ACM Working Paper

Reconciling competition and IP law: the case of patented pharmaceuticals and dominance abuse

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1. Introduction

Both practitioners and academics are generally cautious of applying EU competition law to patented products such as pharmaceuticals. There is however growing evidence that the enforcement of competition law in a patent context can both be justified and carried out in a manner that is compatible with IP law. Below, we will discuss how competition law may be applied with regard to abuses of dominance involving patented pharmaceuticals. We argue that the pay for delay cases in both the US and the EU are only the first step in exploring the application of competition law to such products. In doing so we will examine, first, abuse of the patent system with the aim to exclude competitors and second, exploitation of consumers in cases where price constraints are very weak – excessive prices.

Key to our argument is the assumption that IP law does not bar the application of competition law, but that competition law can and should be applied in such a way that it takes the goals of patent/IP law into account. The corollary of this assumption is that IP rights should be exercised in such a way that the competition rules are respected. We will provide support for this approach with examples drawn from various competition authorities in the EU including our own practice in the Netherlands.[2]

2. Initial reading of the problem and proposed solution

At face value, competition law with its focus on the threat presented by market power and intellectual property rights that aim to create at least temporary legal monopolies are logically at loggerheads. It is worth recalling, however, that in the vast majority of cases IP rights do not create dominant positions and are therefore inherently not

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[2] For a comprehensive collection of papers on the topic see Giovanni Pitruzella and Gabriella Muscolo (eds), *Competition and patent law in the pharmaceutical sector: An international perspective* (Kluwer Law International, Alphen aan den Rijn 2016).

problematic in this sense. This is because the scope of an IP based monopoly to produce a particular product, does not by definition coincide with a relevant market. When competition law is applied, the relevant market is normally the context for analysing the stringency of the competitive constraints involved: it may be the case that within such a relevant market, several IP protected products (and indeed non IP protected products as well) compete effectively, so there need not be dominance concerns.

Moreover neither the nature nor the exercise of IP rights is absolute. As with all forms of property other legal rules continue to apply and coexist with IP rights. Such rights do not therefore amount to an absolute, 'licence to kill'. They merely facilitate the exclusive manufacture or control over product manufacture within the scope of the patent. They also allow the rights holder not to use the patent to produce any product at all as apparently occurs in a majority of cases.[3] Like any other manufacturer IP holders may determine their prices freely but within the applicable legal framework. Hence where they exist, national pricing policies for instance, such as maximum prices for certain products, continue to apply.

3. Arguments for addressing pharmaceuticals

Market context

In our view the above holds for the EU law on dominance abuse as well, including the prohibition on excessive pricing. This is all the more obvious if the test that is applied to abuse in this context reflects the economic essence of IP law by taking into account the incentives to innovate. We want to elaborate this point for the pharmaceuticals sector because the tension between abuse of dominance and IP is especially relevant there for several reasons:

- Firstly patent and additional IP (such as supplementary protection certificates, orphan status, pediatric extension and data exclusivity)[4] protection in

[3] Alireza Chavosh, 'Patent Nonuse: Are Patent Pools a Possible Solution?' (Dissertation thesis, Università di Bologna 2015), available at <https://ssrn.com/abstract=2998474>. See also Herbert Hovenkamp and Mark Lemley, *IP and Antitrust: An analysis of Antitrust Principles Applied to Intellectual Property Law* (3rd edn, Wolters Kluwer 2016) paragraph 14.04 and Oskar Liivak and Eduardo Peñalver, 'The Right Not to Use in Property and Patent Law' (2013) 98 Cornell Law Review. Also compare Case 241/91P and 242/91P *Magill* EU:C:1995:98 and Case C-418/01 *IMS Health* EU:C:2004:257.

[4] These have their legal bases in respectively Regulation (EC) 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products [2009] OJ L152/1; Regulation (EC) 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products [2000] OJ L18/1; Regulation (EC) 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use [2006] OJ L378/1; Regulation (EC) 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency and Directive (EC) 2001/83 of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [2001] OJ L311/67 as amended by Directive (EC) 2004/27 of the

pharmaceuticals is strong because pharmaceuticals are relatively easy to protect effectively as they consist of precisely defined effective substances.

- Second the current model of innovation in the pharmaceuticals sector (unlike other sectors such as software) is heavily dependent on IP rights as other models such as funds, grants and prizes have so far not had significant traction (possibly with the exception of vaccines).

Arguably as a result of this strong and central role of IP dominant positions are created relatively frequently in this sector (until generics or bio-similars can enter the market effectively). Because in addition prices for new pharmaceuticals throughout the EU have increased remarkably over the recent years,[5] this raises the question whether this may amount to exploitation of a dominant position. For these reasons the pharmaceuticals sector is also relevant for policy makers in the Netherlands and elsewhere. Therefore we believe that a short inquiry into the relevance of the abuse of dominance test in this sector, notably in relation to exploitation, is pertinent.

Academic theory

Academic economists and lawyers have traditionally pointed out the risk of applying dominance abuse prohibition to patented products in general and pharmaceuticals in particular. Further strictures within dominance abuse regard excessive pricing.[6] A good

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European Parliament and of the Council of 31 March 2004 [2004] OJ L136/34.

[5] The Dutch Healthcare Institute publishes future medicine registrations and expected costs on <https://www.horizonscangeneesmiddelen.nl/geneesmiddelen>, which shows that many future medicines will cost approximately €100.000 per patient per year. Some medicines will even cost several hundreds of thousands euros per patient per year. See also Sabine Vogler, 'Challenges and opportunities for pharmaceutical pricing and reimbursement policies' (2015) 8 Journal of Pharmaceutical Policy and Practice; Giuseppe Garone, 'Cost-containment policies in public pharmaceutical spending in the EU', available at <http://ec.europa.eu/economy_finance/publications/economic_paper/2012/pdf/ecp_461_en.pdf> accessed 11 January 2018 and Sabine Vogler, 'Study on enhanced cross-country coordination in the area of pharmaceutical product pricing', available at <https://ec.europa.eu/health//sites/health/files/systems_performance_assessment/docs/pharmaproductpricing_frep_en.pdf> accessed 11 January 2018.

[6] David S Evans and A Jorge Padilla, 'Excessive Prices: Using Economics to Define Administrative Legal Rules' (2005) 1 Journal of Competition Law and Economics 97-122; Amelia Fletcher and Alina Jardine, 'Towards an Appropriate Policy for Excessive Pricing' in Claus-Dieter Ehlermann and Mel Marquis (eds), *European Competition Law Annual 2007: A Reformed Approach to Article 82 EC* (Hart 2008); Emil Paulis, 'Article 82 and Exploitative Conduct', in Claus-Dieter Ehlermann and Mel Marquis (eds), *European Competition Law Annual 2007: A Reformed Approach to Article 82 EC* (Hart 2008) 515-524; Lars-Hendrik Röller, 'Exploitative Abuses' in Claus-Dieter Ehlermann and Mel Marquis (eds), *European competition law annual 2007: A reformed approach to article 82 EC* (Hart 2008) 525–532; Claudio Calcagno and Mike Walker, 'Excessive Pricing: Towards Clarity and Economic Coherence' (2010) 6 Journal of Competition Law and Economics 891-910; Pinar Akman and Luke Garrod, 'When are Excessive Prices Unfair?' (2011) 7 Journal of Competition Law and Economics 403-426; Liyang Hou, 'Excessive Prices Within EU Competition Law' (2011) 7 European Competition Journal 47-70; OECD, 'Excessive prices' (OECD, 7 February 2012) 23-82 <http://www.oecd.org/competition/abuse/49604207.pdf> accessed 10 November 2017; Robert

example of this are former DG Competition Chief economist Motta and his lawyer co-author De Streel (2006-7).[7] The application of excessive pricing has been referred to as a messy and difficult business by Calagno and Walker (2010),[8] and in the literature we find different positions on the practical application of Article 102 TFEU to excessive pricing. O'Donoghue and Padilla (2013)[9] take the position that excessive pricing should be restricted to situations where investment and innovation play a minor role. Again Motta and De Streel argue that IPR protects desirable investment and that applying excessive pricing rules would undermine the essential objective of IP rights.[10]

Other contributions to the debate such as Paulis (2007-8)[11] and Liyang (2011)[12] however do not subscribe to such views and consequent limitations of competition law. There is moreover a growing literature that shows the enforcement of competition law in a patent context may both be justified and compatible with IP law,[13] even in an excessive pricing context.[14] In fact Abbott (2016) has argued that precisely in order to address endemic problems relating to pharmaceutical prices, the US should adopt an excessive pricing instrument (which it does not currently have) as part of its antitrust toolbox. Having taken note of this literature, albeit in broad strokes, we will now focus on the role competition law may play in practice regarding abuses of dominance involving unpatented and patented pharmaceuticals. This reflects our insights based on the EU case law and the decisions of NCAs in the UK, Italy and France and the Netherlands.

4. The case law on dominance regarding IP protected pharmaceuticals

The basic distinction with regard to abuse of dominance cases is that between, first, exclusion of competitors, and second, exploitation of consumers, notably excessive pricing. Although we believe our contribution is most relevant with regard to the latter, we will also cover the former category here in order to provide a more general background and context.

O'Donoghue and A Jorge Padilla, *The Law and Economics of Article 102 TFEU* (Hart 2013); Frederik M Abbott, 'Excessive pharmaceutical prices and competition law: doctrinal development to protect public health' (2016) 6 UC Irvine Law Review 281-320.

[7] Massimo Motta and Alexandre de Streel, 'Exploitative and exclusionary excessive prices in EU law' in Claus-Dieter Ehlermann and Isabela Anastasiu (eds), *European Competition Law Annual 2003: What Is an Abuse of a Dominant Position?* (Hart 2006); Massimo Motta and Alexandre de Streel, 'Excessive Pricing in Competition Law: Never say Never?' in Swedish Competition Authority (ed), *The Pros and Cons of High Prices* (Stockholm 2007) 14-46.

[8] Calcagno and Walker (n7).

[9] O'Donoghue and Padilla (n7).

[10] Motta and de Streel (n7).

[11] Paulis (n7).

[12] Liyang (n7).

[13] Cf Christina Bohannan and Herbert Hovenkamp, *Creation without restraint: promoting liberty and rivalry in innovation* (Oxford University Press 2012).

[14] Cf Abbott (n7).

Exclusion cases

This is the category of abuse of dominance cases that the Commission has prioritised from the outset and in particular in its 2009 Guidance paper.[15] Below we will take a look at the relevant antitrust case law, first in relation to the founding pharmaceuticals cases, which primarily regarded restrictions on parallel trade. Next we deal with the recent application of Article 101 and 102 TFEU in the setting of pay for delay, and 102 TFEU with regard to abuse of patent. [16]

IP cases and parallel trade

Fifty years ago, in the *Parke, Davis* case of 1968, the Court held that IP rights in themselves could not form an infringement of EU competition law (regarding an abuse of dominance as well as an anticompetitive agreement), but abuse of such rights could:

> Although a patent confers on its holder a special protection at national level, it does not follow that the exercise of the rights thus conferred implies the presence together of all three elements in question [dominance, abuse and an effect on trade]. It could only do so if the use of the patent were to degenerate into an abuse of the abovementioned protection.[17]

In the 1974 *Centrafarm* case (on using patents to block parallel trade in pharmaceuticals) the Court went further by stating that although the existence of an IP right as such cannot constitute an infringement, its exercise can:

> In relation to patents, the specific subject matter of the industrial property is the guarantee that the patentee, to reward the creative effort of the inventor, has the exclusive right to use an invention with a view to manufacturing industrial products and putting them into circulation for the first time, either directly or by the grant of licences to third parties, as well as the right to oppose infringements.
>
> Although the existence of rights recognized under the industrial property legislation of a Member State is not affected by Article 85 of the Treaty, the conditions under which those rights may be exercised may nevertheless fall within the prohibitions contained in that Article.[18]

In our view these principles on the relationship between IP and competition law have

[15] Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings [2009] OJ C45/7.
[16] Cf Leigh Hancher and Wolf Sauter, 'A dose of competition: EU antitrust law in pharmaceuticals' (2016) 4 Journal of Antitrust Enforcement 381-410.
[17] Case 24/67 *Parke, Davis and Co v Probel, Reese, Beintema-Interpharm and Centrafarm* EU:C:1968:11.
[18] Case 15/74 *Centrafarm BV and Adriaan de Peijper v Sterling Drug Inc* EU:C:1974:114, paras 9, 39.

not been substantially altered in subsequent cases on parallel trade. This notwithstanding the fact that in an unrelated development the Court's view on the merits of price-discrimination (and therefore implicitly of barriers on parallel trade) has arguably become more positive.[19]

Pay for delay

These cases primarily concerned anticompetitive agreements to delay market entry of generic competitors (who copy existing products) to originator companies (who develop new products), which paid so-called reverse settlements in patent suits. In such cases generally the actual applicability of IP rights is contested. Normally the allegedly infringing undertaking and not the patent holder would be expected to pay for a settlement. Additional elements are the existence of potential competitors and a delay in the marketing of competing products. Such reverse payments are therefore an important but not sufficient condition for a finding collusion. Eventually it is the consumers who had to forgo the possibility of purchasing generic products at competitive prices foot the bill for this. Pay for delay cases were found both in the US and more recently at EU level, where the Commission adopted the Lundbeck (2013), Fentanyl (2013) and Servier (2014) Decisions.[20]

In its Lundbeck Decision the Commission explicitly asserted that it was possible for an undertaking to infringe the competition rules by means of a restrictive agreement within the scope for a patent. This was confirmed by the General Court on appeal in 2016:

> [E]ven if the agreements at issue had not gone beyond the scope of the applicants' patents, those agreements would nevertheless have constituted restrictions on competition by object for the purpose of Article 101(1) TFEU, since they consisted in agreements intended to delay the market entry of generic undertakings, in exchange for significant reverse payments (…), which transformed the uncertainty in relation to that market entry into the certainty that it would not take place during the term of the agreements at issue[21]

[19] Thus under Article 102 TFEU see Joined Cases C-468/06 to C-478/06 *Sot. Lélos kai Sia EE and Others v GlaxoSmithKline AEVE Farmakeftikon Proïonton, formerly Glaxowellcome AEVE* EU:C:2008:504. However with regard to Article 101 TFEU see Joined Cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P *GlaxoSmithKline Services Unlimited v Commission of the European Communities (C-501/06 P) and Commission of the European Communities v GlaxoSmithKline Services Unlimited (C-513/06 P) and European Association of Euro Pharmaceutical Companies (EAEPC) v Commission of the European Communities (C-515/06 P) and Asociación de exportadores españoles de productos farmacéuticos (Aseprofar) v Commission of the European Communities (C-519/06 P)* EU:C:2009:610.

[20] *Lundbeck* (Case AT.39226) Commission Decision C(2013) 3803 final of 19 June 2013; *Fentanyl* (Case AT.39685) Commission Decision C(2013) 8870 final of 10 December 2013; *Perindopril (Servier)* (Case AT.39612) Commission Decision C(2014) 4955 final of 9 July 2014.

[21] Case T-472/13 *Lundbeck v Commission* EU:T:2016:449, para 539. See Stefano Barazza, 'Pay-for-delay agreements in the EU pharmaceutical industry: Patent law and competition law in the light of Lundbeck', (2017) 1 European Pharmaceutical Law Review 3-21.

This issue is likely to be revisited in the Lundbeck further appeal before the Court of Justice as well as the appeal before the General Court against the Commission's Servier Decision, which concerned not just an anticompetitive pay for delay agreement but also an abuse of dominant position. In our view, as elaborated below, the pay for delay cases are only the first step in exploring the application of competition law to pharmaceutical products, especially regarding dominance abuse.

Exclusionary price abuses

A first example is the Dutch AstraZeneca decision of 2014.[22] There the ACM had investigated a similar fact pattern to that in the 2001 Napp case in the UK (discussed under excessive prices further below). In the Netherlands AstraZeneca combined intramural prices below cost for a patented so-called proton pump inhibitor for hospitalized patients (Nexium) with extramural prices that were many times higher for patients outside of hospitals. As a result of the low intramural prices, the hospitals often preferred the AstraZeneca product over its competitors. ACM suspected that AstraZeneca deliberately offered Nexium below cost in order to make it unattractive for (non-patented or generic) competitors to enter the market. For various reasons patients generally prefer using the same brand on which their treatment was originally started in the hospital after they return home and general practitioners are inclined to continue prescribing that brand.

ACM suspected that consequently AstraZeneca faced little competition for extramural patients who had started on Nexium in the hospital, and was thus able to charge high prices outside of hospitals. This then would allow AstraZeneca to offset its losses incurred due to the prices below costs in the hospitals. ACM initially regarded the group of extramural patients as the relevant market where AstraZeneca held a dominant position that it used to exclude its competitors. Ultimately however the ACM did not find an infringement as dominance had not been established in the intramural market.

As regards the role of IP, the hypothesis examined by ACM was that the behavior of AstraZeneca was not justified by its patent. AstraZeneca's intellectual property rights only protected it from market entry and competition by generic producers of the same active substance and even then only within the duration and scope of the patent. In the end however the ACM did not conclude on the question whether dominance abuse could be established with regard to an IP protected pharmaceutical in this case.

Abuse of patent

A second example is the abuse of the IP system itself with the aim to exclude competitors. This type of abuse has been found to exist both at EU level, notably abuse of procedure; and at national level, both regarding abuse of procedure and the denigration of generic and bio-similar products by originator undertakings. This brings

[22] *AstraZeneca* (Case 7069) ACM Decision of 24 September 2014.

us back to the category of abuses that the Court may primarily have had in mind in its 1968 *Parke, Davis* and 1974 *Centrafarm* cases that we have cited above.

In a landmark 2012 judgment the Court of Justice substantially confirmed the Commission's Decision finding abuse of IP procedures by AstraZeneca in a number of EU Member States with regard to a drug for gastrointestinal conditions.[23] This abuse involved both (i) misleading representations to patent offices in order to extend the period of patent protection by means of supplementary protection certificates (SPCs) and (ii) creating obstacles to market entry by requesting the deregistration of market authorisations in order to obstruct parallel trade as well as keeping out generic manufacturers. It is mainly the former that is of interest here.

Not the exercise of a valid IP right in itself was found abusive under the competition rules, but the fact that its starting date was knowingly misrepresented so as to claim an unwarranted duration of subsidiary IP rights. This case therefore supports our thesis that the competition rules and IP rights are active in parallel, and the existence of the latter does not bar the former from being applied. Similar strategies by Pfizer were fined by the AGCM in Italy, likewise in 2012.[24] In France, from 2013 onward the Autorité de la Concurrence has repeatedly acted against so-called denigration strategies whereby originator producers of drugs that had come off patent called into question the safety and reliability of generics – which are in fact fully functional copies of the originals.[25]

Exploitation cases

The standard for excessive pricing

We will now move on from exclusion of competitors which may harm consumers indirectly, to directly exploitative practices. Exploitation of consumers may occur in cases where price constraints are very weak. It is not the patent that is being abused to strengthen a dominant position, but the existence of a dominant position that is in large part based on IP rights that is used to exploit consumers directly. These are the so-called excessive pricing cases. As we have seen above here too the literature has been critical about the standard to be applied both in general, and in relation to pharmaceuticals in particular. However the consensus view is that although it is so far rarely applied in practice,[26] the two-pronged *United Brands* test for excessive pricing still stands. That is to say:

[23] Case C‑457/10 P *AstraZeneca AB and AstraZeneca plc v European Commission* EU:C:2012:770.
[24] Confirmed on final appeal in Consiglio di Stato of 12 February 2014 n693. Critical Damien Geradin, 'The Uncertainties Created by Relying on the Vague Competition on the Merits Standard in the Pharmaceutical Sector: The Italian Pfizer/Pharmacia case' (2014) 5 Oxford Journal of European Competition Law & Practice 334–352.
[25] One of these decisions was confirmed on final appeal in Cour de Cassation of 18 October 2016 n890, FR:CCASS:2016:CO00890.
[26] Joined Cases 110/88, 241/88 and 242/88 *Lucazeau and Others v SACEM and Others* EU:C:1989:326.

> The questions (…) to be determined are whether the difference between the costs actually incurred and the price actually charged is excessive, and, if the answer to this question is in the affirmative, whether a price has been imposed which is either unfair in itself or when compared to competing products.[27]

So (i) the excessive relationship between costs and prices and (ii) the unfair nature of the prices must be examined cumulatively. The 2017 Latvian music rights case confirms this.[28] At the same time it also shows how this test may be applied in practice. Regarding the second leg of the test, whether the prices are unfair, the Court in this case states that they must have been significantly and persistently at an anticompetitive level. However it should be noted that comparisons with competing products are not in themselves a strict requirement: *United Brands* also states that other economic methods may be used to determine whether the price of a product is unfair.

Non-patented pharmaceuticals

At national level, so far there have been infringement decisions regarding excessive pricing cases in the UK in 2001 and 2016, and in Italy in 2016. The pharmaceutical products concerned however had been (long) out of patent and enjoyed no significant IP (other than presumably trademark) protection. Hence these cases are not directly relevant for our discussion of the balance between IP and dominance abuse. As examples of exploitative abuses, however they are relevant to the final section of this paper regarding the excessive pricing dimension of IP protected pharmaceutical products.

The earliest example of a successful excessive pricing case in pharmaceuticals is the Napp case of 2001 in the UK.[29] The OFT fined Napp for excessive pricing with regard to a slow-release morphine product that was no longer patent protected. Similarly to what occurred in the Dutch AstraZenaca case discussed above, this product was charged at rates that were much higher for patients treated outside hospitals than within hospitals, where they were discounted up to 90% in order to exclude competitors. Hence this case combined exploitative and exclusionary elements. The Napp Decision was substantially upheld on appeal by the Competition Appeals Tribunal in 2002.

Fifteen years later, in 2016 the CMA imposed a record fine on Pfizer and Flynn regarding a price increase of 2.600% for an out of patent anti-epilepsy drug that largely affected a captive population.[30] Similarly in 2016 the Italian AGCM fined Aspen Pharmaceuticals for price increases of up to 1.500% for a series of blood cancer drugs that were no longer patent protected. In each of these three cases the test applied was

[27] Case 27/76 *United Brands and United Brands Continentaal v Commission* EU:C:1978:22, para 252.
[28] Case C-177/16 *Autortiesību un komunicēšanās konsultāciju aģentūra / Latvijas Autoru apvienība v Konkurences padome* EU:C:2017:689.
[29] *Napp* (Case CA98/2D/2001) OFT Decision of 4 May 2001.
[30] *Pfizer* (Case CE/9742-13) CMA Decision of 7 December 2016.

that set out in *United Brands*, described above.[31] On the latter two cases the jury is still out: at the time of our writing (in December 2017) both the UK and the Italian 2016 decisions are subject to (further) appeal.

The European Commission itself long appeared to focus exclusively on exclusion – exemplified by its abovementioned 2009 Guidance paper that has so far not seen an equivalent for exploitation. More recently this position has shifted. In a policy speech in November 2016, Commissioner Vestager cited pharmaceuticals (alongside the Russian energy monopoly Gazprom and standard essential patents) as an example where protection of consumers against exploitation could be necessary.[32] Subsequently, in May 2017, the Commission in fact did publicly announce that it had opened such an excessive pricing case against Aspen with respect to all relevant EEA Member States except Italy.[33] As in the earlier Italian Aspen case, this investigation regards price hikes for out of patent blood cancer drugs.

5. Excessive pricing for IP protected pharmaceuticals

Having discussed exploitation and non-patented drugs, we will now address the various objections against and conditions for applying the prohibition on excessive pricing to pharmaceuticals that are protected by IP rights.

Excessive pricing versus incentives to innovate and to enter markets
The first objection against targeting high prices as excessive prices under the competition rules is that this may undermine innovation and the risky investment that is required to fund such innovation. High prices may be considered a reward for risky investment. Moreover, as we have noted excessive pricing is already rarely pursued as a dominance abuse in general. Hence special caution is warranted in doing so with respect to products covered by IP rights because its misapplication might directly impede innovation. A conceptual trap to avoid in this context is survival bias. This means that capping profits on the handful of successful products without taking the ex-ante possibilities of failure into account can lead to an ex-ante expected loss, which would jeopardize the incentive to invest and thereby the possibilities to innovate.

In our view however there is no necessary tension between the goals of intellectual property law –and, in this case specifically, excessive pricing. We believe that the enforcement of the prohibition on excessive pricing can and should take the incentives for innovation into account. Vice versa the existence of patent protection is not a reason to exclude the enforcement of the excessive pricing prohibition. One way to take

[31] *Aspen Pharmaceuticals* (Case A480) AGCM Decision of 29 September 2016.
[32] Commissioner Margarete Vestager, 'Protecting consumers from exploitation' (Chillin' Competition Conference, Brussels, 21 November 2016).
[33] Commission, 'Antitrust: Commission opens formal investigation into Aspen Pharma's pricing practices for cancer medicines' (Press release) IP/17/1323.

innovation incentives into account is to include ex-ante probabilities of success under the first leg of the *United Brands* test. This would allow pharmaceutical companies to make relatively significant but not unlimited profits on successful innovation, protecting socially valuable investment.

The second objection is that high prices also encourage market entry, thereby promoting both dynamic and allocative efficiency. Hence from a perspective of economic efficiency, the preferred mechanism to reduce prices would not be regulation or competition policy intervention, but a competitive response in the market. If excessive pricing cases were to be pursued widely and successfully where scope for effective entry exists, the mechanism promoting entry would be eroded.

In this context of course the issue of entry barriers is key. IP rights may constitute such barriers. This is also why the existence of IP rights reduces our concern about the effect of price as a signal for entry. They make entry less likely per se to the point where protecting entry may no longer be a significant consideration in restraining the application of competition law. This is the case for instance for orphan drugs, which enjoy a ten-year period of exclusivity on the specific disease (the 'indication') that they treat.[34] The complex universe of EU pharmaceutical law provides a number of IP rights and related rights that award various measures of exclusivity that are often cumulative.[35] It is however important to note, that IP rights do not automatically create a monopoly that forms a dominant position, which may be relevant in competition law terms, because the scope of the IP right does not necessarily coincide with the definition of the relevant markets at hand. With the exception of orphan drugs (which as their name indicates monopolise certain diseases both by policy design and effectively in most cases), there may well be therapeutic substitutes that compete with each other. This means that a relevant market must be defined, and dominance established there by looking inter alia at the existence of effective competitors.

Price constraints on pharmaceutical products

The price of all products is constrained both by supply and demand factors. Firms have both the possibility and an incentive to charge high prices when price constraints are weak. For instance patents provide the possibility to enjoy above competitive profits where entry is limited. Price pressures on the supply side are relevant in the pharmaceutical sector, even for patented drugs. As we have seen high prices may be expected to attract new entry, creating therapeutic competition with the exception of drugs within the orphan regime. However the possibility of entrance of rival firms is not

[34] Regulation (EC) 141/2000 (n4).

[35] Such as supplementary protection certificates (SPCs), orphan designation and pediatric extensions, as well as data exclusivity. See Maria Isabel Manley and Marina Vickers (eds), *Navigating European pharmaceutical law* (Oxford University Press 2015) and Sally Shorthose (ed), *Guide to EU pharmaceutical regulatory law*, (6th edn, Wolters Kluwer 2015).

the only factor that matters.[36]

So on the supply side, high prices may attract new entry. On the demand side, higher prices will naturally lead to less consumption of the good or service. A higher elasticity of demand leads to stronger downward pressure on price. In the case of pharmaceutical products however, price pressures from the demand side tend to be weak.

- Firstly, people's willingness to pay for life prolonging or quality of life improving medicines is high.[37]

- Secondly, private individuals and their doctors who make treatment decisions typically do not contribute to the costs of medication to a significant extent and are therefore not exposed to price pressure.

- Thirdly, and related to the previous point, third party payer financing through health insurance and/or government funds strongly increases the average ability to pay.

- Finally, public opinion may have a strong price uplifting effect, especially in cases where patient organizations effectively organize themselves (and at least in some cases are encouraged, including financially, by the industry itself to do so).

It could still be argued that despite the high willingness and ability to pay, strong buyers of care should be able to negotiate good prices by exercising countervailing buyer power. However, a buyer of care only has bargaining leverage to the extent that there are alternatives – outside options. Such an alternative could be another drug or treatment. In the Netherlands, the competition authority has issued guidance on the scope for joint purchasing of expensive pharmaceuticals.[38] In practice however purchasing power only works where there are therapeutic alternatives, which is frequently not the case. For instance the exclusivity on indication under the orphan drug regime excludes market access for alternative substances by design. It may be true that

[36] From a public welfare perspective, it would be more efficient if innovation is directed into those diseases where most health gain is possible than where returns on investment are highest. This is however largely a problem related to the way pharmaceutical innovation is financed and beyond the scope of our chapter.

[37] See for example Marc Radtke and others, 'Willingness-to-pay and quality of life in patients with vitiligo' (2009) 161 British Journal of Dermatology 134-139; Stephanie Hu and others, 'Willingness-to-Pay Stated Preferences for 8 Health-Related Quality-of-Life Domains in Psoriatic Arthritis: A Pilot Study' (2010) 39 Seminars in Arthritis and Rheumatism 384-397; Ana Bobinac and others, 'Willingness to Pay for a Quality-Adjusted Life-Year: The Individual Perspective' (2010) 13 Value in Health 1046-1055; F Beikert and others, 'Willingness to pay and quality of life in patients with rosacea' (2013) 27 Journal of the European Academy of Dermatology and Venereology 734-738;

[38] Wolf Sauter and Susan van Velzen, 'Joint purchasing of pharmaceuticals under competition law: the case of the Netherlands' (2016) 37 European Competition Law Review 458-464.

the terms of even a monopolist could be refused at least in theory. However, such a refusal is unlikely to occur in practice where political decision makers and public opinion would then have to accept that an effective and potentially life-saving drug would be unavailable.

Applying the excessive pricing assessment to IP protected pharmaceuticals
In line with the above, in many cases pharmaceutical products face limited price constraints. This is to some extent consistent with the idea behind intellectual property rights. When price constraints are too weak, pharmaceutical companies may price drugs far above the level that is necessary to recoup investments. Such pricing strategies may displace other more efficient healthcare spending or pose a threat to the very sustainability of national healthcare budgets.

Expensive drugs should not be equated with excessive pricing as such. It is especially important that any excessive pricing action avoids the trap of the survival bias by taking ex ante investment incentives into account. This may raise an, in our view surmountable, technical challenge, but as a matter of principle we see no reason why excessive prices should not be found to exist for patented products that are under very limited price constraints. Hence, there is no necessary tension between IP rights and excessive pricing if the purpose of the IPR – to stimulate welfare enhancing innovation – is be integrated into the excessive pricing assessment. In practical terms this means that the probability of success factor should be integrated into the first leg of the *United Brands* test where costs and profit margins are examined.

In the case of patented pharmaceuticals, there is an additional argument that a finding of excessive pricing does not necessarily harm investment incentives and can be consistent with public welfare on this count as well. This is because in terms of the social returns on investments, incentives are not necessarily better when they are higher. This implies that applying the prohibition on excessive prices above the quality of life adjusted year (qaly) threshold will improve investment decisions (as in: cause them to focus on socially relevant products) rather than harm them, at least in terms of social welfare and one could argue also in terms of consumer surplus. In the Netherlands as in many other countries, a threshold value has been set for the maximum willingness to pay for new drugs and healthcare technology more generally. The threshold varies in the Netherlands depending on the severity of the disease with a maximum value of €80.000 per qaly. Given the existence of a threshold per qaly, one could argue that drugs over this threshold (in this example €80.000) are welfare decreasing rather than welfare increasing. Canoy and Tichem (2018)[39] further develop this point.

Finally, although the existence of a price above this qaly threshold does not in itself prove excessive pricing (and a price below the threshold may still be excessive) it may

[39] M. Canoy and J. Tichem, ACM Working Paper on innovation and excessive pricing (Draft, 2018).

play a role within the second step of the *United Brands* test. Here it can help to determine whether an actual price that is found *unreasonabl*e in relation to costs under the first leg is also *unfair* by allowing comparisons with other drugs and other types of health expenditure – instead of by comparing the price for the same drug in different markets as is often done. [40] (The availability of such alternative methods is suggested clearly both in *United Brands* itself and in the more recent Opinion of AG Wahl on the topic of excessive prices.[41]) We would like to emphasize that this argument – in our view - does not work the other way around. This means that an otherwise excessive price may not be justified because it remains below the qaly threshold. Other potential alternatives to determine the fairness of a price under *United Brands* are comparing the price levels of the same drug before and after a price increase, or before and after authorization for a new treatment or the award of a new orphan indication.

6. Conclusion

Above, we have given an overview of the relevant literature and case law and some of the main economic arguments in relation to the application of the abuse of dominance prohibition to IP protected pharmaceuticals, and the excessive pricing prohibition to both non-IP protected and IP protected drugs. Against the background of this overview we see the IP and competition law regimes as fully compatible or even complementary and applicable in tandem at least with regard to the dimensions that we have examined here: dominance abuse and pharmaceuticals.

Our argument is based on the assumption that competition law can and should be applied in such a way that it takes the objectives of IP law into account, notably innovation. This can be done by looking at the ex-ante probability of success, which is especially important in pharmaceutical markets, where only a limited percentage of products reaches the market. At the same time it is important to note that from a public welfare perspective, there is such a thing as too much investment in innovation. This approach is consistent with the application of the excessive pricing instrument to pharmaceutical products under the *United Brands* standard.

Hence we believe that given the excessive pricing cases regarding pharmaceuticals not covered by IP protection that we have already seen (and that are now in the pipeline), and in view of the arguments canvassed above excessive pricing cases addressing patented products are bound to follow.

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[40] Cf Case C-177/16 *Autortiesību un komunicēšanās konsultāciju aģentūra / Latvijas Autoru apvienība v Konkurences padome* EU:C:2017:689.

[41] Case 27/76 *United Brands* (n 27), para 253; Opinion of AG Wahl of 6 April 2017, in Case C‑177/16 (n 40), ECLI:EU:C:2017:286, paras 36-51. With reference to Nils Wahl, 'Exploitative high prices and European competition law – a personal reflection', Konkurrensverket, *The Pros and Cons of High Prices* (Stockholm 2007), 47ff.

Finally, from our vantage point as a national competition authority, we will add a few words on the role of sectoral regulation, even if we have not covered this body of law systematically above. In our view, it stands to reason that if it turns out that EU based IP rights, or related rights, contribute to excessive pricing of pharmaceuticals by unduly promoting dominant positions across a number of Member States, the relevant incentive structures ought to be revised. Recasting the balance between innovation and competition in that context could further reconcile the two. This does not mean that the application of the competition rules should be suspended until a possible regulatory gap is closed. After all: time waits for no-one.