Alliance Unichem conference
Brussels
Hilton Hotel

26 March 2001

EC ANTITRUST POLICY IN THE PHARMACEUTICAL SECTOR

By

MARIO MONTI

Member of the European Commission in charge of competition policy

Mr.Chairman, Ladies and gentlemen,

Let me first express my gratitude to our host - Alliance UniChem - for giving me the opportunity to share with you some thoughts concerning the European Commission's antitrust policy in the pharmaceutical field. As a matter of fact, you and I would not have been here today had the Commission – back in 1997 – not cleared the marriage between Alliance Santé and UniChem as an unproblematic merger.

AllianceUniChem is thriving. As one of the leading pan-european wholesalers in the pharmaceutical sector, it seeks to increase its visibility with the public at large. I am told that they are nowadays the proud sponsor of the Italian rugby team which is taking part in the famous Six Nations rugby tournament. I guess that the Italian team can use every bit of support in this tournament.

In the time that has been allotted to me, I would like to take you through five antitrust topics in the pharmaceutical sector. The five topics are the following.

[1] I will start off with a few words about our policy regarding mergers. Since 1989, the Commission has the power to vet such operations if their size exceeds certain thresholds.

[2] I will then briefly explain our approach towards other forms of alliances which fall short of genuine mergers. They typically involve cooperation between companies in a particular project, for instance common research and development. Such forms of cooperation, although not comparable to

pernicious forms of cartelization, can fall technically within the scope of the EC Treaty's provision – Art. 81 - which prohibits anticompetitive agreements between companies. The parties can, however, have their agreement cleared if certain conditions are fulfilled.

[3] The same EC Treaty provision – Art. 81 - is relevant for my third topic. It deals with an evergreen : agreements whereby companies ask their dealers to refrain from parallel trade within the Community. The Commission's views have traditionally been diametrically opposed to those of research based pharmaceutical industry. The debate is ongoing in Brussels as well as in the Luxembourg Courts.

[4] From the issue concerning parallel trade within the Community it is only one step to the next topic : can the research based industry stop parallel trade from third countries into the Community? The political context behind this question will be familiar to many of you. The Commission as well as other international authorities and Non Gouvernmental Organizations (NGO's) like *Oxfam* or *Médecins Sans Frontières* urge the industry to improve access to medicines for communicable diseases in the developing countries. Many things need to be done. Just one of these things is to make the medicines available at a low, affordable price in those countries. But these cheap medicines may then be shipped back into the Community where higher prices prevail. Can the industry take measures against this parallel trade ?

[5] My fifth and last topic may well be the most thorny one. Patents are the lifeblood of the research based pharmaceutical industry. I am not questioning this. However, there are limits to what a patent holder can do. There may be a thin line between the legitimate use and the misuse of intellectual property rights. But the point is that there is a line and that it should not be overstepped. My department is currently examining a number of complaints lodged by either generic companies or small, innovative companies. These companies contend that patent holding companies block or seriously delay their market entry for no good reason. Do these companies indeed abuse their dominant position ? That is the question.

1. MERGERS

Let me start with mergers.

We observe an ongoing trend of consolidation in the pharmaceutical sector. And we observe it at all levels. At the level of the manufacturers, the degree of consolidation is still pretty mild. No one reaches a global market share above 7,5%. Investment bankers are pinning their hopes on the pharmaceutical companies to give them new assignments! At the wholesale level, the consolidation is no doubt the most advanced. Three players, including Alliance UniChem, share out roughly 60% of business in the Community. At the retail level, the process is - by and large - just beginning.

I will not endeavour to identify all the factors which are contributing to this consolidation trend. It is clear though that there is a certain amount of cross-fertilization between the consolidations at the three levels just mentioned.

We do not use antitrust policy to second-guess the companies on the efficiencies that they expect to achieve via consolidation. We actually assume the presence of efficiencies. The only question for us is whether the mergers, the majority acquisitions or the full-blown joint ventures of a certain size (called a « Community dimension » in our technical jargon) will enable the parties to achieve or strengthen a dominant position in the markets in which they compete.

So far, no merger operation has faced an outright ban in the pharmaceutical sector. In a few cases, the parties to the merger did acquire too much market power for some of the products involved. However, they accommodated our concerns by offering partial divestitures. They committed themselves to outlicense the relevant products. This happened for instance in *Aventis* (a merger case involving Rhône Poulenc and Hoechst) as well as in the *Glaxo Wellcome / SmithKline Beecham* merger case. In fact, when companies hold large portfolios of products, there is more margin for fine-tuning solutions to the competition problems in some of the affected markets. In other sectors, there is often no alternative to reverting to a « blunt » ban of the entire merger operation.

Of course, commitments to divest can themselves give rise to difficulties. We are experiencing this in particular when the commitments concern the divestiture of so-called pipeline products. These products may look very promising. On that basis, we might consider the divestiture of such pipeline products as a remedy which will give a real tonic to competition. However, pipeline products may look good only on paper. If they do not make it to the market or if they prove less effective than anticipated, the remedy will also prove to be less effective than hoped for.

I mention this issue to make a more general point. Discussions about adequate remedies have become more and more frequent, time consuming and complex. In future, each merger case team will be assisted by colleagues whose sole job is to help design appropriate remedies and to monitor their correct implementation.

2. COOPERATION

So much for mergers. As I pointed out in my introduction, companies often forge alliances which fall short of mergers but entail nonetheless important investments and intense cooperation. To give a typical example : companies set up a joint venture in order to develop a new drug or an improved version of an existing drug and to manufacture that drug for them. In addition, they may enter into agreements with regard to sales. For instance: one partner may become the comarketing or copromotion partner of the other.

Where is the problem ? The short answer is that there is only a problem if the cooperation significantly hampers opportunities a) for the parties themselves to fly on their own wings once their cooperation has enabled them to recoup their investments and b) for third companies to compete effectively in the relevant market. In other words, the ultimate legality test is not all that different from the one used for assessing mergers.

To start with, we will usually have no difficulty accepting that the cooperation generates efficiencies and benefits consumers. For instance, it takes little imagination to understand that an inhalable drug may be infinitely more user-friendly than an injectable one. And the same is true for a drug whose effects are more enduring than a previous version and which can therefore be taken less frequently. The difference with mergers is, however, that parties must demonstrate this to us.

For the rest, what matters is the impact of the cooperation on the market. Here too, remedies are often the crux of the matter. We may have to ask parties to scale down their cooperation or at least to turn their cooperation into an non-exclusive one after a certain period of time.

Just two months ago, we published for the first time guidelines on the application of Art. 81 to horizontal cooperation agreements. Horizontal means : between competitors. In these guidelines, we explain that - as a rule and to keep it simple – R&D agreements are given the green light for at least seven years following market introduction of the product. We add that we

would consider giving comfort for a longer period of time if parties demonstrate that they need this in order to guarantee for themselves an adequate return on the investment.

I am well aware that the pharmaceutical industry takes the view that the seven years « hallmark » does not sufficiently take into account the specificities of its sector. Two remarks on this. First, you will appreciate that the Commission cannot possibly « box in » all conceivable sectoral specificities in one set of general guidelines. Second, the guidelines do enable my department to take into account these specificities in the cases which are brought under its attention, provided that the parties come up with facts and figures making their case for a longer period of comfort.

3. PARALLEL TRADE WITHIN THE COMMUNITY

The Commission has never ruled formally on cooperative arrangements between competing companies. So far there have been only two formal Commission decisions applying Art. 81 of EC Treaty to the pharmaceutical sector: *Sandoz* in 1987 and *Bayer* (perhaps better known as the *Adalat* case) in 1996. Both cases dealt with parallel trade within the Community. This is my third topic.

In these two cases, the Commission fined the pharmaceutical companies for having agreed on an export ban with their wholesalers. The first decision was upheld by the (European) Court (of Justice). The second one was struck down

at the end of last year by the Court (of First Instance). It is important to stress that this Court did not question an established point of law, namely that contractually agreed obstacles to parallel trade within the Community fall foul of Art. 81. The Court merely concluded that the Commission had not proven its case against Bayer. Meanwhile the Commission has lodged an appeal against this judgement. In its view, the judgement effectively raises the standard of proof as set out in *Sandoz* and in a number of other parallel trade cases outside the pharmaceutical sector.

The matter is important. The type of supply quota arrangements which were at the heart of the *Bayer* case are indeed widespread in the industry. Taking into account the particularities of the distribution of pharmaceuticals, the Commission is convinced that the arrangements between manufacturers and wholesalers involve a sufficient degree of concertation to bring them within the ambit of Art. 81.

Some of the industry members wish to convince the Commission that there are compelling reasons for impeding parallel trade. The Commission continues to regard parallel trade as a driving force for market integration and existing national price control regulations as insufficient justification for impeding such trade. It has, however, no difficulty examining the merits of the compelling reasons advanced by the industry. But this debate can only take place if there is consensus that Art. 81 applies to the agreements at stake in the first place. Since the *Adalat* judgement the industry may think it no longer

does. The Commission sees things differently. Let us see what the appeal will bring.

4. PARALLEL TRADE FROM THIRD COUNTRIES INTO THE COMMUNITY

The parallel trade issue leads me to my fourth topic. In a communication issued last month, the Commission has unveiled the details of an action programme which strives for accelerated access – at affordable conditions – to medicines combating three major communicable diseases (HIV/AIDS, malaria and tuberculosis) which most affect the poorest developing countries. In its communication, the Commission proclaims to be « at the forefront of international efforts to establish a global tiered pricing system ». It further acknowledges that such a system « must be able to prevent product diversion to other markets ».

Although it seems to be the world « on its head », the industry has repeatedly voiced antitrust concerns about these ideas.

In its view, the reference to a tiered pricing « system » suggests that the research-based companies are being asked to enter into forms of price concertation which constitute a « cardinal sin » under Art. 81 of the EC Treaty.

That is not how I see it. The Commission simply calls on each of these companies to make a long-term commitment, namely to supply medicines at

more affordable prices in those countries which are in great need of them. Besides, a number of companies have taken individual price initiatives that seem to be going in the right direction. The press has reported on these initiatives. They do not raise any antitrust concern. For the rest, I would go along with the industry's view that neither the Commission nor any other public or private body should take or propose measures which could lead to restrictions of competition between the companies.

The industry is also concerned that attempts to block parallel imports into the Community may not pass muster under Art. 81 EC Treaty.

However, measures against parallel trade *within* the Community are one thing, those against parallel trade *into* the Community another.

Measures interfering with parallel trade within the Community indeed jeopardize the achievement of a prime Community policy objective : market integration. The Commission outlaws such measures without even thoroughly analyzing their anticompetitive effects.

Measures aimed at stopping parallel trade at the external Community borders are of a totally different nature. Companies are in principle free to take such measures. The only gloss to make is this: *if* these measures would - somehow - lead to an appreciable restriction of price competition in the Community *and* to an equally appreciable restriction of trade between the Member States, they *might* fall within the scope of Art. 81. But you will have noted that the

restrictions must be appreciable. Moreover, this would not be the end of it. The companies would, in any event, have ample opportunity to justify their measures. The Commission itself has already acknowledged in its recent communication that it is probably impossible for the industry to practice tiered pricing without such measures. I refer to my earlier quote. The industry should definitely take comfort from this acknowledgement.

Besides, my department has had informal contacts with EFPIA on these issues earlier this month and I understand that these contacts have been fruitful. What matters above all is that antitrust technicalities do not jeopardize the Commission's policy objective as set forth in its recent communication.

5. ABUSE OF DOMINANT POSITION

Ladies and Gentleman, I would like to address now my fifth and last topic. One could say that the sting is in the tail.

Apart from Art. 81, the EC Treaty contains one other major antitrust provision - Art. 82 - which prohibits companies from abusing their dominant position. Under this Treaty provision, we are currently looking into the following issue : within what limits can a pharmaceutical company use its intellectual property rights (IPR), typically its patents, to prevent potential newcomers from entering the market ?

As I have mentioned in my introduction, this is a novel and highly complex issue. It is novel, not just because we have never dealt with an abuse case in the pharmaceutical sector but also because the type of possible abuse is either entirely new or has given rise to very scant case law so far.

Our investigations require an in-depth analysis and understanding of patent law, including Community patent law provisions. The allegations against some of the research-based pharmaceutical companies are manifold. To give you at least the flavour, I could perhaps mention one or two of these allegations.

As you all know very well, companies can effectively prolong the period during which they enjoy patent protection for their drugs by obtaining so-called SPC's (Supplementary Protection Certificates). There is a Community Regulation from 1992 which governs the conditions under which such SPC's can be obtained. One of the allegations that have been made to us is that pharmaceutical companies tend to « play around » with dates in order to have their SPC's cover the longest possible time span. And of course every extra day of patent production means extra monopoly profits.

Another allegation is that patent holding companies sometimes withdraw and deregister one particular formulation of their drug and have it replaced by another formulation in order to delay market entry of equivalent generic drugs. Here another piece of Community legislation is highly relevant : the 1965 Directive on market authorizations for branded drugs. Manufacturers of generic drugs can obtain a market authorization under an abridged procedure if

there is a « reference product » on the market. To put it simply : if the reference product is withdrawn from the market, market entry of generics is delayed.

I have obviously stripped these two examples of all their technical detail. They amply illustrate, however, that one cannot properly assess the allegedly abusive practices without going to the very bottom of all the relevant facts. We are determined to do it. It is actually our duty to do it. The financial stakes for the companies involved are tremendous. We are very well aware of this. But consumers are entitled to cheaper equivalent generic drugs or upgraded versions of patented drugs *if* the companies which try to bring these drugs to the market do so without infringing the existing patents.

CONCLUSION

Mr. Chairman, Ladies and Gentlemen, it is about time for me to wind up. Rather than summarizing the main points I have just conveyed to you, I would like to say a few words about a topic which – I discovered - features prominently on the today's programme, namely electronic commerce.

New technologies offer new opportunities even though the specificity of medecines implies that regulators, including those at the Community level, must make value judgements about the scope for letting these technologies develop themselves in this market. But if I stick to my brief, namely antitrust law, I would just say this.

Electronic commerce does not raise new antitrust issues. The issues are classic. Only the factual setting in which they arise is new. Electronic commerce in general offers a lot of potential. There is no doubt about it. It is, however, a matter of making proper use of it. To give a clear-cut example, I could paraphrase Adam Smith : when people in the same trade meet virtually in cyberspace, their electronic conversation should not end in a conspiracy against the public or in some contrivance to raise prices.

As you are approaching lunch time, I hope to have given you a healthy appetizer with some food for further thought. Thank you for your attention.