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COMPETITION LAW AND INTELLECTUAL PROPERTY GO ANOTHER ROUND

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In a new judgment that further explores the application of competition law to intellectual property rights, the EU General Court has upheld a 2005 Commission decision finding that AstraZeneca[1] abused a marketdominant position by blocking or delaying the entry of generic versions of its ulcer drug Losec[2]. However, the Court has also reduced to €52.5 million the €60 million fine originally imposed on AstraZeneca, reflecting the Commission's failure to prove one element of its case.

Dominance

The Court endorsed the Commission's finding that the product market relevant to Losec was the market for proton pump inhibitors ("PPIs"), since these were substantially superior to other products with the same therapeutic use. Losec's very high share of the market for PPIs gave AstraZeneca a dominant market position in the territories in which it engaged in the conduct challenged by the Commission.

The abuse

The Court's decision establishes that conduct relating to patent applications and extensions, and to marketing procedures, may constitute an abuse of market dominance, within the meaning of Article 102 of the Treaty on the Functioning of the European Union ("TFEU"), where that conduct blocks or delays competitors' market entry.

The conduct at the centre of the case involved:

- a pattern of misleading representations made by AstraZeneca to patent attorneys, national patent offices and national courts in a number of Member States with a view to gaining extended patent protection for omeprazole, the active substance in Losec, through supplementary protection certificates ("SPCs")[3] and
- a marketing strategy combining three elements:
  - selective requests by AstraZeneca for deregistration of market authorizations for Losec capsules in Denmark, Norway and Sweden,
  - withdrawal by AstraZeneca of Losec capsules from those markets and
  - the launch by AstraZeneca of Losec multiple unit pellet system ("MUPS") tablets.

The appeal

AstraZeneca appealed on the basis that it had not intentionally provided misleading information in order to obtain SPCs for Losec; and that the introduction of a new Losec formulation and the withdrawal of Losec capsules amounted to a legitimate commercial policy designed to protect AstraZeneca's business from competition from generic producers and parallel importers.

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The General Court's judgment of 1 July 2010

Misleading representations to extend patent protection

The Court found that AstraZeneca did in fact make misleading representations in order to obtain SPCs to which it was not entitled. This type of conduct was not in keeping with the special responsibility of a dominant company not to impair genuine undistorted competition. It amounted to conduct that did not constitute competition on the merits.

AstraZeneca had argued that the existence of a fraudulent intention to cause harm to competition could not amount to an abuse of market dominance, but should be dealt with by the patent authorities under the relevant patent rules. It further argued that the competition authorities had Article 102 jurisdiction only over the enforcement (or threatened enforcement) of a fraudulently obtained patent or SPC. The Court disagreed: *"...the submission to the patent offices of objectively misleading representations by an undertaking in a dominant position which are of such a nature as to lead those offices to grant it SPCs to which it is not entitled or to which it is entitled for a shorter period, thus resulting in a restriction or elimination of competition, constituted an abuse of that position".*

AstraZeneca's conduct had had an effect on competition from the time the SPCs were granted, despite the fact that they had not been enforced – their existence had kept competitors away. Further, the existence of a specific remedy for fraudulent representations in the patent system did not preclude the application of competition law.

De-registration of marketing authorisations

The Court confirmed that the launch of Losec MUPS and the withdrawal of Losec capsules from the market did not in themselves constitute an abuse – they were not capable on their own of blocking competition from generic products and parallel imports. However, when these activities were combined with the deregistration of marketing authorisations for Losec capsules, they were capable of having these effects. In addition, the deregistrations had not been motivated by a legitimate need to protect AstraZeneca's investment, since it no longer had the exclusive right to exploit the results of its pharmacological tests and clinical trials. They were also not necessary to enable AstraZeneca to launch Losec MUPS.

Reduction in penalty

Although the Court upheld the substance of the Commission's decision, it reduced AstraZeneca's fine by €7.5 million to €52.5 million. It found that the Commission had failed to prove that deregistrations of marketing authorisations for the Losec capsule in Denmark and Norway were specifically capable of restricting parallel imports.

What happens next?

This is the first time that the EU courts have had the opportunity to apply Article 102 TFEU to the way in which a dominant pharmaceutical company protects and uses its intellectual property rights ("IPRs"). It remains to be seen whether the judgment will stand unchallenged – judgments of the General Court may be appealed to the Court of Justice, on limited points of law only, within two months from the judgment date, so AstraZeneca has until 1 September to appeal.

Implications of the judgment

In the meantime, the Court's judgment highlights the need for dominant firms to take particular care not to mislead when applying for patents, patent extensions or SPCs. The judgment blurs the traditional competition law distinction between the existence of IPR (not an abuse) and the exercise (or enforcement) of IPR (potentially an abuse) – in this context, it is clear that simply holding IPR will create liability under Article 102. Even a

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genuine error in information provided for the purpose of obtaining could constitute an abuse, although liability is likely to be reduced significantly if, on discovering the error, the company in question informs the patent authorities so that irregularities can be rectified. In addition, activities that in isolation are lawful may, when combined with other activities, result in liability, if their impact is to exclude competition from generics or parallel imports.

Endnotes

1 AstraZeneca AB and AstraZeneca Plc

2 Case T-321/05, Judgment of 1 July 2010; Action brought on 25 August 2005 — AstraZeneca/Commission, OJ 2005/C 271/47 – against Commission Decision of 15 June 2005, relating to a proceeding under Article 82 of the EC Treaty and Article 54 of the EEA Agreement (Case COMP/A. 37.507/F3 AstraZeneca) [2006] OJ L322/24.

3 SPCs are granted according to the provisions of Council Regulation 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (OJ L 182). SPCs grant longer patent protection to pharmaceutical products, not exceeding five years after the expiration of the patent. SPCs were introduced to take into account of the lapse of time between patent registration and market authorization.