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The AstraZeneca Competition Case: Patent Strategies Constituting Abuse of Dominance

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Abstract

On 6 December 2012, the Court of Justice of the European Union affirmed that AstraZeneca abused its dominant position by engaging in certain intellectual property strategies aimed at protecting its product against generic competition. The judgement provides guidance on when life science companies abuse their dominant position through abuse of intellectual property and regulatory procedures. This article analyses the decision and discusses in particular how AstraZeneca's patent strategies were caught by Article 102 of the Treaty on the Functioning of the European Union.

1. INTRODUCTION

On 6 December 2012, the Court of Justice of the European Union ("CJEU") decided that the pharmaceuticals group AstraZeneca had abused its dominant position on the pharmaceuticals market by making deliberately misleading representations to patent offices in several Member States and by misusing the procedure governing the deregistration of marketing authorisations, in order to prevent or delay the entry into the market of the generic competition to its blockbuster drug Losec and to prevent parallel imports of the drug.[1]

The judgment of the CJEU, as well as the preceding decision of the European Commission ("Commission") and the judgment of the General Court of the European Union ("GC"), caught high attention. AstraZeneca was one of the first pharmaceutical companies to face action from the Commission in 2005. The decision of the Commission of 2005 was the first to impose a fine on a pharmaceutical company for abuse of its dominant position in the market and the AstraZeneca case was the first occasion for the European institutions to assess the relevant markets in the field of pharmaceuticals outside the area of merger control.

The judgment of the CJEU comes as a disappointment to many life science companies. It sets a precedent that will make it harder for innovator drug companies with strong intellectual property portfolios to fend off competition from generic drugs and to demonstrate the lack of a dominant position in future cases involving allegations of abuse of dominance.

The AstraZeneca case is also part of a much broader action of the Commission against the pharmaceutical sector. As part of its pharmaceutical sector inquiry carried out in 2008, the Commission accuses pharmaceutical companies of engaging in anticompetitive behaviour by preventing generic drugs from reaching consumers.[2] As a result of the inquiry, companies such as AstraZeneca, Pfizer, Wyeth, Sanofi-Aventis,

[1] Case C-457/10 P, *AstraZeneca AB and AstraZeneca plc v European Commission* [2012], (CJEU, 6 Dec 2012).
[2] See Commission Communication, "Pharmaceutical Sector Inquiry Final Report, Part I" (8 July 2009); see also, Commission Communication, "Executive Summary of the Pharmaceutical Sector Inquiry Report" (8 July 2009).

GlaxoSmithKline, Novartis, Johnson & Johnson, Servier and Lundbeck have been subject to antitrust investigations.

This article focuses on a question which left both the competition and intellectual property community uncertain for a long time and on which the CJEU finally decided, also for the first time: the question how the patent strategies pursued by AstraZeneca could be considered a violation of competition law, and more particularly, an abuse of dominance.

2. FACTS

AstraZeneca is a global innovation-driven biopharmaceutical company specializing in the discovery, development, manufacturing and marketing of prescription medicines. One of the blockbusters marketed by AstraZeneca is an anti-ulcer drug known as Losec.[3]

2.1 Antecedents of the CJEU judgment

The AstraZeneca case covers a period of twenty years. The alleged abusive activities occurred between 1993 and 2000. In 1999, generic companies made complaints to the Commission. In 2000, the Commission raided AstraZeneca. On 15 June 2005, the Commission published its decision[4] that AstraZeneca held a dominant position and that AstraZeneca had abused this position by engaging in the patent and regulatory strategies mentioned further below[5] in order to block generic competition to its Losec drug. The Commission imposed a fine of EUR 60 million on AstraZeneca for its abusive conduct. AstraZeneca appealed against the Commission's 2005 decision before the GC. The GC's judgment of 1 July 2010[6] upheld a substantial part of the Commission's actions but reduced the Commission's fine to EUR 52,5 million.[7] AstraZeneca lodged an appeal against the GC judgment. On 15 May 2012, the Advocate General delivered his Opinion and on 6 December 2012, the CJEU dismissed AstraZeneca's appeal and the cross-appeals lodged by the European Federation of Pharmaceutical Industries Associations ("EFPIA") against the GC's judgment.

2.2 Concerned strategies

AstraZeneca adopted two strategies to protect Losec against the erosion of profits due to generic competition and parallel trade. First, AstraZeneca applied to patent offices of several Member States for extensions of the patent protection for Losec (2.2.1). Second, AstraZeneca introduced a tablet form of Losec, took the original capsule form of Losec off the market and withdrew the marketing authorisation for that original version (2.2.2).

2.2.1 Patent protection extensions for Losec

The applicable pharmaceutical regime allows a pharmaceutical company to obtain a Supplementary Protection Certificate ("SPC"). An SPC is a unique (sui generis) intellectual property right that enters into force after expiry of a patent upon which it is based. This right gives a pharmaceutical company up to five extra years of patent protection as of the first marketing authorisation, as a compensation for the long delays that can occur between the filing of a patent for a drug and the grant of the marketing authorisation to market that drug. In short, SPCs extend the monopoly period for certain products that are protected by a patent.

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[3] See AstraZeneca's website, available at http://www.astrazeneca.com.
[4] Commission Decision C(2005) 1757 of 15 June 2005 (Case COMP/A.37.507/F3 - AstraZeneca).
[5] See under 2.2.
[6] Case T-321/05 *AstraZeneca v Commission* [2010] ECR II-2805.
[7] The GC reduced the fine because it found that the Commission had not established that deregistration of the marketing authorisations was capable of preventing parallel imports in Denmark and Norway.

Under the applicable EU regulation[8], the supplementary patent protection begins on the date of "*the first authorisation to place the product on the market*". At the time that AstraZeneca engaged in its strategy of patent protection extension through SPCs, the meaning of this phrase was ambiguous. The common interpretation of the phrase was that it referred to the date on which the national authority granted the authorisation. However, AstraZeneca adopted another interpretation. It did not consider the date on which the national authority granted the authorisation as the correct date because there remained various administrative steps that had to be taken before the product could actually be placed on the market. Accordingly, AstraZeneca took the position that the relevant date was the first date when all administrative steps had been completed and the marketing authorisation actually became effective, which was the date when the national government approved the price of the product. In other words, AstraZeneca adopted an interpretation of the regulation that meant that the SPC would begin later, which meant a longer period of exclusivity. AstraZeneca applied for the SPCs, put forward its application on different bases to different authorities and failed to explain that certain submissions in its applications were premised on the particular interpretation of the ambiguous provision in the regulation[9]. Some of the authorities had therefore granted the rights in error. AstraZeneca delayed generic competitors to enter the market because a generic drug manufacturer cannot launch a generic version of a medicine until the patent protection on the active ingredient has expired.

2.2.2 Withdrawal of marketing authorisations for capsule versions of Losec

The second strategy related to AstraZeneca's exercise of a legal right to withdraw marketing authorisations relating to certain medicinal products and to stop selling those products in certain Member States. The exercise of these rights of withdrawal made it more difficult for rivals to introduce generic alternative medicines to compete with AstraZeneca's products.

AstraZeneca took the original capsule form of Losec off the market in several countries and introduced a tablet form of Losec. A tablet could be dissolved in water and was said to be easier to take for patients who had trouble to swallow pills. Accordingly, AstraZeneca withdrew the marketing authorisation for the original capsule version in Denmark, Norway and Sweden. By doing this, AstraZeneca made it more difficult for generic competitors to enter the market once the patent protection on the capsule version expired because generic competitors could no longer rely on AstraZeneca's clinical trial data on its original capsule version, to obtain their own marketing authorisation. Indeed, under the regulatory regime applicable at the time of AstraZeneca's conduct in question, generic manufacturers could only avail of an abridged marketing authorisations procedure where the related innovative product was still the subject of a valid marketing authorisation. AstraZeneca's actions also prevented parallel imports of the Losec capsules from low-price Member States into Member States that required that a marketing authorisation for the imported product be in force.

3. THE CJEU JUDGMENT

This chapter analyses how the CJEU, following the Commission and the GC, applied the concept of abuse to the two concerned strategies set out above and for which AstraZeneca was accused of having violated Article 102 of the Treaty on the Functioning of the

[8] Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, amended several times and repealed by Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products.

[9] AstraZeneca's interpretation was later held to be incorrect in unrelated proceedings. See Case C-127/00, *Hässle AB v Ratiopharm GmbH*, [2003] ECR I-14781.

European Union ("TFEU"). Article 102 TFEU prohibits any abuse by one or more undertakings of a dominant position within the internal market or in a substantial part of it.[10] This chapter does not elaborate on the analysis of the market definition and touches only briefly upon the analysis of AstraZeneca's dominant position. However, market dominance is a requirement for competition law enforcers to prove an infringement, so the requirement has to be taken into account.

3.1 The Commission's key allegations on AstraZeneca's abuse

3.1.1 AstraZeneca's dominant position

A dominant position is a situation where the economic power of a company allows it to hinder the maintenance of effective competition in the relevant market by having the ability to operate to an appreciable extent independently of its competitors, customers and ultimately consumers. As a general rule of thumb, a company is unlikely to be dominant if it has a market share of less than 40%. For these purposes it is necessary to define the relevant product market as well as the relevant geographic market (which may be EU-wide, national or even local, depending on the facts). Holding a dominant position is not in itself unlawful but dominant undertakings have a special responsibility to behave in a way which does not damage or hinder the development of competition.

The Commission and the European courts have to consider the unique circumstances of each case when they assess a dominant position. To find market power, they have to carefully analyze market shares, barriers of entry and buyer power. Patents play an important role in the assessment of the market power of companies but holding strong patents in itself does not prove market dominance[11].

The Commission found a number of factors that indicated AstraZeneca's dominance in the relevant market of oral prescription proton pump inhibitors (PPIs). AstraZeneca had high market shares over the relevant period of abuse in a number of national markets for PPIs. AstraZeneca had also strong intellectual property rights for the active ingredient in Losec, which was the first and the most expensive PPI. The patent protection eventually gave AstraZeneca the power to control the generic market entry.

3.1.2 AstraZeneca's abuses of its dominant position

The concept of abuse is an objective concept relating to the behaviour of an undertaking in a dominant position which is such as to influence the structure of a market where, as a result of the very presence of the undertaking in question, the degree of competition is weakened and which, through recourse to methods different from those which condition normal competition in products or services on the basis of the transactions of commercial operators, has the effect of hindering the maintenance of the degree of competition still existing in the market or the growth of that competition.[12]

In its 2005 decision, the Commission had made two key allegations of abuse. The GC and the CJEU affirmed that AstraZeneca had abused its dominant position by engaging in the two strategies mentioned above, respectively the patent protection extensions through SPCs for Losec and the withdrawal of marketing authorisations for capsule versions of Losec. AstraZeneca's abuses were particularly found in artificially maintaining market

[10] Article 102 TFEU states that "any abuse by one more undertakings of a dominant position within the common market or in a substantial part of it shall be prohibited as incompatible with the common market in so far as it may affect trade between Member States".

[11] This has been recognized by the European Courts for a long time. See joined Cases C-241/91 P and C-242/91 P *RTE and ITP v Commission* [1995] ECR I-743, para. 46 ("So far as dominant position is concerned, it is to be remembered at the outset that mere ownership of an intellectual property right cannot confer such a position.").

[12] Case 85/76, *Hoffmann-La Roche & Co. AG v Commission*, [1979] ECR 461, recital 91.

dominance by extending the term of patent protection through the fraudulent acquisition of SPCs (3.2.1) and by excluding generic competition through a deregistration strategy to prevent or delay generic manufacturers' capability to obtain marketing authorisation (3.2.2).

3.1.2.1 First abuse: fraudulent acquisition of SPCs

In 1993 and 1994, AstraZeneca submitted applications to a number of national patent offices in order to obtain SPCs for the active ingredient in Losec[13]. The first abuse was that AstraZeneca deliberately made misleading misrepresentations to patent offices or national courts in Belgium, Denmark, Germany, the Netherlands, Norway and the United Kingdom concerning the dates when marketing authorisations were obtained, in an attempt to extend the term of patent protection for Losec by securing SPCs which AstraZeneca was not entitled to, or which it was entitled to for a shorter period. Not all of the patent offices concerned identified that the information was inaccurate. The Commission found that AstraZeneca's misleading representations were designed to delay the entry to the market of competitors creating generic versions of Losec.

3.1.2.2 Second abuse: misuse of the deregistration procedure

The second abuse concerned AstraZeneca's strategy of withdrawing marketing authorisations for Losec capsules in Denmark, Sweden and Norway combined with the launch of a tablet version. The Commission concluded that AstraZeneca misused the procedure governing the deregistration of marketing authorisations and that its overall aim was to prevent or delay the market entry of generic products and to obstruct parallel trade in Losec capsules, by extending the market exclusivity of Losec.

3.2 The GC judgment on AstraZeneca's abuse

The GC judgment largely upheld the Commission decision that AstraZeneca abused its dominant position, contrary to Article 102 TFEU.[14] The GC judgment outlined certain principles relevant to when conduct may be considered as abusive under Article 102 TFEU (3.2.1.) and then applied them to the factual specifics (3.2.2.). Those statements are very pertinent to other practices of potentially dominant companies in the pharmaceutical sector. The judgment may assist generic manufacturers challenging certain patent strategies of originator companies.

3.2.1 The GC's general Article 102 TFEU principles on abuse

The GC judgment outlined the following general Article 102 TFEU principles on abuse:

- A dominant company has a "special responsibility" not to impair, by conduct falling outside the scope of competition on the merits, genuine undistorted competition in the EU.[15]
- A dominant company may not engage in conduct which eliminates a competitor and thereby strengthen its dominant position by using methods other than those which come within the scope of competition on the merits.[16]
- A dominant company can legitimately seek to minimise erosion of sales of its products when challenged by a competitor. However, unless there is objective justification for doing so, an undertaking in a dominant position cannot use regulatory procedures solely in such a way as to prevent or make more

[13] See under 2.2.1 above for AstraZeneca's patent strategy and in particular for its interpretation on the date of "the first authorisation to place the product on the market".

[14] Nevertheless and as said above, the GC reduced the Commission's fine of EUR 60 million to EUR 52,5 million finding that the Commission had failed to prove that the deregistration of the marketing authorisations was capable of preventing parallel imports in Denmark and Norway.

[15] See paras 355-361 GC judgment.

[16] See para. 354 GC judgment.

difficult the entry of competitors on the market unless it amounts to legitimate competition on the merits.[17]

- Behaviour can be abusive even if it is designed to protect an investment previously made by the dominant company, if that behaviour does not come within the scope of competition on the merits.[18]
- Conduct by a dominant company can be abusive when it is undertaken even if the anti-competitive effects of that conduct do not arise until later, or if by the time those effects arise the company has ceased to be dominant.[19]
- Behaviour can be deemed abusive for the purposes of Article 102 TFEU even if it is not prohibited by other rules or legislation.[20]

3.2.2 The GC's application of the Article 102 TFEU principles on abuse to the facts

The GC applied those general Article 102 TFEU principles on abuse to AstraZeneca's above-mentioned first and second abuse of patent and regulatory strategies.

3.2.2.1 On the first abuse: fraudulent acquisition of SPCs

The GC considered that the submission to the public authorities of misleading information that was liable to lead them into error and therefore to make possible the grant of an exclusive right to which AstraZeneca was not entitled, or to which it was entitled to for only a shorter period, constituted a practice falling outside the scope of competition on the merits. The GC found that such conduct is not in keeping with the *special responsibility* of an undertaking in a dominant position not to impair, by conduct falling outside the scope of competition on the merits, genuine undistorted competition in the common market. The GC held that in so far as an undertaking in a dominant position is granted an unlawful exclusive right as a result of an error by it in a communication with public authorities, its special responsibility requires it, at the very least, to inform the public authorities of this so as enable them to rectify those irregularities. In this context, the GC held that if the dominant company fails to inform those authorities, the fact of its holding of that exclusive right can in itself be abusive and the conduct would be abusive even if the public authority later revoked those rights.

AstraZeneca claimed that an abuse of a dominant position can be identified only where the behaviour in question has a direct effect on competition and that, in this case, the unlawful SPC applications had only remote effects on competition. However, the GC stated that AstraZeneca's behaviour could be regarded as an abuse of a dominant position even though it did not have a direct effect on competition. It was sufficient that competition may be restricted indirectly, provided that it is shown to the requisite legal standard that the practices in question are actually liable to restrict competition.

3.2.2.2 On the second abuse: misuse of the deregistration procedure

The GC stated that a dominant company is entitled to take steps to protect its own commercial interests when challenged by a competitor, provided that the company uses methods that come within the scope of competition on the merits.

However, in this case the GC found that AstraZeneca's deregistration of the Losec capsule marketing authorisations was not based on the legitimate protection of an investment designed to contribute to competition on the merits. The GC held that AstraZeneca had engaged in conduct in order to delay or prevent the market entry of

[17] See para. 804 GC judgment.
[18] See paras 669-670, 674-677, 812, 829, 831 GC judgment.
[19] See paras 376-377, 380 GC judgment.
[20] See para. 677 GC judgment.

generic products and parallel imports. As such, the GC held that AstraZeneca had misused the regulatory procedures and its actions did not constitute competition on the merits.

3.3 The CJEU judgment on AstraZeneca's abuse

As set out above, the CJEU dismissed AstraZeneca's appeal and the cross-appeals lodged by the EFPIA. The CJEU followed the Advocate General's Opinion and the GC's decision upholding that the fine imposed on AstraZeneca for misleading patent offices and deregistering marketing authorisations in order to block generic competition to its Losec drug was correct.

3.3.1 On the first abuse: fraudulent acquisition of SPCs

AstraZeneca had argued that the GC's approach to competition on the merits was legally flawed and that a mere application for an SPC was insufficient to constitute an abuse. Thus, AstraZeneca argued that the GC's assessment of whether its representations to the patent offices were objectively misleading failed to consider the reasonableness and alleged good faith of AstraZeneca's interpretation of the SPC Regulation, which introduced the use of SPCs for medicinal products. In addition, EFPIA argued as part of its cross-appeal that an "objectively misleading" representation requires a representation to be "objectively wrong" as otherwise even unintentional errors would constitute an abuse. As regards its argument that a mere SPC application is insufficient to constitute an abuse, AstraZeneca argued that this also required an assessment of whether competition was affected or whether the conduct in question had a tendency to restrict competition.

The CJEU dismissed this ground of appeal on the basis of the following conclusions:

- The concept of an abuse is an objective one and Article 102 TFEU prohibits methods employed by a dominant undertaking other than those which come within the scope of competition on the merits.[21]
- AstraZeneca's conduct was characterised by highly misleading representations to various patent offices and courts and a manifest lack of transparency. It deliberately attempted to mislead the relevant authorities to secure exclusivity for as long as possible. The onus was on AstraZeneca to disclose all relevant information to the patent authorities. Therefore, AstraZeneca's conduct fell outside the scope of competition on the merits and also discredited any of its good faith claims.[22]
- As regards EFPIA's argument, the GC did not find that dominant undertakings have to be infallible in their conduct and/or that a misrepresentation made unintentionally and later rectified constitutes an abuse. The CJEU made clear that it cannot be inferred that any patent application that does not meet the patentability criteria automatically constitutes an abuse. This requires an assessment of the facts.[23]
- AstraZeneca's mere act of making an SPC application constituted an abuse in itself. Nevertheless, the CJEU also noted that representations made to obtain exclusive rights unlawfully only constitute an abuse if they are actually liable to result in the grant of the exclusive right.[24]
- Unlawfully obtained SPCs lead to a significant exclusionary effect after the expiry of the basic patent and to a change in the market structure by affecting potential competition even before that expiry. The existence of an abuse is not

[21] See para. 74 CJEU judgment.
[22] See para. 95 CJEU judgment.
[23] See para. 99 CJEU judgment.
[24] See para. 106 CJEU judgment.

affected by the fact that a dominant company's strategy may not ultimately be successful.[25]

- Finally, the anti-competitive effect required for the finding of an abuse does not need to be concrete. A demonstration of potential anti-competitive effects is sufficient.[26]

Therefore, the CJEU dismissed AstraZeneca's appeal in relation to the fraudulent acquisition of SPCs.

3.3.2 On the second abuse: misuse of the deregistration procedure

AstraZeneca argued that the GC's approach to competition on the merits was legally flawed in considering that the mere exercise of a right conferred upon an undertaking by EU law was incompatible with competition on the merits. In addition, it argued that the exercise of such lawful rights can only amount to an abuse in exceptional circumstances; a tendency to restrict competition however was not sufficient.

The CJEU dismissed this ground of appeal on the basis of the following conclusions:

- A dominant undertaking's competitive strategy is legitimate and part of the normal competitive process provided the conduct does not depart from practices coming within the scope of competition on the merits, which is such as to benefit consumers.[27]
- Deregistration without objective justification and after the expiry of the exclusive right to make use of the results of pharmacological and toxicological tests and clinical trials in order to hinder generic market entry and parallel imports does not come within the scope of competition on the merits. AstraZeneca could not base its conduct on the legitimate protection of its investment because it no longer had the right to make use of such results.[28]
- It is irrelevant that AstraZeneca was legally entitled to withdraw the marketing authorisations. It should be noted that the abuse of a dominant position is unrelated to its compliance or non-compliance with other legal rules. Rather, a dominant undertaking has a special responsibility to use regulatory procedures in ways that do not prevent generic entry. Thus, the obligations set out in Article 102 TFEU are not displaced by other legal rules.[29]
- Onerous pharmacological vigilance obligations can constitute an objective justification for the deregistration of a marketing authorisation. However, AstraZeneca failed to demonstrate that the additional burden of such an obligation would have been so significant as to constitute an objective justification. The CJEU highlighted that these arguments were never mentioned in AstraZeneca's internal documents about its commercial strategy, which in turn made it doubtful that the deregistration was indeed based on such considerations.[30]

[25] See para. 108 CJEU judgment.
[26] See para. 112 CJEU judgment.
[27] See para. 129 CJEU judgment.
[28] See paras 130-131 CJEU judgment.
[29] See para. 132 CJEU judgment.
[30] See para. 135 CJEU judgment.

- It was the act of the deregistration alone, without any objective justification, that was liable to produce anti-competitive effects and thus constituted the abuse of AstraZeneca's dominant position.[31]
- AstraZeneca's analogy to the IMS Health case[32] and the use of compulsory licences was misplaced. The possibility of deregistering a marketing authorisation is not equivalent to a property right. The obligation of a dominant undertaking does not constitute an "effective expropriation" of a right or an obligation to grant a licence.[33]
- The GC did not err in holding that, for the purposes of the assessment of the existence of an abuse, it was sufficient to demonstrate that the conduct is such as to restrict competition and, in particular, restrict generic market entry and to prevent parallel imports. The GC had also not erred in ascertaining that the Commission had actually proven this.[34]

Therefore, the CJEU dismissed AstraZeneca's appeal in relation to the misuse of the deregistration procedure.

4. IMPLICATIONS OF THE CJEU JUDGMENT

The rather severe tone of the CJEU judgment when describing the facts underlying the abuse of the fraudulent acquisition of SPCs has the effect of narrowing the judgment in terms of precedent value. It is only a dominant company which makes "*highly* misleading representations with the aim of leading public authorities into error" which should have to fear this judgment.

On the other hand, the abuse in respect of the misuse of the deregistration procedure could potentially have wider implications. Given that the rules have changed in the pharmaceutical sector such as to prevent a repeat of the facts of the AstraZeneca case, the real implications of the CJEU judgment could come in other regulated sectors where follow-on entrants seek to make use of a regulatory dossier of an earlier entrant.

5. LESSONS FOR DOMINANT PHARMACEUTICAL COMPANIES

The CJEU judgment was long-awaited for any guidance on what dominant companies can and cannot do, particularly in respect of the enforcement of patent rights and especially in the pharmaceutical industry. The AstraZeneca case is significant for how broadly the concept of an abuse can be defined and is an example of the legal risks for dominant companies in knowing how far they can respond to the threat of a new entry.

However, the CJEU's findings were based on what was arguably an unhelpful set of facts. As said, only dominant companies which make *highly* misleading representations with the aim of leading public authorities into error should have to fear this judgment and should carefully analyze their patent strategies of successful drugs against this judgment.

In particular, as far as patent strategies are concerned, dominant companies need to take particular care when providing information to a public authority if that information may lead to the dominant company receiving exclusive rights, or potentially other material commercial benefits, against competitors. It may be abusive conduct contrary to Article 102 TFEU if the dominant company provides (even if it does not intend to do so) information that is materially incorrect or misleading. If the dominant company should subsequently discover that the information provided, and on the basis of which those rights or benefits were conferred by the authority, is materially inaccurate, the company

[31] See para. 140 CJEU judgment.
[32] Case C-418/01 *IMS Health* [2004] ECR I-5039.
[33] See para. 148 CJEU judgment.
[34] See paras 153-154 CJEU judgment.

is expected proactively to contact the authority and correct the misunderstanding. If the dominant company fails to do so, that may be abusive conduct contrary to Article 102 TFEU.

6. CONCLUSION

The AstraZeneca case was the first time that the CJEU ruled on the application of Article 102 TFEU in the pharmaceutical sector. The CJEU endorses the Commission's strict treatment of manufacturers of medicinal products that seek to prevent generic entry.

In particular, the AstraZeneca case confirms that conduct in the course of patent strategies and regulatory procedures may constitute abuse. The abuse in this case was based on what the CJEU qualified as AstraZeneca's highly misleading representations to patent offices and AstraZeneca's manifest lack of transparency, which led these authorities wrongly to grant AstraZeneca exclusive rights.

The AstraZeneca case is significant for how broadly the concept of an abuse can be defined and is an example of the legal risks for dominant companies in knowing how far they can respond to the threat of a new entry. The case serves as a reminder of the need for dominant companies to ensure compliance with their special responsibility when determining their commercial strategies in relation to generic market entry.

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TiGenix NV (NYSE Euronext: TIG) is a leading European cell therapy company with a commercial product and a strong clinical stage pipeline of adult stem cell programmes.