Exploring Excessive Pricing in the Pharmaceutical Sector

A Search for Best Practices

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### Abbreviations

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<tbody>
<tr>
<td>ACM</td>
<td>Autoriteit Consumenten &amp; Markt</td>
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<tr>
<td>AG</td>
<td>Advocate General</td>
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<tr>
<td>AGCM</td>
<td>Autorità Garante della Concorrenza e del Mercato</td>
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<td>CA</td>
<td>Competition Authority</td>
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<td>CJEU</td>
<td>Court of Justice of the European Union</td>
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<td>CMA</td>
<td>Competition and Markets Authority</td>
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<tr>
<td>FRAND</td>
<td>Fair, reasonable and non-discriminatory</td>
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<td>NCA</td>
<td>National Competition Authority</td>
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<td>NHS</td>
<td>National Health Service</td>
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<td>OFT</td>
<td>Office of Fair Trading</td>
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<td>R&amp;D</td>
<td>Research and Development</td>
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<tr>
<td>TEU</td>
<td>Treaty on European Union</td>
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<td>TFEU</td>
<td>Treaty on the Functioning of the European Union</td>
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<td>TRIPS</td>
<td>Agreement on Trade-Related Aspects of Intellectual Property Rights</td>
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Chapter 1: Introduction

‘Often people’s health relies on drugs that are sold by just one company. [...] That isn’t a problem in itself, if prices stay at a reasonable level. But there can be times when prices get so high that they just can’t be justified. [...] The best answer is often to adjust regulation, or to give the health systems that buy those medicines better bargaining power. But as the recent action by the British and Italian competition authorities shows, there can be times when competition rules need to do their bit to deal with excessive prices.’

The quote above derives from a speech Commissioner Margrethe Vestager delivered in November 2016. It reflects the frequent criticism the pharmaceutical sector faces due to the high prices being charged. In a report of the European Commission on competition enforcement in the pharmaceutical sector from 2009 to 2017, the Commission noted that ‘[h]igh prices of medicines impose a high burden on the national healthcare systems, where pharmaceuticals already account for a significant share of spending.’ This illustrates the importance of keeping pharmaceuticals affordable, for example through regulation or competition law.

High prices may be ascribed to patents, which is mentioned in Vestager’s speech. Patents reward undertakings that innovate, *inter alia* by charging high prices through which undertakings can recoup the costs they have spent on research and development (R&D). Innovation is crucial in the pharmaceutical sector, where new drugs are being produced to cure diseases. Therefore, governments have often been reluctant to intervene against high prices, afraid that intervention might hamper innovation. This reluctance also comes from competition authorities (CAs), which have so far only pursued excessive pricing cases concerning off-patent drugs, where (R&D) plays a lesser role.

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When regulating the pharmaceutical sector, governments and regulators need to strike a balance between the affordability of pharmaceuticals on the one hand, and safeguarding innovation and a high quality of medicines on the other hand – which may require higher prices for these products. Competition law faces similar challenges, including balancing these different objectives. Furthermore, applying competition law to excessive prices is already controversial. The idea is that high prices should normally attract new entrants which can compete with the incumbent in the market. This would then lead to price competition, and in the end, to lower prices. However, barriers to entry in the pharmaceutical market may be high. Some of these barriers are created by patents, whereas other barriers are caused by consumers’ reluctance to switch to other pharmaceutical products. Hence, the market may not self-correct and intervention may be necessary.

This thesis will aim to answer the following question: when is competition law enforcement against excessive prices in the pharmaceutical sector desirable, and how can it be supplemented? In order to understand how competition law works in the pharmaceutical sector and to assess when it is desirable, chapter 2 will address the question of what is causing the excessive prices. This question will be tackled by explaining the structure of the pharmaceutical market, in which both (price) regulation and competition law apply, and by describing the main market failures witnessed in the case law of both the European Commission (hereafter: Commission) and national competition authorities (NCAs). Chapter 3 will examine when competition law enforcement is desirable. To this end, the market failures discussed in chapter 2 will be considered and enforcement priorities of competition authorities (CAs) will be assessed, particularly where it concerns the distinction between patented and off-patent pharmaceuticals. After having explained the desirability of competition law enforcement, chapter 3 will assess different remedies, drawing on the market failures outlined in chapter 2 and the criticism that CAs have faced when they pursue excessive pricing cases. Finally, chapter 4 will examine how competition law enforcement can be supplemented. It will assess whether we need more regulation, more competition enforcement, or if there are alternative ways to keep prices in the pharmaceutical sector affordable.
Many authors have joined the debate on the correct legal test for excessive prices,5 but there are only few discussions about the policy implications of applying competition law in the pharmaceutical sector and its relation to (price) regulation. As this topic has already been discussed in the context of telecommunications, this thesis will draw on the corresponding literature. Moreover, this dissertation will aim to fill the gap in the sparse discussion on remedies for excessive prices, particularly remedies that can be imposed in the pharmaceutical market – a market where innovation is of crucial importance.

Chapter 2: Causes of Excessive Pricing in the Pharmaceutical Sector

‘There is a growing political consensus in Europe that when it comes to incentives, especially in the field of rare diseases, the system may be, or is, abused, overused or misused. […] There are concerns that these incentives have been distorted and are now being used for profit maximization, or profiteering, rather than for the benefit of patients.’

In recent years CAs in the EU have increasingly started pursuing excessive pricing cases. These cases occur in numerous sectors, including the pharmaceutical sector. This chapter will address the question of why excessive pricing comes up in the pharmaceutical sector. In order to answer this question, the regulatory context of the pharmaceutical sector will first be explained, after which certain failures of the regulatory system for the pharmaceutical sector will be discussed.

2.1 Regulating Pharmaceuticals

Regulation and Competition Law: an Introduction

Regulation for pharmaceuticals covers, *inter alia*, marketing authorization, but more importantly, price regulation for pharmaceuticals. Methods of price regulation commonly used in the EU are Reference Price Regulation and Price Cap Regulation. These mechanisms aim to ensure that pharmaceutical companies do not charge prices that are too high or excessive, especially when the product is still patented and therefore faces less competition.

Competition law also targets excessive prices in the pharmaceutical sector. Article 102 of the Treaty on the Functioning of the European Union (TFEU) prohibits abuses of a dominant position, which may consist in ‘directly or indirectly imposing unfair prices’, for example by charging excessive prices. The legal test for excessive pricing was established by the Court of Justice of the European Union (CJEU) in *United Brands* and consists of two limbs. The first

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9 Consolidated version of the Treaty on the Functioning of the European Union (TFEU) [2012] OJ C 326, Article 102 sub a TFEU.
entails an analysis of whether the difference between the cost incurred and the price charged is excessive, and the second assesses whether the price is unfair either in itself or compared to competing products. This test for excessive pricing is, unfortunately, not very clear and it remains difficult to establish which prices are excessive. Though some benchmarks have been used by the Commission, the test for excessiveness depends on the characteristics of that specific case, which makes it difficult to apply the test in other cases too. As for the second part of the United Brands test, the unfairness test, there is also no predictable and concrete definition of which prices are deemed to be unfair.

So essentially, there are two sets of regulation: price regulation which constitutes a form of ex ante regulation of the market, and competition law which, with the exception of merger control, is a form of ex post regulation. Though the existence of (price) regulation does not preclude the application of competition law, experience has shown that price regulation occurs more often, or is more comprehensive, for patented products, whereas excessive pricing cases have so far only focused on off-patent drugs. For off-patent drugs, more competition is possible due to generic entry and therefore, effective competition can lead to lower and more affordable prices of pharmaceuticals. However, competition is not always sufficient and hence, competition law enforcement may be required to remedy the market failures which are causing excessive

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10 For the determination of whether a price is excessive, see e.g. Case C-177/16 AKKA/LAA (2017) ECLI:EU:C:2017:286, Opinion of AG Wahl, paragraphs 17-19; and Calcagno, Chapsal and White (n 4), 166.

11 Case C-27/76 United Brands v Commission [1978] ECR 00207, paragraph 252. For the unfairness limb, see Opinion AG in AKKA/LAA (n 10), paragraph 21.


13 ibid, 7.


15 The cases discussed in this thesis, Aspen, Pfizer/Flynn and CD Pharma all concern off-patent drugs.

16 See e.g. Directorate-General for Internal Policies, Difference in costs of and access to pharmaceutical products in the EU, (IP/A/ENVI/ST/2020-12), 35.

Entry of generics is also stimulated to further increase price competition, see e.g. Organisation for Economic Co-operation and Development (OECD), Excessive Prices in Pharmaceutical Markets: Background Note by Secretariat (DAF/COMP(2018)12), 20.
prices. Moreover, the patent confers an intellectual property right and therefore, the manufacturer should be able to utilize their exclusivity period, which also includes the possibility to charge higher prices.\footnote{Calcagno, Chapsal and White (n 4), 168.} As manufacturers may face high R&D costs, this exclusivity period can also help companies to recover such costs and be rewarded for their innovation.\footnote{Canoy and Tichem (n 3), 16-17.}

**Characteristics of the Pharmaceutical Sector**

There is not only a lot of regulation for pharmaceuticals, but the sector also exhibits characteristics that distinguish it from other economic sectors. One of the main features relevant to this thesis is that many pharmaceutical products are price-inelastic. This means that a price increase does not (significantly) affect the demand for the products. Many people’s health, or even their life, relies on those products and therefore, demand for these products will continue, even when the price increases.\footnote{Lehnhausen (n 8), 16.} Moreover, in most cases either the state or a national health service (NHS) pays for the medicines, rather than the patient. Even when prices of pharmaceuticals rise, a state or an NHS will often still cover these products, as a patient’s well-being, or even the patient’s life, may depend on it. Furthermore, as patients are often not the ones paying for their medicines, they lack the incentive to search for more affordable medicines, for example by switching to a different supplier.\footnote{OECD note (n 16), 19.} This explains why the demand for pharmaceuticals still exists, despite higher prices being charged for it. A counter-argument to this would be that the NHS is in a better position to secure affordable prices for medicines, but the recent experience in *Aspen* has shown that this is not always successful. This argument on countervailing buyer power will be developed further in section 4.2 on how to prevent excessive pricing cases.

**2.2 Intervention against High Prices**

The prohibition of abuse of dominance in Article 102 TFEU includes charging excessive prices, which will be discussed in more detail in the next chapter on the application of competition law. The European Commission, though able to pursue excessive pricing cases, has been reluctant to take on excessive pricing cases, as it does not wish to become a price regulator.\footnote{Amelia Fletcher and Alina Jardine, ‘Towards an Appropriate Policy for Excessive Pricing’ (2020) European Competition Law Annual 2007: A Reformed Approach to Article 82 EC 533, 533.}
Not all jurisdictions have an equivalent to this provision in the TFEU. In the US, for example, competition law is not used to deal with excessive pricing cases. In the absence of price regulation, the ‘invisible hand’ of the market is ought to ensure that the prices of pharmaceuticals remain affordable. The idea is that when high prices exist in the market, this will attract new entrants which will compete with the incumbent and that therefore, prices will go down.\(^{22}\) Moreover, some believe that intervention against high prices may reduce incentives for undertakings to enter the market, as CAs might intervene when they charge high prices.\(^{23}\)

It is, however, contended that the ‘invisible hand’ of the competitive process will lead to lower prices and better quality for consumers.\(^{24}\) The remainder of this chapter will explain firstly the market failures the pharmaceutical in particular faces and has faced, secondly what has caused the excessive pricing cases that have occurred so far, and thirdly where the ‘invisible hand’ alone was insufficient to bring about lower prices for consumers.

### 2.3 Exclusionary Conduct and Entry of Competitors

As mentioned before, a difference exists between patented and off-patent drugs when it comes to price competition. For patented products, competitors cannot just enter the market due to the patent protection. However, when patent protection expires, generics offering off-patent drugs could enter the market and compete with the originator – the undertaking previously enjoying patent protection. As a result of this competition, prices decrease. On average, prices of generic medicines once they enter the market are 25% lower than those of originators, and after two years, prices of generics are approximately 40% lower than the previous price of the originators.\(^{25}\) As originators want to maintain their high profits, they engage in several anticompetitive practices to prevent or slow down generic entry, which will be explained below.

#### Reverse Patent Settlements

One example of slowing down generic entry is reverse patent settlements. In Generics (UK) and Others, generics wanted to enter the market and therefore, they challenged the validity of

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\(^{22}\) See e.g. Jones, Sufrin and Dunne (n 14), 559.

\(^{23}\) ibid, 559. See also AG Wahl in AKKA/LAA (n 10), paragraph 48.


the patent of the originator, GlaxoSmithKline. To prevent generic entry, GlaxoSmithKline offered a large sum to the generics wishing to enter the market. In exchange for this money, the generics would not challenge the patent and they would be allowed to sell some of GlaxoSmithKline’s medicines. This agreement was found to be contrary to Articles 101 and 102 TFEU, as consumers could be ripped from certain benefits such as price reductions.\(^\text{26}\)

Before pursuing excessive pricing cases, CAs should focus on such exclusionary practices. When this is successful, generic entry is stimulated and excessive pricing cases may be prevented.

**Misusing the Regulatory System: AstraZeneca**

The prevention of generic entry also occurred in *AstraZeneca*, in which the undertaking abused its dominant position by misusing the regulatory system for pharmaceuticals. Generics wanting to enter the market could have used AstraZeneca’s marketing authorization and therefore, generics would not have to go through an extensive process of obtaining authorization.\(^\text{27}\)

In *AstraZeneca*, the CJEU considered that “an undertaking which holds a dominant position has a special responsibility in that latter regard [...] and that [...] it cannot therefore use regulatory procedures in such a way as to prevent or make more difficult the entry of competitors on the market, in the absence of grounds relating to the defense of the legitimate interests of an undertaking engaged in competition on the merits or in the absence of objective justification.”\(^\text{28}\)

Thus, even though withdrawing authorization is not unlawful in itself, this conduct could amount to an infringement of Article 102 TFEU.

Besides withdrawing marketing authorization, AstraZeneca also provided misleading information when it applied for a supplementary certificate to extend its patent protection. As there is usually a significant time gap between obtaining a patent and actually putting the product on the market, an undertaking may not be able to benefit from the patent during its entire duration. Therefore, undertakings can apply for supplementary certificates to extent patent protection. In order to apply for a supplementary certificate, the undertaking has to give the national patent office information on when it obtained marketing authorization. AstraZeneca gave a misleading date of marketing authorization, and the Court held that such mistakes, intended to mislead the patent office, can constitute an abuse of a dominant position.

\(^\text{26}\) Case C-307/18 Generics (UK) and Others [2020] ECLI:EU:C:2020:52, paragraphs 69-70.


\(^\text{28}\) ibid, paragraph 134.
The rationale for the abuse was also of relevance, as AstraZeneca committed this abuse to extend its patent production and thereby to prevent competitors from entering the market.  

_NAPP: Exclusionary Conduct Resulting in Excessive Prices_

In 2008, the Office of Fair Trading (OFT) (now superseded by the Competition and Markets Authority (CMA)) found that Napp had abused its dominant position by _inter alia_ charging excessive prices. In this case, the market consisted of two different customer segments: the community segment where the product is sold by community pharmacies, accounting for 86-90% of the supply, and the hospital segment, accounting for 10-14% of the supply. Napp offered discounts of over 90% in the hospital segment and by giving these discounts and thus charging very low prices, Napp excluded its competitors from the market. This is an exclusionary pricing abuse, where low prices (could) lead to the strengthening of a dominant position. The strengthening of Napp’s dominance in the hospital segment also lead to a more powerful position of Napp in the community segment. Hospitals are seen as a strategic entry point for new competitors and they play a central role in establishing a drug’s reputation. Therefore, once a strong market position is acquired in the hospital segment, the market position in the community segment will also be strengthened. Moreover, Napp had the possibility to recoup the losses in the hospital segment in the community segment.

Napp’s conduct in the hospital segment constituted an abuse of a dominant position, as Article 102 TFEU also covers predatory pricing. Whereas excessive pricing, which occurred in the community segment, is an exploitative abuse, predatory pricing is an exclusionary abuse, as it aims to exclude competitors and strengthen an undertaking’s dominance. The peculiarity of this case is that the initial low prices by Napp occurred in a different segment of the market than where the excessive prices occurred. In predatory pricing cases, often low prices are charged which exclude competitors in the market and thus, the undertaking’s dominant position is strengthened. After the competitor(s) is (or are) gone, the undertakings can raise its prices and ‘recoup’ the losses it has incurred due to its predatory pricing strategy. However, Napp’s predatory pricing strategy in the hospital segment did not only exclude competitors in that segment, but also in the community segment, where Napp could recoup its losses and charge

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29 ibid, paragraphs 18 and 96-99.
31 ibid, paragraphs 236-237.
32 ibid, paragraphs 162-163.
33 ibid, paragraphs 148-151.
excessive prices. Nevertheless, the case of Napp is illustrative of how initial low prices can be followed by high (excessive) prices and that therefore, it is important for CAs to tackle exclusionary abuses in order to prevent excessive pricing cases.

Experiences from CD Pharma

Higher prices may, however, not always attract generic entry. In CD Pharma, a Danish case on excessive pricing of pharmaceuticals, the undertaking had increased its prices after a parallel importer was no longer able to deliver the drug Syntocinon to the pharmaceutical procurement service for five regional authorities in Denmark (Amgros). Because CD Pharma had an exclusive distribution agreement with the producer of Syntocinon, CD Pharma had a stable source of supply, which the parallel importers lacked. This exploitative abuse of excessive pricing also constituted an exclusionary abuse, as parallel importers who could not deliver the agreed amount of Syntocinon to Amgros had to cover Amgros’ loss due to the failure to deliver. Therefore, new suppliers in the Danish market bore the risk of significant claims for compensation when CD Pharma increased its prices and consequently, those suppliers were disincentivized from entering the market. This is a unique situation, where CD Pharma’s exclusive distribution agreement and the resulting stability of supply, which the parallel importers lacked, in the end led to weakened future incentives to enter the market. It also shows that high prices may not always lead to more competitors entering the market, but that it might actually deter them from entering the market.

2.4 Gaps in the Regulatory System

As mentioned before, the pharmaceutical sector is a heavily regulated sector, which includes price regulation. In a case from the UK, Pfizer/Flynn, the undertakings concerned made use of certain gaps in the regulatory system to impose high prices. This case concerned the rebranding

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34 ibid, paragraphs 251-252.
37 Katsoulacos and Jenny (n 7), 29.
38 OECD note by Denmark (n 36), 4-5.
of a drug after which the drug was no longer part of a price scheme. This allowed Pfizer and Flynn to increase the prices of the drugs, which led to a complaint from the Department of Health to the CMA.\(^{39}\) Though the CMA’s decision was not upheld on appeal, this case shows that gaps in the regulatory system, or making strategic use of the system, may warrant competition law enforcement.\(^ {40}\)

After the CMA’s decision in *Pfizer/Flynn*, the UK regulator changed the regulation in order to prevent a situation like *Pfizer/Flynn* from happening in the future.\(^ {41}\) The action of the CMA thus signaled to the regulator that there was a regulatory gap which allowed the undertaking to charge very high prices. This shows that even if competition law intervention is not successful, as the decision of the CMA was not upheld on appeal, it may still have some success by exposing certain failures in the regulatory system and then leaving it to the regulator to take action to narrow these gaps.

### 2.5 Bargaining Power of the Regulator

In many EU Member States, the sectoral regulator negotiates prices of pharmaceuticals with pharmaceutical undertakings. These sectoral regulators are usually powerful buyers and are therefore expected to achieve better prices from pharmaceutical undertakings.\(^ {42}\) In *Aspen*, there were price negotiations between the Italian pharmaceutical regulator and Aspen concerning certain off-patent drugs. Aspen engaged in aggressive negotiation tactics, including the threat to withdraw the drugs from the Italian market if the price increases were not accepted by the Italian regulator. Aspen’s tactics led to enormous price increases of 300 to 1500%. As this was an off-patent drug, R&D considerations no longer played a role and the drug had been on the market for long enough to recover any investments that had been made in the past. Finally, it concerned a life-saving drug and for certain patients no substitute for this drug existed.\(^ {43}\) This case shows that involvement of the sectoral regulator may not be sufficient, as the CA in this case had to ‘save’ the regulator that had been confronted with aggressive negotiation tactics.

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39 OECD note (n 16), 15.
40 *Competition and Markets Authority v Flynn and Pfizer* [2020] EWCA Civ 339.
41 Katsoulacos and Jenny (n 7), 72.
42 This is also referred to as ‘countervailing buyer power’; see Jones, Sufrin and Dunne (n 14), 354-355.
2.6 Difficulties Switching Between Medicines

In Pfizer/Flynn it was not only the gap in the regulatory system that allowed the undertakings to charge very high prices, consumers could also not easily switch to another drug – at least not without potential danger to their health. The drug phenytoin sodium capsules, sold by Pfizer and Flynn, is prescribed to epilepsy patients. When there is a small change to the dose of the drug, this can give rise to serious and unpredictable health effects. Therefore, the clinical guidance in the UK is for ‘continuity of supply’, meaning that the patient should stay on the same brand once that brand of the drug has been prescribed to the patient. This meant that patients could not just switch to another drug when the prices of these capsules increased and that the NHS in the UK had no other choice but to pay higher prices for the drug.\(^{44}\)

Though the capsules were no longer patented and competition between generics and the originator would in principle be possible, the health dangers of switching to a different brand of the drug prevented price competition from taking place. Therefore, it is not always the case that generic competition and lower prices will follow after the expiry of a patent.

2.7 Takeaways

This chapter aimed to address the causes of excessive prices by giving a short introduction to price regulation and competition law and by highlighting the main market failures in the pharmaceutical market which could lead to excessive prices. Even though price regulation and the ‘invisible hand’ of the market could help in ensuring affordable prices, practice has shown that this is not always sufficient to prevent companies from charging excessive prices. Moreover, though the possibility exists that generic entry after patent protection expires could lead to lower prices, this is not always the case. Generic entry may be prevented by the originator, for example by engaging in certain exclusionary practices such as reverse patent settlement agreements, predatory pricing, or by misusing the regulatory system for pharmaceuticals. Furthermore, the market may simply not be profitable enough for generic companies to enter. Finally, even when generics enter, it could be that consumers cannot (or that it is dangerous to) switch to other products.

In case of market failures or where the regulatory system is insufficient, further intervention in the market is required. The health and sometimes even the livelihood of people is at stake and

\(^{44}\) Katsoulacos and Jenny (n 7), 24 and 76.
medicines should be reasonably priced. Though high prices can be seen as acceptable when these are justified by the high costs – for example relating to R&D – certain prices bear no relations to the costs and are just too high. In these cases, further intervention is required.

To this end, the following chapter will discuss the application of competition law in the pharmaceutical industry, an industry that is characterized by extensive (price) regulation. The chapter will focus on where it is desirable to apply competition law to remedy the market failures discussed in this chapter, and whether it can be applied next to the current price regulation schemes already in place. Furthermore, remedies for excessive pricing cases will be discussed.
Chapter 3: The Application of Competition Law to Excessive Pricing

‘The telecommunications carrier may be able to charge a higher price than market price for a limited period of time and that may be a suitable reward for telecommunications innovation. Call that the genius of the free market. But, should we transpose a decision involving telecommunication to life-saving pharmaceutical therapies?’

Though the main focus of CAs has been on exclusionary abuses which aim to exclude competitors from the market, in recent years CAs have been pursuing more cases concerning exploitative abuses, including excessive pricing cases in pharmaceutical markets. As the quote above shows, the pharmaceutical market is not just any other market, which should be taken into account by competition law.

This chapter will revolve around the question of when the application of competition law to combat excessive prices should be seen as desirable and what kind of remedies should be imposed in order to successfully remedy the market. In order to address this question, first the desirability of competition law enforcement will be explained, after which the remedies will be discussed, addressing the causes of excessive pricing discussed in chapter 2 and the criticism on competition law enforcement.

3.1 The Desirability of Competition Law Enforcement

As discussed above, there are few excessive pricing cases that have been pursued by CAs, as it is also not always necessary to intervene against high prices. High prices may have beneficial effects, attracting new entrants to the market which will compete with the incumbents, leading to lower prices. Competition law intervention against high prices may even constitute a market barrier, as new entrants might be less willing to enter the market when CAs intervene when high prices are being charged.

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46 Jones, Sufrin and Dunne (n 14), 559.
47 ibid, 565.
48 Gal (n 12), 5-6.
49 OECD note (n 16), 8.
Advocate General (AG) Wahl acknowledged in *AKKA/LAA* the reluctance of the Commission to use the excessive pricing provision. According to Wahl, there is ‘simply no need to apply that provision in a free and competitive market: with no barriers to entry, high prices should normally attract new entrants. The market would accordingly self-correct.’\(^{50}\) However, Wahl adds that there may be markets where barriers exist to entry and which therefore do not face effective competition.\(^{51}\) Examples of such barriers to entry, also discussed in the previous chapter, are insufficient incentives for generics to enter, or consumers’ inability to switch to other medicines. In the absence of this self-correcting market, competition law enforcement may be necessary to prevent undertakings from charging excessive prices.

Next to the question on the desirability of competition law enforcement, there is the question of whether these market failures should be addressed through competition law or through sectoral regulation. Sectoral regulation is sometimes favored because sectoral regulators possess more knowledge about the market and therefore, it is argued, they are better equipped to intervene.\(^{52}\) Furthermore, one should look at the causes of excessive prices; in markets that are likely to exhibit market failures that may lead to excessive prices, *ex ante* intervention in the form of price regulation may be warranted.\(^{53}\) The next section will explore this issue further, by highlighting the distinction and different enforcement priorities between patented and off-patent pharmaceuticals

### Patented vs Off-Patent Pharmaceuticals

Competition enforcement has so far only focused on off-patent pharmaceuticals and in the literature, there are diverging opinions on whether the excessive pricing provision should be applied to patented pharmaceuticals as well. As mentioned in the previous chapter, price regulation for pharmaceutical products is much more comprehensive for patented than for off-patent drugs, as there is more price competition for drugs which are off-patent due to generic entry.\(^{54}\) Because sectoral regulation is often already in place to prevent excessive prices of

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\(^{50}\) Opinion AG in *AKKA/LAA* (n 10), paragraph 3.

\(^{51}\) ibid, paragraph 4.

\(^{52}\) See OECD note (n 16), 4-5; Katsoulacos and Jenny (n 6), 72.

\(^{53}\) Frank Naert, ‘Competition authorities and regulators in Belgium: hierarchy versus cooperation’ (2009) 10(2) Competition and Regulation in Network Industries 139, 141.

\(^{54}\) OECD (n 16), 19-20.
patented pharmaceuticals, it will generally not be necessary to resort to competition law.\textsuperscript{55} Moreover, it should be kept in mind that patents incentivize undertakings that innovate by giving them a certain period to exploit their innovation. By charging higher prices in this initial period of exclusivity, companies can recoup their R&D costs.\textsuperscript{56}

Although there may be good reasons to not intervene against excessive prices of patented drugs, the possibility of bringing such cases should still exist. A patent creates a type of legal monopoly and raises entry barriers.\textsuperscript{57} Therefore, consumer exploitation, something that competition law tries to prevent, can be facilitated by the patent system.\textsuperscript{58} Also a working paper published by the Netherlands Authority for Consumers and Markets (ACM) supports the idea that excessive pricing cases may be brought against patented drugs. It is important to note that medicine prices are only regulated for medicines where, according to the Minister of Health, Welfare and Sport, the availability of the medicine must be guaranteed by the government.\textsuperscript{59} If this is deemed to be the case, a maximum price will be determined by reference to the average price in four reference countries, which are currently Norway, Belgium, France and the UK.\textsuperscript{60} Also in other Member States not all prices of patented pharmaceuticals are regulated and even if prices are regulated, the regulatory mechanisms differ across Member States.\textsuperscript{61} So, even though more extensive regulation exists for patented pharmaceuticals than for off-patent pharmaceuticals, situations may exists where a patented pharmaceutical is not, or is imperfectly, covered by price regulation. In such circumstances where excessive prices are being charged, competition law intervention is valuable. However, this does the raise the question of how to reconcile competition law with intellectual property law. Though it is recognized that the cautious approach of CAs to intervene against high prices is often justified, Canoy and Tichem state that intervention may be necessary when ‘the price of a drug is higher than its value to

\begin{itemize}
\item \textsuperscript{55} For a discussion on competition law when there is already sectoral regulation in place, see Damien Geradin and Robert O’Donoghue, ‘The concurrent application of competition law and regulation: the case of margin squeeze abuses in the telecommunications sector’ (2005) 1(2) Journal of Competition Law and Economics 335.
\item \textsuperscript{56} Benoît Durand, ‘Competition Law and Pharma: an Economic Perspective’ in Pablo Figueroa and Alejandro Guerrero, \textit{EU Law of Competition and Trade in the Pharmaceutical Sector} (Elgar Competition Law and Practice series, 2009) 3.
\item \textsuperscript{57} This is not to say that there is no price competition for patented products, there may still be some substitutes available. See Abbott (n 45), 287.
\item \textsuperscript{58} Jones, Sufrin and Dunne (n 14) 563. See also Abbott (n 45) 294.
\item \textsuperscript{59} Wet Geneesmiddelenprijzen 1996, Article 2(1).
\item \textsuperscript{60} ibid, Article 2(2).
\item \textsuperscript{61} For an overview of regulatory mechanisms across the EU Member States, see Directorate-General for Internal Policies (n 16), 35-37.
\end{itemize}
society. Of course stimulating innovation by issuing patents is important, but undertakings should not be allowed to charge prices that are no longer in line with these innovation incentives. When prices reach such levels, competition law intervention is justified.

**R&D Considerations as Part of the Unfairness Test**

As mentioned before, the test for excessive pricing is a two-stage test. The first stage examines whether the price charged is excessive, which is mostly quantitative, as it involves an analysis of whether the costs incurred and the price charged is actually excessive. The second stage is more of a qualitative nature and looks at, if the price is deemed to be excessive, whether this price is also unfair. As AG Wahl noted in *AKKA/LAA*, several factors can be of relevance in order to conclude that a price is unfair.

The main objection against competition enforcement with regard to patented pharmaceuticals is that it could hamper innovation. It is quite difficult to put a price on innovation and include the costs of innovation in the first limb of the test that looks at the difference between the costs incurred and the price charged. Therefore, it may be better to consider the innovation costs as ‘overhead costs’, something which has also been suggested by AG Wahl.

Thus, I propose that the arguments against intervention of excessive prices of patented products should not be seen as arguments to exclude competition enforcement against high prices, but rather as arguments to be incorporated in the second limb of the test for excessive pricing. This still opens the possibility, as well as the threat, of excessive pricing cases for patented drugs, but it would raise the threshold for unfairness. Hence, though those cases are rare and difficult to pursue there would always be a possibility for legal action in case prices of patented pharmaceuticals reach levels which can no longer be justified. There is, however, one drawback from taking this approach. Undertakings may not want to disclose the costs that they have incurred for R&D. So, though it may be a good test in theory, it may not work in practice if an undertaking is unwilling to disclose the costs for R&D. This brings us to the concept of objective justifications, which may be used to address this exact issue.

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62 Canoy and Tichem (n 3), 3.
63 ibid, 20.
64 AG Wahl in *AKKA/LAA* (n 10), paragraphs 124-125.
65 ibid, paragraph 127.
Objective Justifications

The concept of objective justifications exists for conduct that is found to be abusive but which can still be objectively justified.\textsuperscript{66} Justifications for excessive prices have been discussed in AKKA/LAA, where the CJEU held that when prices are ‘indicative of abuse of a dominant position’,\textsuperscript{67} it is up to the undertaking under investigation to show that its prices are fair ‘by reference to objective factors […]’.\textsuperscript{68} Costs relating to R&D could potentially justify high prices for patented drugs, as well as increased costs for the production of medicines.

In \textit{Microsoft v Commission}, the General Court held that ‘it is for the dominant undertaking concerned, and not for the Commission, before the end of the administrative procedure, to raise any plea of objective justification and to support it with arguments and evidence. It then falls to the Commission, where it proposes to make a finding of an abuse of a dominant position, to show that the arguments and evidence relied on by the undertaking cannot prevail and, accordingly, that the justification cannot be accepted.’\textsuperscript{69}

So, applying the concept of objective justifications entails a shift in the burden of proof, meaning that it is now for the undertaking to prove that its (presumably) excessive prices are justified based on R&D costs. One reason to use the concept of objective justifications rather than the aforementioned possibility of incorporating R&D considerations in the second limb of the excessive pricing test is that pharmaceutical undertakings are often not transparent about the costs they have incurred, including the R&D costs. Due to the lack of transparency on R&D costs undertakings can often say that they have very high R&D costs, whilst this may not always be the case.\textsuperscript{70} By shifting the burden of proof to an undertaking, this undertaking will have to disclose its R&D costs which will allow for a better assessment of whether the prices violate Article 102 TFEU.


\textsuperscript{67} Case C-177/16 AKKA/LAA [2017] ECLI:EU:C:2017:689, paragraph 61.

\textsuperscript{68} ibid, paragraph 61.


3.2 Framework for Remedies in European Competition Law

Merely applying competition law and finding an infringement is insufficient to solve the anticompetitive effects on the markets; remedies are therefore required. Regulation 1/2003 lays down the enforcement powers of the Commission concerning competition law and authorizes the Commission to issue infringement and commitment decisions.\textsuperscript{71} When the Commission concludes that Article 102 TFEU has been infringed, the Commission can adopt an infringement decision, ordering the infringement to be brought to an end. Moreover, the Commission can impose both behavioral and structural remedies, ‘proportionate to the infringement committed and necessary to end the infringement effectively.’\textsuperscript{72} Additionally, the Commission may issue a fine when adopting an infringement decision.\textsuperscript{73} Undertakings can also offer commitments during the investigation to address the concerns expressed by the Commission. A commitment decision will then make the commitments offered binding on the undertaking(s) and the Commission will conclude that there are no longer ‘grounds for action’ by the Commission.\textsuperscript{74} When the undertaking(s) subsequently fail(s) to meet one of the commitments in the commitment decision, the Commission may still impose a fine on that undertaking.\textsuperscript{75}

3.3 Remedies for Excessive Pricing

Designing appropriate remedies in excessive pricing cases is difficult.\textsuperscript{76} After all, CAs do not want to become price regulators, which would blur the line between CAs and sectoral regulators.\textsuperscript{77} This section will discuss the remedies which could be imposed after an infringement has been found, or which commitments could be offered by an undertaking in a commitment decision.

\textsuperscript{72} ibid, Article 7(1).
\textsuperscript{73} ibid, Article 23.
\textsuperscript{74} ibid, Article 9(1).
\textsuperscript{75} ibid, Article 23(2)(c).
\textsuperscript{76} Abbott (n 45), 317.
Fines

The Commission, as well as the CAs of the EU Member States, have the authority to impose fines when they conclude that a competition law infringement has been committed. Fines are imposed to punish the firms for their behavior, which is an effective way to achieve deterrence. High fines may thus incentivize undertakings to keep their behavior in line with competition law. Hence, competition law may also have some *ex ante* effects, as undertakings will try to comply with the law to prevent getting a fine. Furthermore, the possibility of getting a fine may also give undertakings incentives to cooperate with the CA during a commitment decision.

In *Pfizer/Flynn*, the CMA ordered the parties to reduce their prices and imposed a fine. This fine was the highest fine that the CMA had imposed since its inception in 2013 and the fine was also said to be aimed at sending a message to pharmaceutical companies. Similarly, in *Aspen* a fine was imposed in accordance with Italian law. However, in *CD Pharma*, no fine has been imposed at the time of writing this thesis. After the decision of the Danish CA, the case was appealed to the Maritime and Commercial Court which upheld the decision of the CA on 2 March 2020. The case has now been referred to the Danish State Prosecutor for Serious Economic and International Crime, which will conduct a criminal assessment of the case which could result in a crime.

Though fines have deterrent effects, they cannot fully ensure that undertakings will stop charging excessive prices. As Wils explains in his article, it is very difficult to calculate an

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78 For the competition authorities of the EU Member States, see Regulation 1/2003 (n 71), Article 5; and for the Commission, see Regulation 1/2003 (n 71), Article 23. Note, fines are an option when an infringement decision has been adopted, it is not an option for commitment decisions.

79 For a useful overview of the use of fines in competition law and for a discussion on how fines can contribute to competition law enforcement, see also Wouter P.J. Wils, ‘Optimal Antitrust Fines: Theory and Practice’ (2006) 29(2) World Competition 183.


82 A480 – *Price Increase of Aspen’s Drugs* [2016] Measure No. 26185, 57-58

83 OECD note by Denmark (n 36), 4.

84 Danish Competition Authority (n 35).

84 Though these deterrent effects are also questioned. For this, see also Alexandr Svetlicinii and Marco Botta, ‘Article 102 TFEU as a Tool for Market Regulation: Excessive Enforcement against Excessive Prices in the New EU Member States and Candidate Countries’ (2012) 8(3) European Competition Journal 473, 488-489.
‘optimal’ fine. In order to achieve deterrence, a fine should exceed the gains of the infringement. When a fine is lower than what the undertaking has gained by infringing competition law, an undertaking might still infringe the law, as in the end the company will profit from its infringement. However, it may be very difficult to calculate the gains of the infringement of competition law and to determine an economically optimal fine. Another issue associated with fines is that companies may underestimate the chances of getting caught and the fines that will be imposed, which could lead to insufficient deterrence.85 Finally, after issuing an infringement decision and imposing a fine, CAs will still have to monitor the undertaking to ensure that the prices are brought in compliance with competition rules.86 Below, certain alternatives will be discussed to remedy excessive pricing abuses.

Setting the Right Price

When issuing an infringement decision, a CA could also impose a behavioral remedy ordering the firm to keep its prices below a certain level. This raises the question of what would be the right price, which requires a judgement call on the side of the CA. The latter risks blurring the line between a CA and a regulator. Furthermore, price regulation requires constant monitoring, for which CAs are often not well-equipped.87

An alternative for a CA is to merely impose a decision concluding that the prices are excessive and then leave it to the undertakings to self-assess which prices would be in line with competition law. The CMA, for example, did this in Pfizer/Flynn, where it found that the undertakings had charged excessive prices and therefore imposed a fine, adding that it is not a price regulator ‘and it is for an undertaking to self-assess their own compliance with competition law.’88 This lack of clarity concerning which prices would be considered fair by the CA may lead to uncertainty for the undertakings. Furthermore, when failing to bring down the prices to a level acceptable by the CA, the CA will have to bring another case, spending resources that could have been invested into other cases.

85 Wils (n 79), 31-32.
87 OECD note (n 16), 9.
88 Katsoulacos and Jenny (n 7), 91.
When the Italian CA, the AGCM (*Autorità Garante della Concorrenza e del Mercato*), found that Aspen had abused its dominant position by charging excessive prices, it held that Aspen ‘must carry out all which is necessary to define fair prices [...] and must not carry out future behaviours analogous to those object of the infringement ascertained above [...]’. This order meant that it was up to Aspen to decide how to comply with the order and thus how to find a price that did not infringe competition law. In March 2017, the AGCM found that Aspen had not complied with the AGCM’s order, and therefore started a non-compliance proceeding. Then, only in April 2018, Aspen managed to reach an agreement with the price regulator, and substantial price reductions followed. These price reductions were, however, retroactive and to be applied from the moment that the AGCM issued its infringement decision. By renegotiating prices with the regulator, Aspen complied with the decision of the AGCM and therefore, the AGCM closed the file on Aspen in 2018.

The case of *Aspen* shows that there may be certain difficulties in leaving it to the undertaking to set a price which does comply with the current competition rules. The AGCM had to start a non-compliance proceeding against Aspen to ensure that Aspen was charging prices that were compatible with competition law. Though it is understandable that the AGCM, as a CA, does not want to set a new price and that it therefore might act as a price regulator, it was now forced to start new proceedings, which could have been avoided if other remedies were imposed. The following sections will explore situations where the CA does not act as a price regulator, but where alternative efficient and effective remedies can be imposed.

**Cooperation Between the Competition Authority and the Regulator**

Instead of imposing a ‘cease and desist’ order and leaving it to the undertaking to self-assess which prices would be in conformity with competition law, the CA could also impose pricing remedies itself. However, the CA is not a price regulator and it may therefore face certain difficulties when it wants to impose pricing remedies. Regulating prices requires constant monitoring which would warrant a lot of resources from the CA, bearing in mind that CAs

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89 A480 – *Price Increase of Aspen’s Drugs* (n 82), 58.
90 OECD note by Italy (n 43), 8.
92 OECD (n 16), 9.
often have little experience with regulating prices.\textsuperscript{93} Sectoral regulators generally have more knowledge about the industry and the factors influencing the market.\textsuperscript{94} However, instead of seeing these arguments as reasons not to intervene against excessive prices, the idea could also be proposed to let CAs and sectoral regulators work together when it comes to designing remedies and regulating prices.

By working together with the regulator, the regulator could use its more extensive knowledge of the market to aid the CA in creating remedies.\textsuperscript{95} Furthermore, when the remedy involves the capping of prices or another form of price regulation,\textsuperscript{96} the regulatory authority could be the one in charge to monitor the markets and the evolution of the prices. This has two advantages: first of all, the sectoral regulator has more knowledge about the market, and therefore is better equipped to monitor the market. Secondly, it will ensure that the CA does not become a price regulator and can use its resources for other competition cases.\textsuperscript{97}

\textbf{Price Revision Clauses and Arbitration}

Another interesting remedy follows from Gazprom, a case which concerned \textit{inter alia} excessive prices in the gas sector.\textsuperscript{98} In Gazprom, an Article 9 commitment decision was taken, making the commitments offered by Gazprom binding. The commitments concerning excessive pricing included the introduction of a price revision clause in the contracts with the customers that yet lacked such a clause. By inserting this clause, customers had the option to request a revision of gas prices when economic circumstances had changed or when the contract prices do not reflect, for example, development of prices in other Member States. Furthermore, when revising the prices, attention should be paid to prices in other European gas markets. Finally, if the parties were not able to reach an agreement within a period of 120 days, the matter would be referred

\begin{footnotesize}
\addcontentsline{toc}{section}{Notes}
\begin{enumerate}
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\item Katsoulacos and Jenny (n 7), 40.
\item Jones, Sufrin and Dunne (n 14), 67. See also AG Wahl in AKKA/LAA (n 10), paragraph 49.
\item For example, in Argentina, the Central Bank of the Argentine Republic cooperated with the competition authority to design and implement pro-competitive regulatory changes, as well as assess the impact of remedial measures on the market. See Directorate for Financial and Enterprise Affairs Competition Committee, ‘10 years on from the Financial Crisis: Co-operation between Competition Agencies and Regulators in the Financial Sector’ (2017) DAF/COMP/WD(2017)19, 4.
\item For an overview of different methods of price regulation, see Directorate General for Internal Policies (n 16), 34–49.
\item For a discussion on cooperation between the sectoral regulator and a competition authority, see Geradin and O’Donoghue (n 55), 414–415.
\end{enumerate}
\end{footnotesize}
to arbitration. By imposing such a commitment, the CA does not act as a price regulator and leaves discretion to the parties in how to comply with the decision of the CA, thus keeping the remedy proportional.

For the pharmaceutical market, this remedy would most likely mean that the health authority would be the one to ask for a revision of the prices. One way to guide the negotiation would be to compare the pharmaceutical prices in the Member State concerned with the prices in other Member States. This proposed remedy does not stop excessive prices as such, but it does give the health authority an option to ‘fight’ these prices and to secure more affordable prices. Moreover, when it notices that prices in other EU Member States are significantly lower, it can use this to request lower prices.

**Commitment versus Infringement Decisions**

A commitment decision might be an easier way to secure effective (and more extensive) remedies as the remedies do not follow the strict proportionality requirement which applies to infringement decisions. For an infringement decision, a logical consequence would be imposing a fine, as well as either imposing a ‘cease and desist’ order, or the Commission (or CA) setting a price which is fair, for example by cooperating with the regulator. A commitment decision might be easier to set a fair price, for example by including a price revision clause or arbitration obligations like in *Gazprom*. The commitments in *Aspen* that have now been offered in the Commission investigation are also interesting, as substantial price reductions have been offered for a period of 10 years.

**3.4 Recommendations**

This chapter aimed to address the question of when competition law enforcement in the pharmaceutical sector is desirable, and which remedies should be imposed in those cases. Despite the arguments against pursuing excessive pricing cases when patents exist, it has been proposed that certain circumstances still warrant competition enforcement. However, competition authorities should be careful when pursuing these cases. Patented pharmaceuticals

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99 ibid, 102-103.
100 Case C-441/07 Commission v Alrosa [2010] ECR I-05949, paragraph 120.
are often already covered by price regulation, which makes competition law enforcement less necessary. Furthermore, innovation is extremely important in the pharmaceutical industry and therefore, CAs have to take the costs of R&D into account when assessing if the prices are unfair. They could, for example, assess these innovation arguments in the second limb of the *United Brands* test, which deals with the unfairness of the price. Alternatively, R&D costs can be considered by the undertaking raising an objective justification.

The remedies that have been proposed in this chapter also address the criticism that the CA should not become a price regulator. The proposed remedies either leave it to the parties to bring their prices in conformity with competition law, for example by including a price revision and arbitration clause such as in the commitment decision of Gazprom, or they allow CAs to set proportionate and effective remedies. Finally, a further exploration is warranted on how CAs and sectoral regulators can cooperate together to design remedies. Such cooperation is desirable, as it allows the CA to make use of the specialized knowledge of the regulator.

The next chapter will assess if this framework of price regulation and competition law can be supplemented. Is more regulation necessary or are there other alternatives to stimulate competition in the pharmaceutical market, leading to more affordable prices?
Chapter 4: Supplementing the Framework for Excessive Pricing

‘One of the most important contributions of a competition policy system is to serve as an advocate within the government, and the country at large, for reliance on pro-competition policies. This is true, for instance, when the root of an observed competition policy problem resides in other government regulatory programs that distort the competitive process. In that case, the competition agency’s aim should be to identify first-best solutions, which may involve reforms to the other regulatory regimes.’

The quote derives from an article of former US Federal Trade Commissioner William E. Kovacic, in which he recognizes that competition law enforcement is not always the best instrument to use and that CAs may identify instruments which are better suited to deal with market failures. The previous chapters have addressed the causes of excessive prices in the pharmaceutical sector and the role which competition law could play in addition to the price regulation already in place. This chapter will look at alternative ways of dealing with excessive pricing cases, in particular how to prevent these cases and the use of compulsory licensing when situations of excessive pricing come up.

4.1 Is There a Need to Change the Current Framework?

Currently, the pharmaceutical sector is regulated by price regulation and competition law. Price regulation in most EU Member States covers both patented and off-patent drugs, even though there are fewer compelling arguments for price regulation of off-patent drugs. For these drugs more competition is possible, which in theory leads to lower prices. According to economic theory, price regulation of generics should thus not be necessary. Furthermore, there is some concern that the regulation of generics’ prices would actually restrict competition and it has been shown that competition is greater in unregulated or weakly regulated markets than in highly regulated markets. Hence, more regulation to combat excessive prices of generics may not be desirable as it may restrict competition. Instead, competition must be stimulated and if

103 ibid, 422.
105 The study compared the unregulated or weakly regulated markets of the US, Germany, UK and Canada and compared it to highly regulated markets of France, Italy and Japan. See Puig-Junoy (n 104), 651.
that fails and prices remain too high, excessive pricing cases could be pursued to remedy market failures.

4.2 Preventing Excessive Pricing Cases

However, this still raises the question on how to stimulate competition and avoid excessive pricing cases. There are several options to be explored by CAs, which will be discussed below.

Merger Control

Merger control is, contrary to other fields of EU competition law, a form of *ex ante* regulation. With merger control, competition authorities can prevent the creation (or strengthening) of a dominant position, thereby preventing certain infringements of Article 102 TFEU. When the Commission has concerns about a merger, it can block the merger but it can also clear the merger with commitments. These commitments ensure that the merger can still happen, but that some the competition authority’s concerns are addressed. Similar to infringements of Article 102 TFEU, the Commission prefers structural remedies for commitments during merger proceedings as behavioral remedies require constant monitoring by the Commission. Examples of such structural remedies are divestiture, as well as the transfer of intellectual property rights.

In the period of 2009-2017, the Commission has assessed more than 80 mergers, but it did not block any merger, even though 19 mergers raised anticompetitive concerns, for example concerns that prices of medicines would increase after the merger. The intervention rate in the pharmaceutical sector has been much higher than in other sectors: whereas in other sectors the Commission intervened in 6% of the notified mergers, this number is 22% for the pharmaceutical sector.

The analysis of a merger can be very similar to the analysis under Article 102 TFEU, which was confirmed in the case *Tetra Laval*. Moreover, when the Commission takes a decision blocking the merger, it has to be able to show that the merger will either create or strengthen

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106 This can be the Commission, but also NCAs. This depends on whether a merger has an EU dimension, see Council Regulation (EC) No 139/2004 on the control of concentrations between undertakings (the EC Merger Regulation) [2004] OJ L24, Article 1.


108 Regulation 139/2004 (n 106), Articles 6 and 8.

109 For a short discussion on merger remedies, see Whish and Bailey (n 107) 843-844.


111 ibid, 11.

112 Case C-12/03 *Commission v Tetra Laval* [2005] ECR I-00987, paragraph 40.
the dominant position of the undertaking within a limited period of time.\textsuperscript{113} So, the possibility of the undertaking becoming dominant as well as the likelihood of the undertaking abusing that position is already assessed when the merger is notified to the Commission. This could ensure that a competitive pharmaceutical market is maintained and therefore, consumer harm will be limited.

An example of a merger in the pharmaceutical sector is provided in the case \textit{Teva/Allergan}, in which a merger was approved by the Commission subject to certain conditions. This merger concerned two generics companies, both of which were in the top four generic pharmaceutical manufacturers worldwide. Generics competition is crucial to secure lower prices, and the merger between these two companies was expected to lead to less (price) competition and a loss of quality of service and supply. The remedies subsequently involved some divestiture of assets, as a result of which there would no longer be competition concerns.\textsuperscript{114} By divesting parts of the business, conditions can be created for the emergence of a new competitor or the positions of existing competitors will be strengthened.\textsuperscript{115} The increase or strengthening of competition subsequently reduces the risk of price increases.

\textbf{Stimulating Entry}

Another way to ensure competitive market structures is encouraging the entry of (generics) competitors. In section 2.3 several exclusionary practices were discussed: reverse patent settlements, misusing the regulatory system and predatory pricing. It is important to detect this conduct and focus on such exclusionary practices in order to prevent an excessive pricing case from happening. Nevertheless, it is important to remember that some cases may not be caught by Article 102 TFEU. When the company has not yet acquired a dominant position at the time of the exclusionary conduct, this conduct cannot fall under Article 102 TFEU and therefore, there is little that the CA can do. However, the exclusionary conduct may lead to the company acquiring a dominant position. If this is the case and the company has indeed acquired dominance, competition law intervention against excessive prices is possible. Therefore, in

\textsuperscript{113} ibid, paragraphs 148-153.


\textsuperscript{115} Commission Notice on remedies acceptable under Council Regulation (EEC) No 4064/89 and under Commission Regulation (EC) No 447/98 OJ C 68, paragraph 13. For a further discussion on divestiture, also see paragraphs 14-25 of this notice.
these gap cases or when CAs fail to detect exclusionary practices, CAs can always pursue excessive pricing cases as a last resort.

Countervailing Buyer Power

Instead of focusing on maintaining competitive structures through merger control and preventing or punishing exclusionary practices, one could also look at the demand side and at how to strengthen buyer power. This concept, referred to as countervailing buyer power, is mentioned in the Commission’s guidance on Article 102 TFEU. According to the guidance, a customer may have countervailing buyer power and can thereby exercise competitive constraints. Countervailing buyer power may result from the size of the customer, for example when a national regulator negotiates with the pharmaceutical company, but it could also result from the customer’s ability to switch to competing suppliers.\textsuperscript{116}

In the EU, prices for pharmaceuticals are often negotiated upon by the national regulator and the pharmaceutical companies. The regulator thus has ‘monopsony power’, meaning that the pharmaceutical company has to negotiate with that regulator in order to bring its drug on the market. Therefore, one would assume that the regulator has very strong bargaining power. However, this is not always the case.\textsuperscript{117} For example, in the Italian Aspen case, Aspen threatened to withdraw its drug from the market if the Italian regulator did not accept the prices that Aspen wanted.\textsuperscript{118} In such cases, where it is difficult to switch to competing suppliers, the bargaining power of the regulator may actually be very limited.

A threat of withdrawing a drug from the market is more difficult to make to hospitals, as they could more easily consider other medicines with a similar therapeutic use because hospitals are in a better position to control which medicines are prescribed by their doctor. The same applies to patented medicines when there is a choice between several patented medicines that could treat the same disease.\textsuperscript{119} Buyer power could be further stimulated through collective procurement, which will be explained below.

\textsuperscript{116} Guidance on Article 102 Enforcement Priorities (n 66), paragraph 18.
\textsuperscript{117} Durand (n 56), 6 and 33.
\textsuperscript{118} A480 – Price Increase of Aspen’s Drugs (n 82), 56.
\textsuperscript{119} Durand (n 56), 6.
Collective Procurement

Connected to the idea of increasing countervailing buyer power is collective procurement. This idea entails that hospitals and health insurance agencies cooperate with each other, leading to a stronger bargaining position when negotiating drug prices. In the Netherlands, the ACM has published guidelines for the collective procurement on prescription drugs.\(^{120}\) The ACM considers that the possible negative impacts are limited, as pharmaceutical companies have a strong bargaining position and they do not only sell their products in the Netherlands but also in other countries. Moreover, according to the ACM, it is unlikely that the collective procurement of pharmaceuticals will lead to coordination between the parties and a decrease in competition. The ACM has drafted three conditions for the joint purchasing of pharmaceuticals: 1) there can only be harmonization of a limited part of the costs; 2) admission to the joint purchasing scheme is possible on the basis of previously known, objective and non-discriminatory criteria; and 3) the purchasing scheme does not impose unnecessary legal or factual restrictions on the participants in terms of contract duration, purchase commitments and withdrawal from the scheme.\(^{121}\)

There is a slight chance that collective procurement will lead to an infringement of Article 101 TFEU when the agreement, or concerted practice, has as its object or effect the ‘prevention, restriction or distortion of competition within the internal market […]’.\(^{122}\) This is particularly so when it can lead to the fixing of purchase or selling prices.\(^{123}\) However, also at EU level it is recognized that the joint purchasing of medicines may increase buyer power and lead to a stronger negotiation position, resulting in lower prices.\(^{124}\) In particular, the EU Directive on public procurement provides for the possibility that participating contracting authorities set up a joint entity in order to strengthen buyers’ bargaining powers.\(^{125}\) Such cross-border


\(^{122}\) TFEU (n 9), Article 101(1).

\(^{123}\) ibid, Article 101(1)(a).


agreements can lead to the purchase of a larger amount of medicines and concomitantly to lower prices of the medicines. Though such agreement will have its (political) challenges, it can be a useful instrument to achieve lower prices.\textsuperscript{126}

\subsection*{4.3 Compulsory Licensing}

In the previous section different options to be employed to prevent excessive pricing cases were explored. This section will examine compulsory licensing as an alternative to competition law and price regulation when faced with excessive prices for patented pharmaceuticals. Though compulsory licensing can be a remedy for certain competition law cases,\textsuperscript{127} compulsory licenses could also be issued by a minister or other governmental authority. This means that there is no competition case preceding the compulsory license, but that a minister deems it necessary to issue such licenses to keep the prices in the industry at a reasonable level.\textsuperscript{128}

\textit{Compulsory Licensing and the TRIPS}

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) also provides for the issuance of compulsory licenses in Article 31. Though compulsory licensing was initially intended for developing countries, developed countries – such as the EU Member States – can also issue these.\textsuperscript{129} This is confirmed by the Doha Declaration, which states that ‘[e]ach member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.’ Compulsory licensing is further regulated on EU level by Regulation 816/2006, which \textit{inter alia} lays down the conditions for compulsory licensing in the EU.\textsuperscript{130}

Before issuing a compulsory license, one should additionally try to reach an agreement with the holder of the patent ‘on reasonable commercial terms and conditions’.\textsuperscript{131} However, this

\begin{itemize}
  \item \textsuperscript{126} Den Exter (n 125), 13.
  \item \textsuperscript{127} For example, when it concerns standard essential patents and one needs the patent in order to comply with the relevant standard in the industry. See e.g. C-170/13 \textit{Huawei Technologies} [2015] ECLI:EU:C:2015:477. See also Whish and Bailey (n 107), 815-820.
  \item \textsuperscript{129} Den Exter (n 125), 4.
  \item \textsuperscript{130} Regulation (EC) No 816/2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems [2006] OJ L157, Articles 9-10.
  \item \textsuperscript{131} Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) [1994], Article 31(b).
\end{itemize}
requirement ‘may be waived by a Member in case of a national emergency or other circumstances of extreme emergency’. The patent-holder is still protected in the TRIPS, as the holder must be notified, receive remuneration and the holder is still recognized as the owner of the patent. This means that when the conditions for the compulsory license no longer exist, the patent holder no longer has to license the patent to other parties.\(^{133}\)

**National Experiences**

Compulsory licensing has been debated in several countries,\(^{134}\) including the Netherlands. The potential plans of the Netherlands to issue compulsory licenses was subject to criticism as some feared for a reduction of innovation and entrepreneurship.\(^{135}\) However, it is important to bear in mind that this plan does not have as its aim to replace patented medicines with a cheaper copy of the medicine. Compulsory licensing in the Netherlands can only be used when prices are excessive and the negotiation for cheaper prices or a voluntary license fails.\(^{136}\) The party asking the minister to grant a compulsory license has to make a plausible argument that the price will significantly drop after issuing the license and payment for the license has to reflect the costs for R&D.\(^{137}\)

Also the threat of knowing that a minister, or whoever is in charge of issuing compulsory licenses, might issue a compulsory license can ensure that companies lower their prices. This happened in the US and Canada when they tried to stockpile ciprofloxacin, which is a treatment against a terrorist attack with anthrax. Bayer, the company selling ciprofloxacin, first charged

\(^{132}\) ibid.

The same requirements can be found in the EU, see Regulation 816/2006 (n 130), Articles 9-10.


a regular price, but after a threat by the US and Canada to issue a compulsory license, Bayer reduced its price. This shows how effective a threat to issue a compulsory license can be.

**COVID-19**

It will be interesting to see how compulsory licensing will develop in the context of COVID-19. As the COVID-19 pandemic is a public health crisis, this could be seen as an emergency or another circumstance of extreme urgency, which means that the normal requirements of Article 31 TRIPS would not be applicable and countries can issue a compulsory license more easily and faster. Countries may want to force compulsory licenses when a vaccine becomes available and there is not enough stock for the vaccine, or if the vaccine is simply too expensive. However, licenses can also be issued for treatments for COVID-19. Israel did this for an antiviral drug which is a possible treatment option for COVID-19 because there was insufficient supply of the drug. Thailand and Brazil also issued licenses because the drug was too expensive. Nevertheless, in light of the current pandemic going on, the company supplying the antiviral drug actually decided not to enforce its patent.

Domestic legislation has to provide for compulsory licenses, and due to the ongoing pandemic some countries have already initiated legislative changes to ensure that governments can quickly move to issuing compulsory licenses when this is necessary to deal with COVID-19. This does, however, not mean that compulsory licenses are the only viable solution. As shown above, a company may decide not to enforce its patent due to the pandemic, or it may already offer licenses itself against affordable rates or on FRAND (fair, reasonable and non-discriminatory) terms.

**Compulsory Licensing: a ‘Nuclear Option’?**

Compulsory licensing is sometimes also referred to as a ‘nuclear option’ used to stimulate pharmaceutical companies to lower their prices. Though it can be effective in securing lower

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138 There was sufficient capacity in both the US and Canada to manufacture the drug and therefore, after issuing a compulsory license they could manufacture the drug themselves.


141 ibid, 3.

142 ibid.

143 Den Exter (n 125), 8.
prices for pharmaceuticals, it is questionable whether this is a proportionate way of achieving that aim. As mentioned several times throughout this thesis, innovation is crucial for the pharmaceutical sector, and therefore there should be a thorough analysis of the influence of compulsory licensing on innovation. For example, the question has been raised whether the threat of compulsory licensing is currently influencing the amount of money that is being invested into the R&D for the development of a vaccine against COVID-19.144

4.4 Recommendations

This chapter has searched for alternative options of dealing with excessive pricing cases by looking at ways to prevent these cases and by exploring the option of compulsory licenses. It reaches the conclusion that more price regulation for off-patent drugs is (often) not desirable, as this may distort the market and because there are other ways to maintain competitive market structures for off-patent drugs. Through merger control and by targeting exclusionary practices, as well as by strengthening buyer power, competition for off-patent drugs can be stimulated. When this fails, excessive pricing cases can still be pursued.

The issue is more complicated for patented pharmaceuticals, for which there is less competition. Hence, price regulation may often be necessary as there is a high risk of excessive pricing. There are, however, some ways to ensure lower prices for patented pharmaceuticals. Buyer power could be strengthened, for example by enabling collective procurement. Another option which should be further explored is issuing compulsory licenses. Though this option is somewhat controversial, also referred to as a ‘nuclear option’, it can be a very effective way to secure more affordable prices.

144 For a discussion on the relationship between compulsory licensing and the development of a COVID-19 vaccine, see Lo Bianco (n 133).
Chapter 5: Conclusion

I started my dissertation with a quote from a speech of Commissioner Vestager that illustrates the importance of keeping pharmaceutical prices affordable. As individuals rely on pharmaceuticals for their health and sometimes even their life, high prices of pharmaceuticals may put significant strains on national healthcare systems. This thesis has addressed the following question: ‘when is competition law enforcement against excessive prices in the pharmaceutical sector desirable, and how can it be supplemented?’

Excessive pricing cases remain rare in the pharmaceutical sector, which is evidenced by the few cases that have come up so far. When it comes to excessive pricing cases, it is important to distinguish patented and off-patent pharmaceuticals. Price regulation for off-patent pharmaceuticals is less comprehensive than price regulation for patented pharmaceuticals, which should not change. For off-patent pharmaceuticals, the main focus should be on securing competitive markets by targeting exclusionary practices, merger control and strengthening bargaining power. Excessive pricing cases should only be pursued when this fails. For patented pharmaceuticals, on the other hand, there is a much higher risk of excessive prices, as a patent presents a significant (legal) barrier to entry. This explains the need for more comprehensive price regulation for patented pharmaceuticals. However, when price regulation imperfectly covers (or does not cover) patented pharmaceuticals, there should still be some space for competition law enforcement targeting excessive prices. When pursuing these cases, the threshold for finding an excessive price should be higher than for off-patent pharmaceuticals. This can be achieved by taking R&D costs into account – either by incorporating R&D costs in the United Brands test for excessive prices, or by allowing undertakings to objectively justify their excessive prices due to their R&D costs.

To prevent the CAs from becoming price regulators, several remedies were discussed in this thesis. Instead of issuing merely a ‘cease and desist’ order and leaving it to the parties to bring its prices in conformity with competition law, the CA could decide on what constitutes a ‘fair’ price. However, a CA may have insufficient knowledge and expertise of the market to decide on what a fair price entails. Therefore, I have proposed the idea that CAs could work together with the sectoral regulator to establish what constitutes a fair price. To this end, more research should be conducted on the possibilities for cooperation between CAs and sectoral regulators. Furthermore, commitment decisions could be a useful tool in achieving effective remedies.
Lastly, price revision clauses and arbitration obligations such as in *Gazprom* and the price reductions offered in *Aspen* show that effective commitments can be obtained that address the anticompetitive concerns the Commission (or an NCA) might have.

Finally, this thesis discussed alternative ways of dealing with excessive pricing cases. A first approach can be to tackle the exclusionary behavior which has also been discussed in chapter 2. Furthermore, merger control can ensure that competitive structures are maintained, leading to more affordable prices of pharmaceuticals. A final way to prevent excessive prices is by strengthening bargaining power, which can *inter alia* be achieved through collective procurement. If several hospitals or insurers negotiate together on fair prices, their bargaining position is strengthened and they can charge lower prices. When this fails, one option would be to apply competition law and punish excessive pricing. However, for patented pharmaceuticals the possibility of compulsory licensing should also be given attention. By using compulsory licensing, additional market players can be created in some cases, but in other cases the threat of a government using compulsory licenses is sufficient to secure lower prices. It is likely that more discussion on compulsory licensing will emerge in the context of both medicines and a possible vaccine for COVID-19. Though compulsory licensing is controversial, it may be an effective way to secure (more) affordable prices. Future research should explore compulsory licensing and specifically how to ensure that innovation is not hampered by issuing compulsory licenses.

This thesis has demonstrated that excessive pricing cases are desirable when the regulatory framework has failed and CAs have been unable to maintain competitive market structures through the focus on for example merger control and exclusionary practices. CAs should pursue excessive pricing cases for both off-patent and patented products, though for the latter CAs should exercise caution and make sure that these cases do not hamper innovation incentives. To this end, section 3.1 has discussed different options to ensure that innovation considerations are taken into account in the test for excessive pricing. Moreover, this thesis has aimed to fill the gap in the literature, where only a sparse discussion on remedies for excessive pricing sector and alternative options to prevent high prices in the pharmaceutical sector exists. This thesis has argued that fines and cease-and-desist orders will be insufficient to effectively tackle excessive pricing and instead, CAs should investigate possibilities for cooperation with sectoral
regulators.\textsuperscript{145} By doing this, CAs can utilize the knowledge regulators have of the market and avoid becoming a price regulator itself. Furthermore, cooperation with sectoral regulators will save time and resources of CAs as regulating prices in a market is a significant burden for a CA. These resources could be better spent on, for example, exclusionary abuses and merger control. An alternative avenue outside the realm of competition law is compulsory licensing. When excessive prices exist for patented pharmaceuticals, compulsory licenses can help lower drug prices by creating more competition on the market. Adding up the suggestions made throughout this thesis, a more comprehensive framework to combat high prices in the pharmaceutical sector emerges.

\textsuperscript{145} See section 3.3 on remedies.
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