



# Article 82 update

'A GOOD UPSWING – BUT MORE WORK NEEDED ON THE DOWNSWING'

Two recent events have contributed to the European Commission's efforts to clarify the competition law principles applying to dominant firms (article 82 EC): the Commission's public hearing on 14 June regarding exclusionary abuses and the publication of the decision (now on appeal) by which the Commission last year fined AstraZeneca €60m for abuse of patent and other regulatory laws.

Two recent events have contributed to the European Commission's current efforts to clarify its policy under article 82 regarding dominant firms and to strike a better balance between, on the one hand, a dominant firm's right to compete and to protect its legitimate interests and, on the other hand, the need to safeguard effective competition.

The first is the Commission's public hearing on 14 June to discuss the key issues that have arisen during the consultation exercise following publication of its December 2005 discussion paper on exclusionary abuses.

The second is the publication of the AstraZeneca decision (now on appeal), the Commission's first decision ever on the question whether, in specific circumstances, the use of governmental procedures (such as patent and other regulatory procedures) may amount to exclusionary conduct that is illegal under article 82.

## Public hearing on exclusionary abuses

At the Commission's public hearing on 14 June the Director General for Competition, Philip Lowe, summarised the reaction to the discussion paper as 'a good upswing – but more work needed on the downswing'. He said that the consultation was formally closed with the public hearing, and that the Commission wanted to conclude the review process by the end of 2006. He expressly left open the question of whether exploitative and discriminatory abuses would be included in any guidelines that might be published by year end. He also insisted that it was still not decided whether there

would be guidelines at all, but admitted that the submissions (over 100 written submissions were made to the Commission in response to its discussion paper) had given a strong impetus in this direction.

The Commission received broad support for its effort to review and summarise in a single document the state of law and policy in relation to article 82. The general direction of the discussion paper was also praised: most of those who spoke supported the clear espousal of an effects-based approach, taking economic principles into account more consistently than previously, and focusing on consumer welfare.

Many contributors emphasised the need for legal certainty (for companies, but also in view of the application of article 82 by competition authorities and courts in 25 member states), which, in their view, was not yet sufficiently reflected in the approach of the discussion paper. In that context, it was frequently suggested that the guidelines provide for safe harbours, in the contexts of both assessing whether a company is dominant and analysing alleged abuse. Some also argued in favour of more per se rules.

The discussion paper was criticised for taking too static an approach to the concept of dominance, relying too heavily on market shares in that context, and failing to exclude a finding of dominance even at a market share of below 40 per cent.

It was frequently requested that, as a condition of a finding of abuse, the conduct in question should be shown actually to have had a negative effect on

competition or to have been likely to produce such an effect. Some said that this should at least have to be shown in the case of past conduct.

Concerning efficiencies, it was frequently argued that article 82 sets out a unitary test that includes the review of efficiencies, and that the burden of proof of the absence of sufficient efficiencies should be placed on the authority or party alleging the abuse (though some speakers accepted that the dominant company should have to show the facts on which the efficiency claim was based). Some speakers said that the third and fourth criteria of the test of article 81(3) (indispensability and no elimination of competition) did not fit with the concept of article 82 and that it should suffice that the efficiencies outweigh the potential restrictive effects.

There was a very open-ended debate on the relationship between intellectual property rights (IPRs) and article 82: while some thought that the Commission's approach chilled innovation, others said that IPRs were often granted for very mundane 'inventions' and should therefore not prevail as a matter of principle in all situations over the protection of effective competition.

### **AstraZeneca: novel abuses involving patents and market authorisations**

On 15 June 2005 the European Commission fined AstraZeneca €60m for abuse of its dominant position on a number of European Economic Area (EEA) national markets for oral prescription proton pump inhibitors (PPIs) by hindering competitors from marketing generic equivalents. The main PPI is Losec, an extremely successful and profitable anti-ulcer medicine.

The two types of abuse relate to misrepresentations held to have been made by AstraZeneca to obtain and defend supplementary protection certificates (SPCs) (IPRs that extend the basic patent protection period) and to its selective withdrawal of certain marketing authorisations. The decision casts light not only on the broad range of circumstances in which IPRs and similar rights may be considered an instrument of abuse by dominant companies but also more broadly on the Commission's continued reliance on its traditional approach in its article 82 enforcement policy.

### **Dominance**

The decision includes very detailed consideration of the relevant market, which it finds to be oral prescription PPIs, excluding sales to hospitals. This definition is based on the fourth ATC level and excludes histamine receptor antagonists (H2 blockers) on the grounds that, although used within the same broad therapeutic area in that they both inhibit stomach acid secretion, PPIs do so through a much more effective mechanism and give superior medical results for lower cost. It also cites persistent price differences and a price correlation study that indicates the two products are not substitutable for each other.

AstraZeneca had patents for omeprazole, the active ingredient in Losec, and Losec had very high market shares in the relevant jurisdictions (always over 50 per cent and often over 80 per cent or even higher) and was the most expensive PPI. As to AstraZeneca's position in comparison with its main competitors in that market, the Commission found that its general resources and performance (considering factors such as total sales, total assets, net earnings, return on equity, financial strength, R&D expenditure and marketing and staff costs) were markedly superior. It also had more of its own marketing operations in the relevant countries than did its competitors. It was therefore held to be dominant.

### **Misrepresentations to national patent offices and national courts**

The first abuse lay in misleading representations found to have been made by AstraZeneca, both to EEA national patent offices in the course of applying for SPCs for omeprazole in Belgium, Denmark, Germany, the Netherlands, Norway and the UK, and to national courts in Germany and Norway when defending the validity of those SPCs.

The Commission stressed that there was a pattern of intentional misleading representations made as part of a 'centralised and coordinated strategy' with the aim of acquiring or preserving SPCs to prevent or delay generic market entry. Specifically, it found that earlier authorisation dates were concealed in the course of patent office filings and in court cases brought by generic manufacturers to invalidate SPCs. The Commission held that such behaviour cannot be characterised as normal business behaviour or competition, or reasonable steps to protect AstraZeneca's commercial interests.

The Commission applied a low threshold for a finding of an effect on competition. In some jurisdictions the strategy resulted in SPC protection, which would not otherwise have existed, causing uncertainty and disruption of generic firms' preparations for market entry. However, the Commission found abuse even in jurisdictions where the strategy failed, on the basis that there was conduct intended to exclude competitors.

### **Selective withdrawal of marketing authorisations**

The second abuse involved AstraZeneca's request for withdrawal of marketing authorisation for Losec capsules in Denmark, Norway and Sweden when it was stopping marketing capsules on those markets and launching Losec tablets instead. The Commission found that AstraZeneca had requested withdrawal only in countries where it believed this would be effective in preventing or limiting generic market entry.

The fact that the Commission found this to be part of a centralised strategy intended to exclude competitors was again key: isolated requests for withdrawal would not have constituted abuse. The Commission held that although the market authorisation legislation allowed AstraZeneca to request withdrawal, a dominant company is under an obligation to use such an entitlement reasonably, which it had not done. Nor does such strategic use of a market authorisation to prevent or delay generic entry form part of the subject matter of market authorisation.

Again the Commission states that, given the exclusionary intent, there is no requirement to show actual exclusionary effects. However, it did in fact find some such effects with respect to parallel trade and/or generics in all three countries.

### **Implications for article 82 enforcement policy and dominant IPR holders**

Any conduct preventing or hindering parallel imports or the marketing of generics risks close competition law scrutiny, and an official has recently specifically stated that the Commission intends to pay close attention to patent dispute settlements and attempts to evade patent limits. Since the Commission lost the *Bayer* appeal because it had not proved any agreement under article 81 EC, it has focused on the potential of article 82 for tackling barriers to parallel trade of pharmaceuticals.

Although *Bayer* involved the withholding of supplies, and this decision concerns conduct relating to SPCs and marketing authorisations, from a policy perspective they are part of the same drive to use competition law to overcome the imperfections of the pharmaceuticals market. This case would also have been a priority because it involves hindrance to marketing of generic products, whereas Community policy is to facilitate access to generics, seen as a key contribution to reducing public expenditure on reimbursement of medicines.

In relation to dominance, the relevance of high market shares in a market driven by frequent major innovation can be questioned. Such markets are characterised by short-lived serial near-monopolies, as producers reap the benefits of their investment and are then displaced by the next innovation. This case shows that the Commission still places significant weight on market shares as indicators of dominance, even in this kind of market.

Similarly, it adopts a very broad concept of abuse, and minimises the importance of showing market effects. Having referred to the 'special responsibility' borne by dominant firms not to allow their conduct to impair genuine undistorted competition it goes on to say that conduct 'that may otherwise be permissible even on the part of a dominant undertaking may be rendered abusive if its purpose is anti-competitive, in particular if it is part of a plan to eliminate competition'.

The Commission's finding that AstraZeneca intended to exclude competitors appears to have been key to the outcome of this case. So far intent has been of limited relevance in establishing abuse, except in the context of predatory pricing. The approach here implies a broader concept of abuse: commercial strategy frequently involves the aim of maintaining or increasing market share at the expense of competitors or potential competitors, and the Commission may interpret this as 'exclusionary intent'.

As in all cases involving IPRs and similar rights, the question can be asked whether the right balance has been struck between protecting incentives to invest in innovation and stimulating competition in markets downstream of the IPRs. If this decision is upheld on appeal, dominant holders of such rights will need to be extremely careful in how they use those rights if they are to avoid allegations of abuse.

This material is for general information only and is not intended to provide legal advice.

© Freshfields Bruckhaus Deringer 2006  
www.freshfields.com

For further information please contact

Thomas Wessely  
T + 32 2 504 7027  
F + 32 2 404 7027  
E thomas.wessely@freshfields.com

Joanna Goyder  
T + 32 2 504 7543  
F + 32 2 404 7543  
E joanna.goyder@freshfields.com