencies (...) by selectively deregistering the market authorisations for Losec capsules in Denmark, Norway and Sweden with the intent of blocking or delaying entry of generics firms and parallel traders.”

It may be interesting to present the product. It belonged to a class called PPI. Losec was launched in 1987 and became one of the most successful products in the 1990s: \$ 6.3 billion dollars in 2000. This is the kind of blockbuster product needed by industry to fund research and development, also to finance products which are not necessarily less useful but less successful. Losec also has a superior therapeutic efficacy compared to older products.

The deregistration issue concerned the switch from capsules to tablets in the late 1990s. The capsule form was withdrawn from several high price markets, e.g. Sweden and Denmark. On September 1<sup>st</sup> 1998, the Swedish authorities decided that the import license needed by parallel traders was no longer valid, since Losec no longer existed in capsule form on the market. It took five years to get a decision from the ECJ overruling the Swedish authority.

The deregistration also had consequences for the entry of generics, because of the data exclusivity. After the data exclusivity expired, UK company, Generics UK, registered an abridged application for the Losec capsules. Approval was granted by Danish authorities, but this was challenged by Astra-Zeneca, again referring to the non-existence of Losec capsules.

Last, but most importantly, the issue of Supplementary Protection Certificates (SPCs): this extends patent protection for a maximum of five years after expiry. In order to obtain this, Astra-Zeneca submitted the date of reimbursement (1988) and not the date of the first marketing approval (1987). Litigation started in the late 1990s and the judgment took place in 2003. In Germany, Astra-Zeneca obtained a four-year extension through SPC.

According to the Commission, Losec holds a dominant market position and the other products don't exercise a significant competitive constraint; whereas Astra-Zeneca argues that it is one of several treatments available. The Commission reasons that any innovative product may be considered dominant in retrospect and that this could have adverse effects on industry competitiveness, contrary to the aspirations of the Lisbon Agenda.

Based on internal documentation, the sequence of actions and the behaviour towards patent offices and Courts, the Commission concluded that Astra-Zeneca was guilty of abusive conduct. Astra-Zeneca responded by pleading good faith; that alternative solutions existed for the registration of generic products; that a company is free to withdraw its products from the market; and that the tablet format of Losec presented

benefits for patients.

The Competition Commissioner Nellie Kroes declared:

*“I fully support the need for innovative products to enjoy strong IP protection so that companies can recoup their R&D expenditure and be rewarded for their innovative efforts.*

*However, it is not for a dominant company but for the legislator to decide which period of protection is adequate. Misleading regulators to gain longer protection acts as a disincentive to innovate and is a serious infringement of EU competition rules. Health care systems throughout Europe rely on generic drugs to keep costs down. Patients benefit from lower prices. By preventing generic competition AZ kept Losec prices artificially high. Moreover, competition from generic products after a patent has expired itself encourages innovation in pharmaceuticals.”*

To conclude:

Is there conflict or co-existence between IP and competition? It is very difficult to provide an answer in this specific case. Astra-Zeneca underlined that this would be the first case ever where an abuse is constructed based on the way in which a company acquired an IP right.

Another question: is the subject matter of IPRs at stake? This is not certain, but the point needs to be clarified. To obtain a patent, you need to publish everything so your competitor is aware of the way the product is obtained and he may be able to do the same eventually.

Could the solution be found in IP law? I believe the IP system is largely self-regulatory; compulsory licensing exists. A patent means that you cannot prevent your competitor from using it to develop knowledge and later a new product. Therefore, the time sequence between the start of a legal procedure and the final court decision is essential. If you hold an IPR, it is presumed that the title is valid. This is a core issue, and the cases before the European Court of Justice may have an impact of life-cycle management strategies and more fundamentally on product development and innovation.

## Discussion

### **Question:**

The SPC seems to change the rules of the game, after the fact. You develop a product and enjoy protection for the duration of the patent. On what grounds are SPCs granted, and are they automatic?

### **Manuel Campolini:**

Pharmaceutical products are protected by patents, but product development, patient trials and safety procedures come first and may take 8-12 years. Assuming that your product reaches the market after ten years, this gives an effective protection of 10 years, rather than the nominal 20 years. It was then considered that this period doesn't allow a company to recoup its investments, hence the extension granted by SPC.

### **Meir Pugatch:**

Patent registration in the United States is based on a formula, taking into account the amount of time needed to develop a product; there is no automatic 5-year extension. In the EU, you cannot get more than 15 years of effective patent protection (14 in the United States). There is also an important difference between technologies: IT products tend to be obsolete after 3-4 years; this is not the case for most medicines.

Two questions for the panel: does the Commission grant a greater importance these days to competition concerns relative to IP rights? Second, given the development of new business models (e.g. open source), is the Commission basing its interpretation of Article 82 more on predictions of the future than on actual knowledge?

### **Duncan Curley:**

The pecking order issue is interesting: should competition law take precedence over IP law? I'm an IP lawyer, but I have to concede that competition law should come first. As we have seen in the Astra-Zeneca case, article 82 is aimed at "bad behaviour" to use a pejorative term. Astra-Zeneca had played the SPC system to its advantage to extend the life of a blockbuster product; there was a great deal of money at stake. Speaking as a consumer of drugs in the EU, I'm glad that the European Commission takes cases like this and addresses them with investigations.

It is definitely right to say that the Commission is ready to step in to address what it sees as bad behaviour and put in place a remedy which has prospective, future effect. The Microsoft decision is about ensuring that the market is opened up for the future.

**Manuel Campolini:**

IP and competition law should be on an equal level. And if IP should comply with competition policy, the contrary is also true. It would be completely devastating to have EU competition rules prevailing over IPRs in all instances and destructive in terms of innovation. If you read the Astra-Zeneca decision very carefully, it seems that the Commission tries to achieve a balance between the two components.

**Anne Jensen (Stockholm Network):**

What do you think of the fact that the Microsoft case was raised, not by consumers complaining about a problem in the market, but by a competitor?

**Duncan Curley:**

A very valid point: as I mentioned, the complaint was raised by Sun Microsystems and one might well view this with a degree of scepticism: is this not just a tactical game from a competitor? But the Commission knows what it's doing and takes on the case on behalf of European consumers. It obviously saw that there was a bigger picture worth investigating. Incidentally, Microsoft has since then settled with Sun, so the battle now is between European consumers, as represented by the Commission, and Microsoft.

Going a bit deeper, this raises the question whether European consumers were actually affected by Microsoft's behaviour. Who can safely put up his hand and say that? The consumer harm aspect was not properly handled by the Commission, and its case would have been improved by articulating a real story on how prices were higher etc. In this sense, the Commission has lost part of the publicity battle, since Microsoft could then seize the initiative and say that this is bad for innovation.

**Meir Pugatch:**

If I may take a somewhat different view, I don't think the Commission represents the consumers necessarily in every case. Sometimes, the best way is testing the situation on the ground. Today, there is an operating system with the MediaPlayer which you can buy in the US or the Middle East, and another without the MediaPlayer in Europe ...

**Duncan Curley:**

... which I gather nobody has bought.

**Meir Pugatch:**

... are consumers better off by paying the same price for getting an incomplete product?

There is a lot of talk about the new operating system, Vista. This is not a problem for many countries which are starting to at least to experiment with it.

**Question:**

Two broader thoughts: first, in many of the earlier cases the idea was that the IP system was not doing its job properly. Astra-Zeneca is one case in point: if the executives of the company had been hauled off to jail for cheating the IP system, would the Commission have intervened? No. There were similar issues in the cases of Magill and IMS Health: was really this about serious IP issues which should have been granted under national law? If the IP system had been more rational, the Commission would not have stepped in.

Secondly, many of these cases pose the problem of “me-too products”. My firm represented NDC in the IMS case several years ago, and NDC doesn’t accept the idea that this is a “me-too” product. In fact, this will be decided by the German courts in the next few months.

Finally, we represent Microsoft which argues that the competitors want to make “me-too” products (active directory): is it me-too or genuine innovation? Magill was really a new product: the new TV guide came out in the middle of the World Cup in 1986 (only one issue was ever published); and 20 years on the Magill case is still with us, although it took the EJC nine years to reach a decision, and by then Mr. Magill was long in bankruptcy.

**Manuel Campolini:**

In the case of pharmaceuticals, me-too products mean that they work better for a certain patient category; this is very important. They may not bring great benefits in innovation, but they improve the therapeutic benefits, so as a patient I support them and they must be protected.

