

Excessive prices in the pharmaceutical sector

Is competition law the best remedy?

Master Thesis European Law

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List of abbreviations

AG	Advocat General
AGCM	Autorità Garante della Concorrenza e del Mercato (Italian Market Competition Authority)
ATC	Anatomical Therapeutical Chemical
CAT	British Competition Appeal Tribunal
CFI	Court of First Instance
CMA	British Competition and Markets Authority
EEA	European Economic Area
EU	European Union
ERP	External Reference Pricing
FRAND	Fair, Reasonable and Non-Discriminatory
GDP	Gross Domestic Product
GSK	GlaxoSmithKline
HHAB	Helsingborg Hamn AB
IP	Intellectual Property
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
OECD	Organisation for Economic Co-operation and Development
OFT	Office of Fair Trading
PPRS	Pharmaceutical Price Regulation Scheme
QALY	Quality-Adjusted Life Year
R&D	Research and Development
SSNIP	Small but Significant and Non-transitory Increase in Price
TFEU	Treaty on the Functioning of the European Union
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UBC	United Brands Company
VBP	Value Based Pricing
WTO	World Trade Organization

Chapter 1: Introduction

1.1 Introduction of the topic

Nowadays, the prices of some particular medicines raise a lot of attention in the public debate. An important reason for the attention is the expectation that the expenses for the costs of medicines will rise by hundreds of millions of Euros during the coming years.¹ According to the Dutch Health Institute, which advises the Minister of Health about the inclusion of particular medicines in the health insurances, the limit of acceptance of increasing costs has been reached. The Dutch Health Institute stated that if pharmaceutical companies are not willing or able to justify a particular price, these medicines should not be included in health insurances anymore.² The need for more transparency about prices was also raised in a discussion in the Dutch Parliament about the question whether a pharmacist would be allowed to make a certain medicine himself, even if that infringes patent law, in order to save tens of millions of Euros on a yearly basis. Almost every political party in the Parliament demanded more transparency from the pharmaceutical companies about, on the one hand, the costs of development and production and on the other hand, about the selling prices of the medicines and the profits that are made.³ With regard to potential enforcement, the Dutch Competition Authority has declared prices of medicines as one of its top four priorities for the upcoming year.⁴ Furthermore, the discussion about high prices of medicines has the interest of the European Commission. In a speech about excessive prices the European Commissioner for Competition, Margrethe Vestager, mentioned the pharmaceutical industry specifically: *“There can be times when prices get so high that they just can’t be justified. After all, people rely on these medicines for their health, even their lives. In those situations, competition rules need to do their bit to deal with excessive prices.”*⁵

Although abuse of a dominant position by imposing unfair purchase or selling prices is regarded as an exploitative abuse and is prohibited by article 102(a) TFEU, excessive prices were not often investigated by the European Commission in the past, due to difficulties to prove that prices were really too high. Especially in the pharmaceutical sector, where the costs of research and development (R&D) are extremely high, it can be hard to determine whether a price is ‘unfair’ or ‘excessive’. Nonetheless, in some Member States, Competition Authorities have fined pharmaceutical companies for imposing excessive prices. In October 2016, the pharmaceutical company Aspen was fined €5.2 million by the Italian Market Competition Authority (AGCM) because of abuse of dominance by artificially inflating the

¹ Van den Brink & De Jong, *NOS* 7 February 2018.

² De Visser, *De Volkskrant* 20 February 2018.

³ *NOS*, ‘Kamer: bekijken of apotheker medicijnen kan maken’, 22 November 2017.

⁴ Dutch Competition Authority 2018, ‘Speerpunten ACM: Digitaal, groene energie, medicijnprijzen en havens’, acm.nl/nl/publicaties/speerpunten-acm-digitaal-groene-energie-medicijnprijzen-en-havens [15 March 2018].

⁵ Vestager, *Protecting Consumers from exploitation*, Speech Chillin’ Competition Conference, Brussels, 21 November 2016.

price of four cancer drugs. This decision was confirmed in appeal.⁶ In May 2017 the European Commission also started a formal investigation into Aspen's pricing practices for cancer medicines.⁷ Moreover, in December 2017 the Competition and Markets Authority of the United Kingdom (CMA) imposed a record fine of £84.2 million on the pharmaceutical manufacturer Pfizer and a £5.2 million fine on Flynn Pharma after finding that both infringed competition law by charging excessive and unfair prices to the National Health Service (NHS) for phenytoin sodium capsules, an anti-epilepsy drug.⁸ However, in June 2018 this decision was overturned by the Competition Appeal Tribunal (CAT), which ruled that CMA had misapplied the test for unfair pricing.⁹

The low number of successful excessive pricing cases raises the question whether competition law is a suitable instrument to prevent high prices of medicines. Furthermore, especially in the pharmaceutical sector the costs of R&D are extremely high. That means that if pharmaceutical companies are not able anymore to charge high prices to cover these costs (and costs of development for medicines that did not enter the market eventually), the innovation of medicines might stop, which harms the health of consumers in the end. For this reason, this research tries to answer the following research question: *'Is the concept of excessive pricing in competition law a suitable instrument to prevent high prices of medicines and, if not, which alternatives can be considered?'*

⁶ Angelli 2017, p. 227.

⁷ European Commission, Press Release of 15 May 2017: *Antitrust: Commission opens formal investigation into Aspen Pharma's pricing practices for cancer medicines* (IP/17/1323).

⁸ UK Government, Press Release of 15 June 2017: *CMA publishes full decision in phenytoin case*.

⁹ UK Competition Appeal Tribunal, Case 1275/1/12/17, *Pfizer/Flynn Pharma* [2018], par. 7.

1.2 Relevance of the topic

1.2.1 Relevance of the topic from a societal perspective

As already touched upon in the foregoing paragraph, prices of medicines are heavily discussed in the public debate nowadays. These discussions are largely due to the increasing amount of expensive new pharmaceuticals entering the market, which put strain on the public healthcare budget.¹⁰

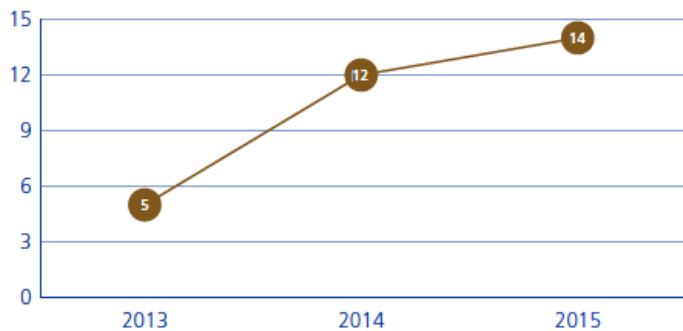


Figure 1: Expenses of newly introduced medicines in the Netherlands in millions of Euros.¹¹

Research by the Dutch Healthcare Authority showed that the expenses of ‘add-on’ medicines (medicines that are invoiced separately of the actual treatment because of the high price) rise with an average of 6,7% each year, which is a stronger increase than the total expenses on the health care budget.¹² The majority of these expensive medicines are anti-cancer medications.¹³ A report of the Dutch Cancer Society showed that from 2011 to 2014, the spending on expensive anti-cancer drugs increased by 80%, up to €675 million per year.¹⁴

While the expenses for medicines are an issue of public debate in many European countries, it is interesting to see that considerably large price differences exist between these countries. While the European Commission has the exclusive responsibility to decide which medicines are placed on the market of the European Union, the Member States have the sole responsibility to decide which drugs they reimburse and at what price.¹⁵ This leads to remarkable price differences between Member States: for two thirds of the medicines, price differences between the highest-priced country and lowest-priced country range between 25% and 100%. For the remaining medicines, mainly low-priced medicines, higher price differences occur, up to 251%.¹⁶ Member States with the prices of medicines at the upper-

¹⁰ De Boer & Geilmann 2017, p. 263.

¹¹ *Monitor Uitgaven geneesmiddelen in de medisch-specialistische zorg* 2017, p. 5.

¹² *Ibid*, p. 10-11.

¹³ *Ibid*, p. 18.

¹⁴ Tax, Scheres & Van der Hoeven 2015, p. 18.

¹⁵ European Medicines Agency (EMA) 2016, p. 3.

¹⁶ Vogler, Zimmermann & Babar 2017, p. 228.

end are Germany, Sweden, Denmark and Ireland, while Greece, Hungary, Slovakia and UK were frequently at the lower end.¹⁷ It is noteworthy that these differences cannot only be traced back to the different economic situations. For example, a relationship between price and economic wealth was not the case for Belgium, France and the United Kingdom, where the prices were rather low but the GDP per capita was comparably high.¹⁸ Other reasons for differences of price levels, even between neighbouring countries within the European Union, are differences in healthcare systems, the size of the market or the focus of the medicine policy on health or industry objectives: earlier research showed a positive relationship between the presence of pharmaceutical industry in a country and a higher price level.¹⁹

In any case, increasing prices of medicines can create sticking points on the national health care budget of countries, which leads to concerns about the accessibility of these medicines for patients in the future.²⁰ In this regard, the Dutch Council for Public Health and Society stated *“a situation has arisen in the Netherlands that is impacting negatively on both society and the individual patients”*.²¹ Concerns about high prices of medicines are rising on the European level too. In June 2016, the European Council of Employment, Social Policy, Health and Consumer Affairs agreed on a conclusion in which it called for measures to ensure that patients have access to essential medicines at affordable prices.²² With concern, the Council noted *“an increasing number of examples of market failure in a number of Member States, where patients access to effective and affordable essential medicines is endangered by very high and unsustainable price levels, market withdrawal of products that are out-of-patent, or when new products are not introduced to national markets for business economic strategies and that individual governments have sometimes limited influence in such circumstances.”*²³ Furthermore, the Council invited the Commission to conduct an in-depth analysis of the existing EU legislation on pharmaceuticals, the related incentives and their impact on innovation, availability and accessibility of medicinal products, including high priced essential medicinal products for conditions that pose a high burden on patients and health systems.²⁴ The Council also asked the Commission to continue, and where possible to intensify, the monitoring and investigation of potential cases of market abuse, excessive pricing and other market restrictions specifically relevant for the pharmaceutical sector.²⁵

¹⁷ Vogler, Zimmermann & Babar 2017, p. 228.

¹⁸ Ibid, p. 226.

¹⁹ Ibid, p. 227.

²⁰ Tax, Scheres & Van der Hoeven 2015, p. 18.

²¹ Dutch Council for Public Health and Society (Raad voor Volksgezondheid en Samenleving) 2017, ‘Smarter development, stronger negotiation’, <raadrvs.nl/actueel/item/smarter-development-stronger-negotiation> [20 April 2018].

²² European Council of Employment, Social Policy, Health and Consumer Affairs 2016, ‘Main results’, <consilium.europa.eu/en/meetings/epsco/2016/06/16-17/> [5 March 2018].

²³ European Council of Employment, Social Policy, Health and Consumer Affairs 2016a, ‘Council conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States’, point 16.

²⁴ Ibid, point 47(b).

²⁵ Ibid, point 48.

Furthermore, high prices of pharmaceuticals have the interest of the European Parliament. In March 2017, it adopted a resolution in which it called for measures to improve the traceability of costs for R&D, public funding and marketing expenditure in order to strike a better balance between EU countries' public health interests and those of the pharmaceutical industry. Moreover, the European Parliament stated that new legislation is needed to ensure the full transparency and effective controls of the procedures used to determine the prices and reimbursement of medicinal products in the Member States.²⁶ Two months after this resolution, the European Commission announced it had opened a formal investigation into Aspen Pharma's pricing practices with regard to cancer medicines. It is interesting to note that concerns about the rising prices of pharmaceuticals are not limited to European countries. Recently, there have been hearings in the US Congress with respect to the question how the prices of prescription drugs can be lowered.²⁷ And of course, one can imagine less developed countries are having even more difficulties with the prices of medicines. In combination with other factors, such as a general lack of proper health care systems, this leads to the fact that access to essential medicines is problematic for one third of all persons worldwide. This lack of access is especially a problem in least-developed countries, but also increasingly in middle-income countries.²⁸

These developments show a high societal interest in the question how excessive prices of medicines can be prevented. While there are several approaches to possibly prevent extremely high prices, such as price regulation or changes in patent law, the European Commission now mainly focuses on the use of competition law. However, the application of the concept of excessive pricing is fairly recent: only very few companies were fined because of charging excessive prices in the past. Therefore, it is interesting to investigate whether the prohibition of excessive pricing is a suitable instrument to prevent high prices of medicines or whether the society should focus on other solutions.

²⁶ European Parliament 2017, 'MEPs propose ways to make medicines more affordable', <europarl.europa.eu/news/en/press-room/20170227IPR64157/meps-propose-ways-to-make-medicines-more-affordable> [6 March 2018].

²⁷ Tribble, *The Washington Post* 12 December 2017.

²⁸ Stevens & Huys 2017, p. 1-2.

1.2.2. Relevance of the topic from an academic perspective

Besides the relevance of the topic from the perspective of society, the topic is also interesting from an academic perspective since it can contribute to the existing legal research in a couple of ways. First of all, this research can present an encompassing view on the topic of excessive pricing in the pharmaceutical sector, in which the current developments are taken into account. This is relevant because during the past months a lot of relevant developments have occurred. Examples of such developments are the decision of the European Commission to formally investigate the pharmaceutical company Aspen and the decisions of the competition authorities of the United Kingdom and Italy. In my research these decisions will be examined to see in which way the concept of excessive pricing was applied by the competition authorities and by national courts. Another interesting recent development is the judgement that was delivered by the European Court of Justice in September 2017 in the case *AKKA/LAA*. In this judgement the Court provided more information about the assessment of potential excessive prices, which is therefore a very interesting case to take into account. Furthermore, this research is relevant from an academic perspective because it does not only focus on the instrument of competition law, but also assesses other instruments which could be useful to prevent high prices.

1.3 Normative framework for the assessment of suitability

In order to answer the question whether competition law is a suitable instrument to prevent high prices, first the normative framework which covers this question should be described. Since 'suitability' is a broad concept, it is necessary to define under which circumstances the research question will be answered in the affirmative. Generally said, competition law can be considered a suitable instrument to prevent high prices in case it can guarantee several essential interests.

First of all, the interests of patients which depend on certain medicines, should be guaranteed. In this regard, medicines form a different category of goods than is usually dealt with under competition law for the simple reason that people can be dependent on them for their lives. The need to protect these interests is not only a matter of ethics, but is also legally prescribed in several provisions. First, it is laid down in article 35 of the Charter of Fundamental Rights of the European Union, which is legally binding since the Treaty of Lisbon, that everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. Furthermore, the article states that a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities. The same holds for article 9 TFEU, which prescribes that in defining and implementing its policies and activities, the Union shall take into account requirements linked to, *inter alia*, the

protection of human health. Accordingly, ensuring access to medicines for patients is an essential interest.

Secondly, it is important to pay attention to society's interests. Next to ensuring access to medicines, it is in the interest of the society to prevent excessive prices of medicines. As was explained in paragraph 1.2.1, pharmaceutical expenses are rising in many Member States, which raises many concerns by governments. These concerns are due to the fact that the high prices create sticking points on the national health care budgets. If a large part of the national health care budget will be spend on medicines, less budget remains available for other health care expenses. Besides that, concerns are rising about the growing health care budget in general. Throughout the European Union, the budget spend on health care is increasing rapidly. According to the OECD, *"particularly in Europe, public expenditure on health and long-term care is set to increase from around 6% of GDP today to almost 9% of GDP in 2030 and as much as 14% by 2016, unless governments can contain costs"*.²⁹ For this reason, rising health care budgets also raise concerns about the sustainability of other expenses in the future: if the health care budget keeps increasing, less public resources will be available for other essential public tasks such as infrastructure, education and defence. Therefore, the interest of society to prevent increasing pricing of medicines is an important factor that should be taken into account as well.

The third interest which should be taken into consideration is the interest of pharmaceutical companies to get a proper return on investment. If pharmaceutical companies are not able anymore to recoup their investments, they will probably not invest in the development of new medicines anymore. These investments are an essential factor in the research process and the development of new medicines. The stimulation of innovation is the main reason for the creation of intellectual property rights, which protect the companies from competition during a certain period of time in order to earn back their investments. In order to protect the innovation process, it is necessary that the financial interests of the pharmaceutical companies are respected as well.

The foregoing leads to the conclusion that the concept 'suitability' consists of different elements which should be taken into consideration. In order for competition law to be a suitable instrument to prevent high prices, it is important that all different interests, of patients, the society and pharmaceutical companies, are guaranteed. Only if a certain instrument protects these three interests sufficiently and balances them in a reasonable way, that instrument is considered suitable.

²⁹ OECD 2015, 'Healthcare costs unsustainable in advanced economies without reform', <oecd.org/health/healthcarecostsunsustainableinadvancedeconomieswithoutreform.htm> [12 June 2018].

1.4 Methods and structure

The question whether the concept of excessive pricing in competition law is a suitable instrument to prevent high prices of pharmaceuticals is a combination of an evaluative and normative question. Firstly, in order to answer this question, relevant documents including academic research, Commission documents, European case law, decisions of national competition authorities and legislation will be investigated. After these sources are analysed, the research question will be evaluated in the light of the normative framework that was described in the foregoing paragraph. Subsequently, alternative solutions will be described. In this research, the focus lies on the prohibition of excessive pricing which is laid down in article 102(a) TFEU. Other forms of abuse which occur in the pharmaceutical sector regularly, such as the prevention of parallel trade, pay for delay settlements or exclusionary price abuses, will only be touched upon generally. Furthermore, although this thesis is written from a European Union perspective, now and then references are made to certain relevant national initiatives. Since this thesis has been written in the Netherlands and the discussion about high prices of medicines was at the time of this writing very topical in this country, references to Dutch policy initiatives or events occur quite regularly. Finally, it is important to note that due to different health policies throughout the European Union, this thesis will not deal explicitly with factors as health insurances or prescribing policies. Although these are of course important factors in this discussion, it would go beyond the scope of this research to take these factors into account as well.

Chapter 2. Abuse of dominance in the pharmaceutical sector

2.1 The purpose of article 102 TFEU

Article 101 and 102 TFEU form the main provisions of European competition law. The competition rules are regarded crucial to protect the EU single market next to the free movement provisions: there is no point in prohibiting State measures which divide the market if on the other hand undertakings would be allowed to create and maintain barriers to trade between Member States by dividing markets and indulging in anti-competitive practices. Therefore, economic integration is promoted by both the free movement provisions and by the competition rules.³⁰

According to article 102 TFEU, any abuse by one or more undertakings of a dominant position within the internal market or in a substantial part of it shall be qualified as incompatible with the internal market insofar as it may affect trade between Member States. This shows that, contrary to article 101 TFEU, which focuses on agreements between undertakings, article 102 TFEU is designed to deal with the unilateral behaviour of undertakings which hold a 'dominant position'. In this way, it constrains the behaviour of undertakings which are not sufficiently restrained by other competitors operating on the market. It is important to note that article 102 TFEU only applies to anti-competitive conduct by undertakings which are already dominant and not to conduct by which an undertaking achieves dominance or to any other conduct by a non-dominant undertaking which causes harm to consumers.³¹ For that reason, the establishment of a monopolist or dominant position is essential for the application of article 102 TFEU. Next to the situation in which a single undertaking is holding a dominant position, there can be a situation of collective dominance in which several undertakings together hold a dominant position vis-à-vis the other operators on the same market.³²

European competition law was influenced to a considerable degree by the ordoliberalism, which had its origin in the so-called Freiburg School during the 1930s.³³ According to the ordoliberalism, the main purpose of competition law was to protect individual economic freedom, which ensures individuals are free to make their choices on the market. Therefore, it is the task of the state to provide laws against restraints of competition and to enforce them as rules of the game with which market participants have to comply.³⁴ In this ordoliberal view, competition law is aimed at securing economic freedom, which allows all

³⁰ Jones & Sufrin 2016, p. 35.

³¹ Ibid, p. 258.

³² Ibid, p. 264.

³³ Ibid, p. 25.

³⁴ Ibid, p. 26.

citizens to participate on the market. For this reason, the focus of this view lied on the structure and process of the market, rather than on the outcomes for consumers.³⁵

During the 1990s, the Commission began to move towards a realignment of competition law in line with the modern economic concepts on efficiency and welfare.³⁶ During this movement, consumer welfare became the main purpose of competition law, which means that only in case an agreement has a negative effect on consumer welfare, it will be prohibited.³⁷ These negative effects on consumer welfare can be, inter alia, higher prices, reduced output, less choice, lower quality of goods or services or diminished innovation.³⁸ Economists calculate the losses and gains to consumer welfare of certain agreements or conduct of undertakings, which leads to a simple sum: if costs are higher than benefits, the agreement is regarded as contrary to competition law.³⁹ Although the consumer welfare approach is primarily concerned with efficient transactions and cost-savings, it can also take other interests into account which are economically calculable, such as safety and health of consumers.⁴⁰

The adoption of the consumer welfare standard by the Commission has not been followed unambiguously by the European Court.⁴¹ In some cases the Court took a broader approach on the ultimate goals of competition law. In the case *T-Mobile* the Court stated that the competition rules are designed to protect not only the immediate interests of individual competitors or consumers, but also to protect the structure of the market and competition as such.⁴² Consequently, in order to enforce competition law, harm to consumer welfare is not definitely a pre-condition. In this regard, an interesting question is whether the other objectives of the Treaty must be taken into account when competition law is enforced, since article 7 TFEU prescribes the Union to 'ensure consistency between its policies and activities'.⁴³ Accordingly, article 8 – 13 TFEU set out specific matters that should be considered when defining and implementing policies, such as the promotion of a high level of employment, the guarantee of social protection, the fight against social exclusion and discrimination and a high level of human health. The effect of these provisions is still subject of debate since until today, the Court has not addressed the legal effect of these policy-linking clauses.⁴⁴ In practice, there are two ways in which non-welfare or efficiency issues and other EU-policies can be taken into account. First, a matter can be excluded from the

³⁵ Jones & Sufrin 2016, p. 27.

³⁶ Ibid, p. 37.

³⁷ Claassen & Gerbrandy 2016, p. 1.

³⁸ Jones & Sufrin 2016, p. 39.

³⁹ Claassen & Gerbrandy 2016, p. 2.

⁴⁰ Cseres 2007, p. 122.

⁴¹ Jones & Sufrin 2016, p. 40.

⁴² Case C-8/08 *T-Mobile Netherlands BV and Others v. Raad van bestuur van de Nederlandse Mededingingsautoriteit* [2009], ECLI:EU:C:2009:343, par. 38.

⁴³ Jones & Sufrin 2016, p. 43.

⁴⁴ Ibid, p. 43.

scope of competition law altogether, as is the case with for example national security. Second, a matter may be covered by the competition rules but other consideration may be taken into account in their application, which is described as a compromise or a ‘balancing exercise’.⁴⁵ As already mentioned in the introduction, the current Commissioner Vestager often emphasises competition law is about ‘fairness’, which has raised quite some discussion about the ultimate goals of competition law. In a recent speech, the Commissioner Vestager stated: *“The competition rules aren’t there just because we think that competition is a good thing in itself. Like any of the other rules that govern our world, we have competition rules because we believe they make our society a better place to live. That they make our markets work more fairly for consumers.”*⁴⁶ However, Vestager also pointed at the limits of the ‘fairness’ approach: *“That doesn’t mean that we at the Commission see ourselves as superheroes, solving all unfairness, and righting every wrong. It doesn’t mean that just because something is unfair, it’s automatically also against the competition rules.”* With regard to this ‘fairness’-approach, many authors argue that fairness is not an abstract standalone goal, but is rather a natural outcome of competition law.⁴⁷ In this way, the goal of the notion of ‘competition on the merits’ is to protect the competitive process and create equal opportunities for undertakings to compete, which naturally benefits all participants in the process: consumers, companies, employees and society overall.⁴⁸

2.2 Defining ‘dominance’

2.2.1 The notion of dominance

As explained in paragraph 2.1, article 102 TFEU only applies to undertakings which have a dominant position on the market. Therefore, the question whether an undertaking has such a position, is of central importance. In many cases, it is not easy to identify with sufficient clarity the point at which an undertaking becomes dominant and so potentially subject to the prohibition.⁴⁹ The landmark case in this context is *United Brands*, in which the Court provided a definition of a dominant position. It stated a dominant position *“relates to a position of economic strength enjoyed by the undertaking which enables it to prevent effective competition being maintained on the relevant market by giving it the power to behave to an appreciable extent independently of its competitors, customers and ultimately of its consumers.”*⁵⁰ Therefore, the notion of dominance entails that a certain undertaking enjoys substantial market power over a period of time.⁵¹ In the case *Hoffmann-La Roche*, the

⁴⁵ Jones & Sufrin 2016, p. 43.

⁴⁶ Vestager, *Fairness and Competition*, Speech GCLC Annual Conference, Brussels, 25 January 2018.

⁴⁷ De Pablo 2017, p. 148.

⁴⁸ *Ibid*, p. 148.

⁴⁹ Jones & Sufrin 2016, p. 285.

⁵⁰ Case C-27/76 *United Brands v. Commission* [1978], ECLI:EU:C:1978:22, par. 66.

⁵¹ Communication from the Commission (2009/C 45/02), *Guidance on the Commission’s enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings*, par. 10.

Court added that a dominant position “does not preclude some competition, which it does where there is a monopoly or quasi-monopoly, but enables the undertaking which profits by it, if not to determine, at least to have an appreciable influence on the conditions under which that competition will develop, and in any case to act largely in disregard of it so long as such conduct does not operate to its detriment.”⁵² So, in order for a company to have a dominant position on the market, it is not necessary for the company to have a monopoly: it is sufficient that the undertaking is in a position in which it can behave to an appreciable extent independently or has an appreciable influence on the conditions of competition.

2.2.2 The relevant market

To see whether an undertaking is in a dominant position, it is necessary to define the relevant market since dominance only exists in relation to a particular market and not in the abstract, as the Court stressed in the case *Continental Can*. In this case, the Court stated the definition of the relevant market is of ‘essential significance’ to the determination of whether or not an undertaking is dominant.⁵³ This is a logical conclusion, because in case the relevant market is defined too narrowly, an undertaking’s position will be exaggerated and a finding of dominance will be more likely. On the other hand, in case the relevant market is defined too widely, a dominant position will probably not be found.

The process of determining the relevant market consists of two steps. In the first place, the relevant product market has to be defined and in the second place, the relevant geographical market should be found. According to the Commission, the objective of defining a market in both its product and geographic dimension is to identify those actual competitors of the undertakings involved that are capable of constraining those undertakings behaviour and of preventing them from behaving independently of effective competitive pressure.⁵⁴

The relevant product market

According to the Commission, a relevant product market comprises all products and/or services which are regarded as interchangeable or substitutable by the consumer. If consumers are in a position to switch easily between different products, these products probably belong to the same product market. In this assessment, specific attention is paid to the products’ characteristics, their prices and their intended use.⁵⁵ Next to qualitative methods, quantitative methods are used to measure substitutability. In particular the SSNIP test, which stands for ‘small but significant and non-transitory increase in price’ is used. This test is essentially applied to assess whether a small (5 – 10%) but non-transitory increase in

⁵² Case C-85/76 *Hoffmann- La Roche & Co AG v. Commisision* [1979], ECLI:EU:C:1979:36, par. 39.

⁵³ Jones & Sufrin 2016, p. 290.

⁵⁴ Commission Notice (97/C 372/03) *on the definition of relevant market for the purposes of Community competition law*, par. 4.

⁵⁵ *Ibid*, par. 7.

price of product A will cause purchasers to buy product B instead.⁵⁶ In case consumers will indeed purchase product B instead of product A, these products can be regarded as interchangeable or substitutable, which would lead to the conclusion that these products belong to the same product market. However, in case changes in price do not have a considerable influence on the demand side, the relevant product market is probably smaller.

In the case *AstraZeneca*, which dealt with exclusionary abuse by a pharmaceutical company, it was established that the general principles of defining a relevant product market also apply to the pharmaceutical sector, despite the applicable regulations in the sector or the reimbursement of the cost of medicines by national health systems.⁵⁷ Generally, the case law related to the pharmaceutical markets shows the relevant product market should be defined through a comprehensive assessment of all the factors of substitutability from a consumer's point of view.⁵⁸ Nevertheless, some specific features of the pharmaceutical market lead to the finding that price changes do not have a significant influence on the demand side. First, the willingness of people to pay for life prolonging or quality of life improving medicines is high. Second, the doctors who make treatment decisions and the private individuals who use medicines do typically not contribute to the costs of the medication to a significant extent. Therefore, they are not as exposed to price pressure as consumers are when they buy typical consumer goods. A third reason, which is related to the previous one, is that the financing of medicines through health insurances and/or government funds strongly increases the average ability to pay. And lastly, public opinion is considered to have a strong price uplifting effect, especially in cases where patient organizations effectively organize themselves.⁵⁹ In the last years, this situation has occurred a couple of times in the Netherlands: after the Minister announced that a specific medicine would not be reimbursed anymore because of the high prices, patient organizations organised protests which led to public consternation and in the end, to a decision of the Minister to reimburse the medicines again.⁶⁰ In this regard, it is said that at least in some cases, patient organizations were encouraged, including financially, by the pharmaceutical industry to raise protests in case a specific medicine would not be reimbursed by health insurances anymore.⁶¹

Since, for reasons described above, price elasticity is low and price pressures from the demand side tend to be weak, the SSNIP-test can only play a limited role in defining the relevant product market in the pharmaceutical sector. Therefore, the analysis of competition authorities should also assess other factors to see whether medicines are interchangeable,

⁵⁶ Jones & Sufrin 2016, p. 291-292.

⁵⁷ Ibid, p. 75.

⁵⁸ Parziale 2018, p. 4.

⁵⁹ Fonteijn, Akker & Sauter 2018, p. 12.

⁶⁰ See for instance: De Visser, *De Volkskrant* 25 October 2017.

⁶¹ Fonteijn, Akker & Sauter 2018, p. 12.

such as therapeutic effects of medicines⁶², prescribing patterns by physicians⁶³ or firm competitive behaviour, which can show how the firm itself regards the issue of competition from other products.⁶⁴ In defining the relevant product market in the pharmaceutical sector, national competition authorities and the European Commission normally use the Anatomical Therapeutical Chemical (ATC) classification system as a starting point. This classification scheme divides pharmaceutical products into different groups, according to the organs or systems on which they act and their chemical, pharmacological and therapeutic properties, and then divides them into five different levels.⁶⁵ Normally, the analysis of the authorities to define the product market starts from the third level of the classification scheme, which groups medicines in terms of therapeutic indications or intended use. However, if appropriate in the circumstances of the case, the market can be defined on another level, such as on the fourth (mode of action) or fifth (individual active chemicals).⁶⁶ In defining the relevant market, competition authorities enjoy a margin of discretion. For example in the case *AstraZeneca* the Commission defined the market fairly narrowly by defining two pharmaceutical products that were used to treat the same conditions as two distinct markets. This decision was based on the fact that the pharmaceuticals had different therapeutic effects. Therefore, the Commission referred to the fourth level of the ATC classification instead of the third.⁶⁷ This approach, which was accepted by the Court, was based on the analysis of data which showed that one medicine did not exercise a significant competitive constraint over the other.⁶⁸

The relevant geographic market

Next to the product dimension of the relevant market, the geographic dimension is important to define the relevant market since it is possible to have the same product market, which is nevertheless divided by geographical limitations. These limitations can exist due to factors as regulation, high transport costs, language, marketing infrastructures or consumer preferences.⁶⁹ In *United Brands*, the Court defined the relevant geographic market as a market in which *“the conditions of competition are sufficiently homogenous for the effect of the economic power of the undertaking concerned to be able to be evaluated”*.⁷⁰ To define the geographic market, the Commission gathers different types of evidence. This evidence can consist of past changes of diversion of orders in other areas, basic demand characteristics, the views of consumers and competitors in a certain area, geographic patterns of purchases, trade flows and barriers or switching costs which occur if orders are

⁶² Morse 2003, p. 634.

⁶³ Ibid, p. 661.

⁶⁴ Ibid, p. 668.

⁶⁵ Case T-321/05 *AstraZeneca v. Commission* [2010], ECLI:EU:T:2010:266, par. 154.

⁶⁶ Jones & Sufrin 2016, p. 75.

⁶⁷ Eccles 2013.

⁶⁸ Case T-321/05 *AstraZeneca v. Commission* [2010], ECLI:EU:T:2010:266, par. 5.

⁶⁹ Jones & Sufrin 2016, p. 312.

⁷⁰ Case C-27/76 *United Brands v. Commission* [1978], ECLI:EU:C:1978:22, par. 11.

diverted to companies located in other areas.⁷¹ Ultimately, the final geographic market can range from a local market to a global one. With regard to pharmaceutical markets, circumstances can defer to a considerable extent between countries, for example due to different medicine regulations and differences with regard to price setting, reimbursement and channels of distribution⁷². For this reason the Commission and national authorities have consistently found geographic markets for pharmaceutical products to be national.⁷³

2.2.3 Relevant factors to assess market power

Once the relevant market is defined, it can be assessed whether the undertaking on that market enjoys market power and accordingly, has a dominant position. Important factors in this assessment are the market shares. When the relevant market is defined, first the suppliers and the consumers which are active on that market, should be identified. In a second step, the total market size and the market shares for each supplier can be calculated on the basis of their sales of the relevant products in the relevant geographic area.⁷⁴ Although also other factors should be taken into consideration, in general an undertaking with a very high market share is likely to be dominant. In the case *Hoffmann-La Roche* the Court held that although the importance of market shares may vary from one market to another, the view may legitimately be taken that 'very large shares' are in themselves, save for exceptional circumstances, evidence of the existence of a dominant position.⁷⁵ In the case *AKZO* it became clear that the Court regards a market share of 50% or higher as a 'very high market share'. Accordingly, a market share of 50% normally entails the presumption of dominance on the market.⁷⁶ However, this presumption is always rebuttable. Even in cases where the undertakings had very high market shares, the Court referred to evidence of other indications of dominance, which show that the 'exceptional circumstances' referred to in *Hoffmann-La Roche* are not present.⁷⁷ Generally, dominance is not likely to occur if the market share of the undertaking is below 40%. However, according to the Commission also undertakings having market shares below 40% can deserve attention in specific cases where competitors are not in a position to constrain effectively the conduct of a dominant undertaking, for example where they face serious capacity limitations.⁷⁸ Apart from looking at the absolute market shares of a certain undertaking, the market shares should be assessed in relative terms. In *Hoffmann-La Roche* the Court already stated that the

⁷¹ Commission Notice (97/C 372/03) *on the definition of relevant market for the purposes of Community competition law*, par. 45-50.

⁷² See for instance: European Commission, Decision in Case COMP/A. 37.507/F3 *AstraZeneca*, [2005], par. 503.

⁷³ Figuera & Guerrero 2016, p. 39.

⁷⁴ Commission Notice (97/C 372/03) *on the definition of relevant market for the purposes of Community competition law*, par. 53.

⁷⁵ Case C-85/76 *Hoffman-La Roche & Co. AG v Commission of the European Communities* [1979], ECLI:EU:C:1979:36, par. 40.

⁷⁶ Jones & Sufrin 2016, p. 322.

⁷⁷ *Ibid*, p. 323.

⁷⁸ Communication from the Commission (2009/C 45/02), *Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings*, par. 14.

relationship between the market shares of the undertaking concerned and of its competitors, especially those of the largest, is a relevant factor.⁷⁹ Logically, the market power of an undertaking with a market share above 50% will be examined differently depending on the position of the second largest competitor.

Next to the market shares, possible barriers to entry and expansion are very important factors in the assessment of whether an undertaking has a dominant position or not. Although rare, it is possible for an undertaking to have a market share of 100% without having substantial market power.⁸⁰ For example, this situation could occur in a very dynamic, innovative market where it is very easy for new undertakings to enter the market. In such situations, an undertaking cannot be considered dominant because it is not able to behave independently of its competitors or consumers since it has to defend its position constantly. For instance, an undertaking will not be able to charge monopoly prices if other firms can freely enter the market and compete with it.⁸¹ For that reason, the potential impact of expansion by actual competitors or entry by potential competitors, including the threat of such expansion or entry, is very relevant.⁸² Possible barriers to entry or expansion can take various forms and can be divided into three groups. First, structural barriers, which arise from the basic conditions in the industry, exist on certain markets. Important structural barriers are absolute costs advantages, economies of scale and high capital costs. Furthermore, legal and regulatory barriers belong to this category and include all kinds of rules, restrictions and conditions imposed by governments on entry on or operation within a market.⁸³ Such barriers include intellectual property rights, which the Chicago School qualifies as 'the most substantial barriers to entry'.⁸⁴ Secondly, a lot of barriers are cost-oriented and consist of sunk costs. Examples of such costs are start-up phase losses, advertising and promotion costs, costs for research and development that does not yield results with alternative uses or the expenses of complying with the applicable regulations.⁸⁵ The third category of barriers of entry or expansion consists of strategic barriers, which are intentionally created or enhanced by competitors. Examples of such strategic barriers are predatory pricing, loyalty rebates, refusal to supply, tying, exclusive dealing arrangements or patent hoarding, whereby an undertaking acquires numerous patents that block the feasible methods of competing and thereby builds a 'fortress' around its market position.⁸⁶ Especially in the pharmaceutical sector there are various barriers to entry and expansion since this sector is highly capital-intensive and highly regulated, entails high costs for research and development and is to a large extent based on intellectual property rights.

⁷⁹ Jones & Sufrin 2016, p. 323.

⁸⁰ Ibid, p. 319.

⁸¹ Ibid, p. 79.

⁸² Communication from the Commission (2009/C 45/02), *Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings*, par. 16.

⁸³ Jones & Sufrin 2016, p. 83.

⁸⁴ Ibid, p. 83.

⁸⁵ Ibid, p. 82.

⁸⁶ Ibid, p. 86.

According to the Commission, the third factor that should be taken into consideration when assessing market power is the countervailing buying power. This factor is important since competitive constraints cannot only be exerted by actual or potential competitors, but also by customers. In case customers have sufficient bargaining strength, undertakings, even those with high market shares, will not be able to behave to an appreciable extent independently.⁸⁷ Such bargaining strength can result from, inter alia, the customers' size, their commercial significance for the dominant undertaking or their ability to switch quickly to competing suppliers.⁸⁸ Consequently, if the undertaking is constrained by a powerful buyer, it is probably not in a dominant position. However, only the fact that powerful buyers extract favourable terms from the supplier for themselves is not sufficient in order to counter the finding of dominance. They must be able to protect the market itself by, for example, defeating any price increase.⁸⁹ With regard to the pharmaceutical sector the argument of countervailing buyer power is often heard, especially since in this sector the products are purchased jointly by organizations such as national health services or large private insurance companies. These organizations, which are generally well organised, enjoy considerable negotiating power against the pharmaceutical companies when it comes to determining the price of medicines. However, a buyer can only have countervailing power to the extent that there are alternatives to the specific product.⁹⁰ This means that only in case of a sufficient degree of competition between medicines from different manufacturers, due to therapeutic alternatives or because there are generics on the market, joint purchasing power can work.⁹¹ In case there is no alternative to a specific drug, the terms of the pharmaceutical company can only be refused in theory. Practically, such situations almost never occur, since political decision makers and public opinion would then have to accept the fact that an effective and potentially life-saving drug would become unavailable.⁹² For this reason, the argument of *AstraZeneca*, which stated there was sufficient countervailing buying power by the public authorities, was dismissed by the Court: because there were no real alternatives to the product the public authorities were not able to reduce the prices, despite their attempts. Therefore, *AstraZeneca* was not, to an appreciable extent, subject to competitive constraints from its consumers.⁹³

⁸⁷ Communication from the Commission (2009/C 45/02), *Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings*, par. 18.

⁸⁸ *Ibid*, par. 18.

⁸⁹ Jones & Sufrin 2016, p. 343.

⁹⁰ Fonteijn, Akker & Sauter 2018, p. 12.

⁹¹ Sauter & Van Velzen 2016, p. 4.

⁹² Fonteijn, Akker & Sauter 2018, p. 13.

⁹³ Case C-457/10 *Astra Zeneca* [2012], ECLI:EU:C:2012:770, par. 180-181.

2.2.4 Intellectual property rights

When the notion of dominance in the pharmaceutical sector is discussed, the concept of intellectual property rights is essential. The pharmaceutical market is characterized by the existence of patents, which are specific types of intellectual property rights, next to for example copyrights, trademarks, geographical indications or industrial design.⁹⁴ They play a major role in the sector and explain to a large extent why competition on the pharmaceutical market is often limited. However, and contrary to what is often argued, the holder of an intellectual property right does not necessarily hold a dominant position. In case the relevant market, which is the starting point when assessing dominance, consists of several (patent protected) products which compete effectively, the holder of a patent will not have a dominant position.⁹⁵ This again explains the importance of the determination of the relevant market: it determines whether an undertaking is in a dominant position and therefore falls under the prohibition of article 102 TFEU, or not. However, it is clear that an intellectual property right can, in certain circumstances, create a dominant position, in particular by enabling an undertaking to prevent effective competition on the market.⁹⁶

Patents are mostly requested for in capital-intensive, innovative sectors such as the chemical, transport, medical technology or digital communication sector. For the past twenty years, most patent applications in the EU have been made in the field of medical technology.⁹⁷ In 1995, the WTO adopted the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) in which multilateral standards for patent protection were laid down.⁹⁸ According to this agreement, patents can only be available for inventions that are new, involve an inventive step and are capable of industrial application.⁹⁹ The goal of patents is to promote technical innovation by restricting competition.¹⁰⁰ Since inventors are rewarded with an exclusive right to exploit a certain innovation, they are shielded from competition. This protection is granted for a period of twenty years after the filing date.¹⁰¹ If applied to the pharmaceutical industry, third parties are not allowed to make, use, offer for sale, sell or import a patent-protected medicine without consent of the patent holder, for a period of twenty years.¹⁰² The patent holders, on the other hand, have the right to assign, or transfer by succession, the patent to other parties and to conclude licensing contracts.¹⁰³ After those twenty years, other companies are allowed to reproduce

⁹⁴ WTO, 'Intellectual property: protection and enforcement', <wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm> [1 May 2018].

⁹⁵ Fonteijn, Akker & Sauter 2018, p. 2.

⁹⁶ Case C-457/10 *Astra Zeneca* [2012], ECLI:EU:C:2012:770, par. 186.

⁹⁷ European Patent Office, 'The future of medicine', <epo.org/news-issues/technology/medical-technologies.html> [1 May 2018].

⁹⁸ WTO, 'Overview: the TRIPS-Agreement', <wto.org/english/tratop_e/trips_e/intel2_e.htm> [1 May 2018].

⁹⁹ Art. 27(1) TRIPS Agreement.

¹⁰⁰ Art. 7 TRIPS Agreement.

¹⁰¹ Art. 33 TRIPS Agreement.

¹⁰² Art. 28(1) TRIPS Agreement.

¹⁰³ Art. 28(2) TRIPS Agreement.

that certain medicine and to enter the market with a so-called 'generic' version. Usually, the patented version (the 'originator') and the generic version are considered as substitutable, especially if the regulatory system encourages switching, and therefore as belonging to the same product market.¹⁰⁴ In this regard, one can easily see that the goals of competition law and patent law are in some way contradictory: while the ultimate goal of competition law is to have free competition in order to maximize consumer welfare, the goal of patent law is to restrict competition in order to boost innovation.

Relevant to mention is that members of the WTO can make exceptions to the patentability of inventions in order to protect "*ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment.*"¹⁰⁵ Furthermore, "*diagnostic, therapeutic and surgical methods for the treatment of humans or animals*" are specifically mentioned as innovations that can be excluded from patentability by the contracting members.¹⁰⁶ However, from the history of this article it becomes clear this exception only covers methods or processes and does not apply to products used in these methods or processes, such as pharmaceuticals.¹⁰⁷ This view is confirmed by the European Patent Convention which implemented the provisions of the TRIPS Agreement. In addition to the exception mentioned above, it is stated that "*this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.*"¹⁰⁸ For this reason, patent law applies to medicines which are new, innovative and capable of industrial application, just as much as to other products which qualify for these criteria. In this sense, the outcome of the balancing test between the interest of promoting innovation by rewarding companies for their investments and the interest of protecting human health turned out different with regard to medical procedures and treatments than it did for medicines. Some authors have argued that this difference between 'methods' and 'products' is striking, especially when it is taken into account that before the establishment of the TRIPS Agreement almost half of the countries did not grant patents to pharmaceuticals, based on the notion that nobody could claim the right to substances and methods essential for human life.¹⁰⁹ Nevertheless, the TRIPS Agreement does offer some room for governments to address certain issues relating to access to or prices of medicines by stating that "*Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health (...).*"¹¹⁰ In this sense the scope of patents is not absolute: holders of patents still have to comply with the applicable legal framework of states, which can for example set maximum prices for certain products.¹¹¹ Moreover, patents are not immune for

¹⁰⁴ See for instance: European Commission, Decision in Case M.6969 *Valeant Pharmaceuticals International / Bausch & Lomb Holdings* [2013], par. 14.

¹⁰⁵ Art. 27(2) TRIPS Agreement.

¹⁰⁶ Art. 27(3)(a) TRIPS Agreement

¹⁰⁷ Davis 2014, p. 195-196.

¹⁰⁸ Art. 53(c) European Patent Convention.

¹⁰⁹ Davis 2014, p. 186.

¹¹⁰ Art. 8 TRIPS Agreement.

¹¹¹ Fonteijn, Akker & Sauter 2018, p. 2.

the application of competition law. Although the European Court of Justice holds that the existence of intellectual property does not infringe competition law, the exercise of these rights may in certain circumstances do so.¹¹² During time, there have been several cases of pharmaceutical companies which were convicted for infringing competition law, even though they had a patent. Examples of such infringements were the use of patents to block parallel trade (*Centrafarm* case) or restrictive agreements within the scope for a patent (*Lundbeck* case).¹¹³

2.3 Different forms of abuse

With regard to the concept of abuse, a distinction is can be made between discriminatory abuses, exclusionary abuses and exploitative abuses. In this paragraph, each of these different forms will be discussed whereby examples of cases of such abuses in the pharmaceutical sector will be given.

2.3.1 Discriminatory abuse

Discriminatory abuse consists of applying dissimilar conditions to equivalent transactions to its customers of suppliers, thereby placing some of them at a competitive disadvantage. By, for example, charging different prices to different types of consumers, companies are able to maximize their profits. This type of abuse is specifically referred to in article 102(c) TFEU. As we have seen in the introduction, prices of pharmaceuticals differ to a considerable extent between countries. However, these price differences are only regarded as abuse if 1) the differences are caused by firms holding a dominant position and 2) parallel trade is made impossible.¹¹⁴ Parallel trade refers to the resale of goods between countries without the authorization of the owner of the intellectual property rights associated with those goods.¹¹⁵ It is a way to equalize different prices, since distributors are able to buy medicines for low prices in a certain state and then sell them for a higher price in another state. Parallel trade is based on free movement of goods, which means that goods legally produced in one Member State should be accepted in another Member State. In several cases, the Court has applied the principle of free movement of goods within the EU also to products based on intellectual property rights. In 1996, the Court explicitly stated that intellectual property rights are not intended to allow their owners to partition national markets and thus promote the retention of price differences which may exist between Member States.¹¹⁶ During the years, there have been several cases in which pharmaceutical companies were convicted for preventing parallel trade. An important case in this regard is the case *GlaxoSmithKline* (GSK),

¹¹² See for instance: Case C-238/87 *Volvo v. Veng* [1988], ECR 1988 06211, par. 8-9.

¹¹³ Fonteijn, Akker & Sauter 2018, p. 6.

¹¹⁴ Papandropoulos 2007, p. 34.

¹¹⁵ Kyle, 2009, p. 339.

¹¹⁶ *Ibid*, p. 341.

where the Court had to answer preliminary questions in a case between the pharmaceutical company GSK and Greek wholesalers, which exported pharmaceutical products to markets where prices were higher. In its ruling, the Court stated that a dominant company's refusal to supply wholesalers with the goal of impeding parallel trade constitutes abuse of a dominant market position, unless it is justified by objective reasons.¹¹⁷ Furthermore, the Court confirmed that differences in national price regulations themselves are not a sufficient justification and that control exercised by Member States over the selling prices or the reimbursement of medicines does not entirely remove the prices of those products from the law of supply and demand.¹¹⁸

2.3.2 Exclusionary abuse

The goal of exclusionary abuses is to exclude competitors from the relevant market and in this way, restrict competition. Examples of this form of abuse are foreclosure, tying, exclusive dealing, loyalty rebates or discounts and predatory pricing, to which article 102(a), 102(b) and 102(d) TFEU refer. It is possible that these forms of abuse can be beneficial for consumers in the short term, by providing them certain advantages, but may have long-term detrimental effects due to reduced competition. Therefore, in the case *Post Danmark* the ECJ understood exclusionary abuse as "*practices that cause consumers harm through their impact on competition.*"¹¹⁹

In the pharmaceutical sector there have been several cases related to exclusionary abuse. An important case in this regard is the case *AstraZeneca*, which was already quickly touched upon in the foregoing paragraphs. In this case, the pharmaceutical company AstraZeneca delayed and prevented the entrance of generic versions of its medicine and prevented parallel traders from entering the market by misleading patent offices and abusing several regulatory procedures. The consequence of these excluding practices was that AstraZeneca was able to maintain much higher market shares than its competitors while charging higher prices.¹²⁰ In 2012, the Court ruled that AstraZeneca's conduct was "*manifestly contrary to competition on the merits*"¹²¹ and upheld the fine of 52.5 million Euros imposed by the General Court. Another important recent case in which a pharmaceutical company was convicted for exclusionary abuse is *Lundbeck*. In this case, Lundbeck's patent over the active ingredient of the blockbuster antidepressant had expired. To prevent competition from generics on the market, Lundbeck closed agreements with the generic producers not to enter the market in return for substantial payments and other inducements from Lundbeck.¹²² These kinds of agreements are also called 'pay-for-delay'-agreements. In 2016

¹¹⁷ Joined Cases C-468/06 to C-478/06 *Glaxosmithkline* [2008], ECLI:EU:C:2008:504, 77.

¹¹⁸ *Ibid*, par. 61.

¹¹⁹ Jones & Sufrin 2016, p. 351.

¹²⁰ Case C-457/10 *Astra Zeneca* [2012], ECLI:EU:C:2012:770, par. 181.

¹²¹ *Ibid*, par. 164.

¹²² Jones & Sufrin 2016, p. 871.

the General Court dismissed the appeal of Lundbeck entirely and confirmed the Commission's decision stating that these pay-for-delay agreements between originators and generic producers are incompatible with article 102 TFEU.¹²³ Accordingly, the General Court upheld the fines on both Lundbeck (93.8 million Euros) and the producers of the generic medicines (52.2 million Euros).¹²⁴ This judgement of the General Court was the first pronouncement by a EU Court in a series of controversial cases that were brought by the Commission in relation to pay-for-delay agreements and has led to a renewed focus on such agreements by competition authorities.¹²⁵ Since questions about circumstances in which these types of agreements are considered illegal still remain, the Court's judgement in appeal will be crucial.

2.3.3 Exploitative abuse

The third category of abuse contains exploitative abuse, which harms consumers directly. This kind of abuse can consist of directly or indirectly imposing unfair purchase or selling prices or other trading conditions, which is specifically mentioned in article 102(a) TFEU. In particular, exploitative abuse consists of excessive pricing practices, which is the most obvious way in which a dominant firm can exploit its position.¹²⁶

Often, it is argued that a free market economy needs the possibility for monopolists or dominant undertakings to charge very high prices, since high prices and profits may act as a signal to attract new competitors on the market.¹²⁷ However, in situations where new competitors cannot easily enter the market because of high barriers to entry, it can be necessary for competition authorities to intervene. As already said, this intervention is subject to many difficulties since it is, in the first place, very hard to determine whether a price is 'unfair'. Besides that, the European Commission did not concern itself much with high prices because it was of the opinion that in many circumstances interference with high prices and profits is a disincentive to innovation and investment.¹²⁸ Therefore, the Commission focused mainly on measures against exclusionary conduct whereby dominant firms seek to preserve their dominance and in this way, solve problems of unfair pricing.¹²⁹ The focus on exclusionary conduct and consumer welfare can be seen in the Guidance Paper on Article 102, where the Commission stated that "*in applying Article 102 to exclusionary conduct by dominant undertakings, the Commission will focus on those types of conduct that are most harmful to consumers.*"¹³⁰ However, it seems that more recently this position is

¹²³ Case T-472/13 Lundbeck [2016], ECLI:EU:T:2016:449, par. 845.

¹²⁴ European Commission, Decision in Case AT.39229, *Lundbeck*, [2013], p. 451 – 459.

¹²⁵ Harrison & Le Croy 2016, p. 1.

¹²⁶ Jones & Sufrin 2016, p. 566.

¹²⁷ *Ibid*, p. 566.

¹²⁸ *Ibid*, p. 567.

¹²⁹ *Ibid*, p. 567.

¹³⁰ Communication from the Commission (2009/C 45/02), *Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings*, par. 5.

shifting: in several Member States there have been proceedings against pharmaceutical companies which charged very high prices, which will be discussed in detail in the next chapter. Next to the competition authorities in the Member States, it seems that the Commission is also changing its focus. In the policy speech that was already cited in the introduction, Commissioner Vestager named a few sectors, including the pharmaceutical industry, in which protection of consumers against exploitation could be necessary. This was followed by the announcement that the Commission has opened an excessive pricing case against Aspen with regard to all relevant EEA Member States except Italy.¹³¹ In this sense, it can be argued the Commission has a renewed interest in the prohibition of exploitative abuse.

¹³¹ See also Fonteijn, Akker & Sauter 2018, p. 10.

Chapter 3: The concept of excessive pricing

3.1 The historical development of the concept of excessive pricing

As already explained in the foregoing chapter, article 102(a) contains the prohibition of imposing ‘unfair’ purchase or selling prices. In addition to the former chapter it is important to add that while excessive pricing is commonly regarded as an exploitative abuse, it can also be seen as an exclusionary abuse if these prices aim to strengthen or maintain the market power of a dominant firm by putting rivals at a disadvantage. This is possible if the dominant firm is active on different, connected market (the so-called up- and downstream markets). In case the dominant firm sets its prices on one market excessively high, which results in competitors on the other market not being able anymore to buy the products they need for their business, these competitors are excluded from the market.¹³² Moreover, excessive prices can be regarded as a form of discriminatory abuse if for example different prices are charged to different types of consumers. Since this research focuses on prices imposed by pharmaceutical companies, which are able to harm the public directly and not mainly its competitors on different markets, only the concept of excessive pricing as an exploitative concept will be discussed. However, in some cases which are discussed below, in which the Commission condemned companies of excessive prices, this conduct was qualified as an exclusionary or discriminatory abuse.

In 1974 the Commission issued its first unfair pricing decision in the case *General Motors*. This case dealt with prices General Motors, which had a monopoly on this market, charged for the service of issuing conformity certificates of vehicles, which were necessary for the import of cars into Belgium.¹³³ These pricing practices were primarily seen as an exclusionary abuse, since the prices for vehicles of General Motors produced in the US were much higher than those for vehicles of General Motors produced in Europe, which was seen as a way of discouraging parallel imports.¹³⁴ In appeal proceedings, the Court introduced the concept of ‘economic value’ by ruling that “*such an abuse might lie, inter alia, in the imposition of a price which is excessive in relation to the economic value of the service provided and which has the effect of curbing parallel imports by neutralising the possibly more favourable level of prices applying in other sales areas in the Community*”.¹³⁵ However, the Court did not further explain this concept since it was not disputed that the charged prices were excessive.¹³⁶ Nevertheless, the Court did not qualify the conduct of General Motors as ‘abusive’ since the inspections were seen as an unusual activity on the part of General Motors and the prices

¹³² Motta & De Streel 2006, p. 1.

¹³³ Case C-26/75 *General Motors Continental NV v Commission of the European Communities* [1975], ECR 1975 01367, par. 1.

¹³⁴ Van Bael & Bellis 2005, p. 913.

¹³⁵ Case C-26/75 *General Motors Continental NV v Commission of the European Communities* [1975], ECR 1975 01367, par. 12.

¹³⁶ *Ibid*, par. 16.

were quickly reduced after complaints made by the parties concerned.¹³⁷ Therefore, the Commission's decision was annulled.

Then, with the case *United Brands* in 1978 the Court issued its most famous judgement with regard to excessive prices. In this case, the Court established the test for the assessment of excessive pricing. The discussion was about the prices of Chiquita Bananas that were charged by United Brands Company (UBC) in Germany, Denmark and Benelux, which the Commission found to be excessive. The Commission reached that conclusion by comparing prices of UBC with those for unbranded bananas, competitors' bananas and with the price of Chiquita bananas in Ireland. On the basis of this comparison it reached the statement that the prices were "*excessive in relation to the economic value of the product supplied.*"¹³⁸ Since the big price differences between prices of Chiquita bananas in several countries were the main argument of the Commission in this case (the prices for bananas in Germany, Denmark and Benelux were sometimes 100% higher than the prices in Ireland), the excessive prices were also seen as a form of discriminatory abuse.¹³⁹ However, the Court did not agree with the Commission in this respect. It made clear that the burden of proof lied on the Commission by stating: "*However unreliable the particulars supplied by UBC may be (...), the fact remains that it is for the Commission to prove that the applicant charged unfair prices.*"¹⁴⁰ Specifically, the Court stated that the question of whether the prices were excessive could, inter alia, have been determined objectively if a comparison was made between the selling prices of bananas and its cost of production, which would disclose the profit margin. Finally, the Court concluded that the Commission did not provide sufficient evidence in this respect since it had not analysed UBC's cost structure.¹⁴¹

After coming to this conclusion, the Court provided a two-stage test for the assessment of excessive prices itself by stating: "*The questions therefore 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.*"¹⁴² Therefore, for a price to be abusive it must be both 'excessive' and 'unfair'. According to the Court, a price can be unfair 'in itself' or 'in comparison with other prices'. The latter comparison demands the set of a benchmark price to which the prices can be compared. In the next paragraph, this test will be further elaborated on. Next to establishing the general test for the assessment of excessive prices, the case *United Brands* is important since it clarifies that price differences between Member States can only be used of evidence of excessive pricing

¹³⁷ Case C-26/75 *General Motors Continental NV v Commission of the European Communities* [1975], ECR 1975 01367, par. 17-19.

¹³⁸ Case C-27/76 *United Brands v. Commission* [1978], ECLI:EU:C:1978:22, par. 235.

¹³⁹ See also: Motta & De Streel 2007, p. 30.

¹⁴⁰ Case C-27/76 *United Brands v. Commission* [1978], ECLI:EU:C:1978:22, par. 264.

¹⁴¹ *Ibid*, par. 251.

¹⁴² *Ibid*, par. 252.

if the markets of these Member States are objectively comparable.¹⁴³ Since the Commission did not provide adequate legal proof, the possibility could not be ruled out that UBC was not making any profit on the Irish market and that therefore, these markets were not comparable.¹⁴⁴ Ultimately, the price difference between Chiquita bananas and those of the principal competitors was 7%, which the Court found too low to automatically regard the prices of UBC as excessive and consequently unfair.¹⁴⁵

A few years later the case *British Leyland*, which was quite similar to *General Motors*, had to be decided by the Court. British Leyland, which just as General Motors had the legal monopoly to issue certificates of conformity, charged much higher fees for left-hand-drive cars (£100 for individuals or £150 for dealers) than for its UK right-hand-drive cars (£25). The reason for this price difference lied in the fact that the left-hand-drive cars were sold abroad for a lower price; British Leyland wanted to prevent this by charging these higher certificate fees. Unlike in *General Motors* the Court accepted the Commission's finding of excessive prices by stating that "*the fee was fixed at a level which was clearly disproportionate to the economic value of the product.*"¹⁴⁶ The proof that the prices were excessive was easily found by the Court by the fact that the fee for left-hand-drive cars suddenly increased from £25 to £100 or £150, while the fee for right-hand-drive cars remained at the same level.¹⁴⁷ For this reason, the Court concluded the fees for left-hand-drive cars were disproportionate to the economic value of the service provided and British Leyland abused its monopoly.¹⁴⁸ From this case, it can be concluded that a sudden price increase can serve as an indication of 'excessiveness'.

In 2001, the test the Court established in *United Brands* was slightly specified by the Commission in the case *Port Helsingborg*. This decision was made after a complaint by Scandlines to the Commission about the port charges of Helsingborg Hamn AB (HHAB). Scandlines considered these port charges, which were charged in Helsingborg (at the narrowest point of Øresund between Sweden and Denmark), to be excessive.¹⁴⁹ According to Scandlines, the port charges were excessive since they were "*unfair in themselves when compared to the costs (plus a reasonable profit) of providing the services.*" Furthermore, Scandlines argued HHAB's port charges were not cost-based and the pricing policy was not transparent.¹⁵⁰ With regard to the latter argument, the Commission stated that the fact that prices were not cost-based or the pricing was not transparent did not constitute an abuse.¹⁵¹ With regard to the argument of 'excessiveness' of the prices, the Commission repeated the

¹⁴³ Van Bael & Bellis 2005, p. 911.

¹⁴⁴ Case C-27/76 *United Brands v. Commission* [1978], ECLI:EU:C:1978:22, par. 262-264.

¹⁴⁵ *Ibid*, par. 266.

¹⁴⁶ Case 226/84, *British Leyland* [1984] ECR 1986 03263, par. 30.

¹⁴⁷ *Ibid*, par. 25.

¹⁴⁸ *Ibid*, par. 27-30.

¹⁴⁹ European Commission, Decision in Case A.36.568/D3, *Scandlines v. Port of Helsingborg* [2004], par. 16.

¹⁵⁰ *Ibid*, par. 19.

¹⁵¹ *Ibid*, par. 97.

United Brands-test. In this respect it rejected Scandlines' statement which held that an excessive profit margin is sufficient to conclude that the price is unfair.¹⁵² The Commission explicitly states the United Brands-test consist of two separate steps: *"the Court made a clear distinction between, on the one hand, the question whether the difference between the price and the production costs – the profit margin - is "excessive" and, on the other hand, the question whether the price is unfair. Had it been otherwise, there would have been no reason for the Court, once the first question has been answered in the affirmative, to proceed to the question whether the price is unfair in itself or when compared to the price of competing products."*¹⁵³ So according to the Commission, even in case the profit margin of HHAB was 'excessive', this could not automatically lead to the conclusion that the price charged bore no reasonable relation to the economic value of the services provided. In any case, the second question would have to be examined as well to see whether the prices are *"unfair, either in themselves or when compared to other ports."*¹⁵⁴

Since the Commission did not find the prices to be unfair when compared with others, it moved on to the assessment of whether they were 'unfair in itself'. To answer this question, the relationship between the price and the economic value had to be examined. In this respect, the Commission made clear that the 'economic value' must be determined with regard to the particular circumstances of the case and must also take into account non-cost related factors such as the demand for the product or service.¹⁵⁵ According to the Commission, the ferry from the port of Helsingborg represented an intangible value in itself, mainly because of its excellent location with excellent connections.¹⁵⁶ Taking all these non-cost related factors into consideration, the Commission came to the conclusion that there was not sufficient evidence to conclude that the port charges did not have any reasonable relation to the economic value of the services and facilities provided by HHAB. This led to the conclusion by the Commission that the prices charged by HHAB were not unfair in itself and could therefore not be qualified as excessive.¹⁵⁷ While this decision explained how the concept 'economic value' should be assessed, it also raised a lot of questions. According to some authors, the fact that also demand-side considerations, such as a unique location, are part of this assessment can raise difficulties. Accordingly, it would be possible to argue that none of the prices which have been agreed to by the purchaser can be qualified as excessive, because prices will always be dictated in part by the purchaser's demand.¹⁵⁸ This could lead to situations in which prices set by monopolists could never be considered excessive, since there is still sufficient consumer demand. Therefore, in the words of Furse, *"admitting*

¹⁵² European Commission, Decision in Case A.36.568/D3, *Scandlines v. Port of Helsingborg* [2004], par. 148.

¹⁵³ *Ibid*, par. 149.

¹⁵⁴ *Ibid*, par. 158.

¹⁵⁵ *Ibid*, par. 232.

¹⁵⁶ *Ibid*, par. 234.

¹⁵⁷ *Ibid*, par. 246-248.

¹⁵⁸ Furse 2008, p. 73.

demand-side factors into the assessment of whether a price is unfair opens the way to a circularity from which there may be no escape."¹⁵⁹

If the case law regarding excessive prices is investigated, it becomes clear that this concept has not been applied often on the European level. Since 1957, when the prohibition of abuse of a dominant position was laid down in the Treaty of Rome¹⁶⁰, only very few cases have been investigated by the Commission and in even fewer cases the Court accepted the founding of excessive prices. Only in the cases *British Leyland*, *Deutsche Post*¹⁶¹ and *Duales System Deutschland*¹⁶² the Court has found infringements of the prohibition of excessive pricing. With regard to this low number of cases, Commission officials stress the fact that several proceedings appear to have been closed because the firms concerned were prepared to lower their prices.¹⁶³ However, it cannot be denied that the low number of successful cases shows the reluctance of European authorities regarding this prohibition, which can be explained both by hesitation to intervene with market prices and by difficulties in proving the excessiveness of a price.

3.2 Different methods to assess 'excessiveness'

As explained in the foregoing paragraph, the Court established a two-stage test in *United Brands* which is still the standard nowadays. This test examines 1) whether the difference between the costs actually incurred and the price actually charged is excessive and 2) whether the price is unfair in itself or when compared to competing products, but still leaves room for interpretation. For instance, which costs should be included exactly in the cost-price calculation? Furthermore, the question whether a price is 'unfair in itself' is of course difficult to answer as well. And with regard to the comparison with competing products, which kind of products should be compared exactly and how is dealt with, for instance, quality differences which could justify a high price difference? It is important to stress that the *United Brands*-test is not the only way to determine the excessiveness of prices. In *United Brands*, the Court explicitly stated that besides this test "*other ways may be devised – and economic theorists have not failed to think up several – of selecting the rules for determining whether the price of a product is unfair*".¹⁶⁴ And indeed, during the years, the Court, the Commission and national competition authorities have used different methods.¹⁶⁵ To put it in the words of Motta and De Streel, the Court developed a "*veritable cocktail of*

¹⁵⁹ Furse 2008, p. 73.

¹⁶⁰ The former art. 86 of the Treaty of Rome.

¹⁶¹ In this case, the Court compared the cross-border tariff of Deutsche Post with its domestic tariff and concluded the former was since it had no sufficient or reasonable relationship to real costs or to the real value of the service provided. See in this regard: Jones & Sufrin 2016, p. 570

¹⁶² The finding of excessive prices in this case was based on the fact that the fee for the packaging service was 'clearly disproportionate to the costs of supplying it'. See in this regard: Jones & Sufrin 2016, p. 571.

¹⁶³ Ackermann 2012, p. 8.

¹⁶⁴ Case C-27/76 *United Brands v. Commission* [1978], ECLI:EU:C:1978:22, par. 253.

¹⁶⁵ Motta & De Streel 2007, p. 33.

approaches to determine whether a price is excessive".¹⁶⁶ This paragraph will describe these different methods, which were identified by these two authors.

Obviously, the first method to examine excessiveness is to make a comparison between the costs and the price, as was proposed by the Court in *United Brands*. The idea of this method is that a threshold price should exist, which guarantees a sufficient margin with respect to the costs. Above this threshold, the price charged by a dominant firm would be excessive.¹⁶⁷ According to Motta and De Streel, this method can raise several difficulties. A first one is the fact that a competitive price is not only determined by supply side factors such as the costs of production, but also by demand side factors such as demand elasticity and ability to pay.¹⁶⁸ A second difficulty arises when it comes to the question what a 'reasonable' margin over costs would be. In several particular cases the Court has indicated a certain margin to be reasonable and others to be unreasonable, but these indications cannot be taken as a standard that holds true for a whole sector.¹⁶⁹ A third difficulty occurs in the calculation of the costs, where it can be problematic to determine which costs should be taken into consideration. One can argue that especially in a sector like the pharmaceutical sector, where huge investments have to be made in R&D, the financial risks should be taken into account as well. This means that also costs that were made for the development of medicines that in the end do not enter the market, should be incorporated in the comparison. Here, another problem arises, especially with respect to the pharmaceutical sector. In the last years, pharmaceutical companies were not willing to be transparent about the actual costs of R&D, even after political pressure. The Dutch Minister of Health stated in this context: "*Pharmaceutical companies regard information about the price structure of their medicines as business-sensitive information. Therefore, a meaningful discussion about socially acceptable prices is difficult.*"¹⁷⁰ A fourth possible problem with respect to a price-cost comparison is the fact that in some cases not the actual costs of the particular firm, but the costs of a hypothetical firm should be considered. The reason for this lies in the case *SACEM II*, in which the Court of Justice considered that the production costs of efficient firms should be taken into account, and not necessarily those of the investigated firm since the possibility cannot be ruled out that it is precisely the lack of competition on the market in question that accounts for those high costs.¹⁷¹ For that reason, it is not always possible for a firm to justify high prices with high production costs if those costs are the consequence of a dominant position.

¹⁶⁶ Motta & De Streel 2006, p. 3.

¹⁶⁷ Motta & De Streel 2007, p. 33.

¹⁶⁸ *Ibid*, p. 33.

¹⁶⁹ *Ibid*, p. 33.

¹⁷⁰ Translated quote from the Letter of 15 January 2018 of the Dutch Minister of Health (Bruins), p. 1.

¹⁷¹ Joined Cases C-110/88, C-241/88 and C-242/88 *SACEM and Others* [1989], ECLI:EU:C:1989:326, par. 29.

Secondly, excessive prices can be proved by a comparison of products of the dominant firm with other products of that firm. In this regard, authorities can compare the prices of products which are charged in the same Member State, as was done in *General Motors*. It is also possible to compare prices of products in different Member States, as was the case in *United Brands*. A precondition for proving unfair pricing is that the prices in different Member States are different without justification for the same service and that both prices are profitable.¹⁷² In *United Brands* the test failed on this latter point since it could not be ruled out that the company was not making profits on the Irish market where prices were much lower. In the very recent case *AKKA/LAA*, the Court confirmed the validity of the method in which price in different markets are compared. In case the price difference is appreciable, which according to the Court means ‘significant and persistent’, this can be an indication of abuse of a dominant position.¹⁷³ In this regard the Court also stressed that these markets cannot be selected randomly: they should be selected according to objective, appropriate and viable criteria.¹⁷⁴ Those criteria may include, inter alia, consumption habits and other economic and sociocultural factors, such as gross domestic product per capita and cultural and historical heritage.¹⁷⁵ Therefore, in order to apply the comparison method, markets have to be objectively comparable. For this reason, this comparison test can be hard to apply with regard to the pharmaceutical market, since Member States defer to a considerable extent due to different health care systems.

The third method to determine excessiveness is to compare a specific price with the prices of similar products offered by competitors (also called: benchmarking).¹⁷⁶ This method can have several variants, depending on the position of the firm: comparisons can be made between products which are sold on the same relevant market, on another market in the same Member State or in another Member State.¹⁷⁷ There have also been cases in which the price of a patented product was compared to the price of a non-patented product.¹⁷⁸ However, in those cases the Court made clear that such a comparison is not sufficient to prove that the price of a patented product is unfair, since the proprietor of exclusive rights may lawfully call for a return of the investments. In this sense, the Court accepted the fact that an inventor must be given the opportunity to charge higher prices as a way to recoup its extra costs and prevent other parties from taking advantage of its efforts to innovate.¹⁷⁹ For this reason, a comparison between patented and generic drugs may not be meaningful. The Opinion of Advocate General (AG) Wahl in the case *AKKA/LAA* provides a detailed framework of the way in which the different methods to prove excessive prices should be

¹⁷² Motta & De Streel 2006, p. 8

¹⁷³ Case C-177/16 *AKKA/LAA* [2017], ECLI:EU:C:2017:689, par. 61.

¹⁷⁴ *Ibid*, par. 41.

¹⁷⁵ *Ibid*, par. 42.

¹⁷⁶ Motta & De Streel 2006, p. 36.

¹⁷⁷ *Ibid*, p. 8.

¹⁷⁸ For example the cases C-53/87 *Renault* [1988], ECR 1988 06039 and C-24/67 *Parke, Davis* [1968], ECR 1968 00082.

¹⁷⁹ Motta & De Streel 2006, p. 11.

applied. In the words of the AG, “*each of those methods reveals some inherent weakness*”.¹⁸⁰ Since no ubiquitous test is available and all existing methods have limitations, the AG regards it crucial for competition authorities to combine several methods. In this way, the risk of errors can be minimised.¹⁸¹ For this reason, competition authorities can get the best reliable answer to the question whether prices are excessive if several methods are combined. Although the Court did not explicitly endorse this view, it stated that competition authorities have a certain ‘margin of manoeuvre’ and that there is ‘no single adequate method’ to determine whether prices are excessive.¹⁸²

Finally, excessive prices can be proved by looking at the profits of the dominant firm and comparing these profits either with a normal industry-specific profit or with profits of other firms. Of course, this approach raises several difficulties. A first, practical one is the fact that it can be very difficult or almost impossible to find a relevant comparator.¹⁸³ A second problem relates to the arbitrariness of a ‘normal’ or ‘reasonable’ profit. Notably the pharmaceutical sector is known for its high profit margins: during the years 2009 - 2015 the pharmaceutical sector had the highest profit margins of industry with an average margin of 17,5% of its total turnover.¹⁸⁴ For this reason, it can be very difficult to compare various profits and to determine what is a reasonable profit.

¹⁸⁰ Opinion AG Wahl in the case C-177/16 AKKA/LAA [2017], ECLI:EU:C:2017:286, par. 36.

¹⁸¹ Ibid, par. 43.

¹⁸² Case C-177/16 AKKA/LAA [2017], ECLI:EU:C:2017:689, par 49.

¹⁸³ Motta & De Streel 2007, p. 37.

¹⁸⁴ Dutch Statistics Authority (Centraal Bureau voor Statistiek) 2017, ‘Highest operating result in pharmaceutical industry’, <[cbs.nl/en-gb/news/2017/15/highest-operating-result-in-pharmaceutical-industry](https://www.cbs.nl/en-gb/news/2017/15/highest-operating-result-in-pharmaceutical-industry)> [6 May 2018].

3.3 The application of the concept of excessive pricing in the pharmaceutical sector

In the foregoing paragraphs the concept of excessive pricing and different methods to prove excessive prices were discussed. In this paragraph, the way competition authorities have dealt with excessive prices cases in the pharmaceutical sector will be explored. Until now, there have been infringement decisions regarding excessive prices on the national level in the cases *Napp*, *Aspen* and *Pfizer/Flynn Pharma*, which will be discussed. By analysing these cases, it will become clear under which circumstances a case regarding excessive prices of medicines can be successful.

3.3.1 *Napp case*

The *Napp* case of 2001, which was handled in the UK, is the earliest example of a successful excessive pricing case in the pharmaceutical sector.¹⁸⁵ *Napp* was accused by the Office of Fair Trading (OFT) of charging excessively high prices for the painkiller morphine, which was no longer patented, to the community segment of the market.¹⁸⁶

With regard to the definition of the relevant market, the product market was defined as containing sustained released morphine tablets and capsules.¹⁸⁷ The geographical market was defined as the UK, which was not unexpected since medicine markets are normally regarded as national.¹⁸⁸ From 1997 to 2000, *Napp* had a market share of over 90%. Thereby, high barriers to entry existed and there was no strong buyer power. These factors led to the conclusion that *Napp* enjoyed a dominant position on the market.¹⁸⁹

With regard to the question whether the prices charged by *Napp* were excessive, the OFT stated that *“it must be demonstrated that (i) prices are higher than would be expected in a competitive market, and (ii) there is no effective competitive pressure to bring them down to competitive levels, nor is there likely to be.”*¹⁹⁰ Generally, the OFT used two methods to prove excessive pricing. First, it made a cost-price comparison and compared the profits of *Napp* on community sales of morphine with the profits of sales of other products and on sales of morphine to other markets. Secondly, the competition authority compared the prices that were charged by *Napp* with prices of competitors and the prices which *Napp* charged elsewhere.¹⁹¹ With regard to these price comparisons, several results were relevant. A first result was the fact that the prices of *Napp* to the community were between 33% and

¹⁸⁵ Fonteijn, Akker & Sauter 2018, p. 9.

¹⁸⁶ UK Office of Fair Trading (OFT), Decision in Case CA98/2D/2001, *Napp Pharmaceuticals Holdings Ltd and Subsidiaries* [2001], par. 142.

¹⁸⁷ *Ibid*, par. 81.

¹⁸⁸ *Ibid*, par. 89-91.

¹⁸⁹ *Ibid*, par 138.

¹⁹⁰ *Ibid*, par. 203.

¹⁹¹ *Ibid*, par. 204-205.

67% higher than those of its competitors, and typically around 40% higher.¹⁹² A second important result was the fact that Napp's prices to the community were considerably higher than the prices charged to hospitals and for export. Generally, the prices of morphine charged by Napp to the community were up to ten times the prices for hospitals.¹⁹³ Moreover, on some variants of morphine, community prices were between four and seven times higher than export prices.¹⁹⁴ According to the OFT, the considerably lower prices in the hospital segment and in export markets resulted from the fact that there was price competition in these sectors, while there was no such competition in the community segment of the UK market. When it came to profit margins, the margin on the sale of morphine to the community was around 80%, while the margin on other products was between 30% and 50%.¹⁹⁵ In this respect, Napp argued that it is normal for pharmaceutical companies to earn high margins on their most successful products in order to pay for the R&D of emerging products, or to subsidise less successful products.¹⁹⁶ This argument was not accepted by the competition authority, which stated: "*Taking account of the fact that MST enjoyed patent protection from 1980 to 1992, Napp has had considerable time and opportunity to recoup its initial investment and compensate it for the risk it has taken (...). There seems little or no justification for such high margins.*"¹⁹⁷ On that basis, the competition authority came to the conclusion that Napp's prices were excessive and imposed a fine of £3.2 million.¹⁹⁸ Later, the Competition Appeal Tribunal (CAT) upheld the decision, but reduced the fine to £2.2 million because of several mitigating circumstances.¹⁹⁹

¹⁹² UK Office of Fair Trading (OFT) Decision in Case CA98/2D/2001, *Napp Pharmaceuticals Holdings Ltd and Subsidiaries* [2001], par 207.

¹⁹³ *Ibid*, par. 215.

¹⁹⁴ *Ibid*, par 221.

¹⁹⁵ *Ibid*, par 224.

¹⁹⁶ *Ibid*, par 225.

¹⁹⁷ *Ibid*, par 233.

¹⁹⁸ *Ibid*, par 264.

¹⁹⁹ UK Competition Appeal Tribunal (CAT), Case No. 1001/1/1/01, *Napp Pharmaceuticals Holdings Ltd and Subsidiaries* [2002], par. 538.

3.3.2 Aspen case

On 29 September 2016, the Italian Competition Authority (AGCM) made a decision in the case *Aspen*. This case was about five cancer drugs (the so-called ‘Cosmos’ products), of which Aspen Pharma acquired the rights from the originator company GlaxoSmithKline. These products were not patented anymore, but since there were no substitutes in the market there was still room to exploit them.²⁰⁰ After the acquisition of these rights, Aspen Pharma raised the prices of each of these drugs by 300% to 1500%.²⁰¹

The AGCM defined four relevant product markets according to the active ingredients of the drugs, referring to the fifth level of the ATC classification system.²⁰² This rather narrow product market was confirmed by the Italian Court later on. Although normally the third level of the ATC classification system is used as a starting point, the Court considered this level not sufficient to identify relevant competitive constraints among competing undertakings.²⁰³ Interestingly, the Italian Court added that despite the fact that the ATC classification system is often mentioned in competition law decisions on both the national and European level, this system was never codified with the idea of carrying out a competition law analysis.²⁰⁴ An important reason for the narrow product market was the fact that there were no viable substitutes for the treatment of children and elderly patients since only the Cosmos drugs were available in tablets, which allowed for home treatment of these patients.²⁰⁵ The Court agreed with the AGCM that given the lack of therapeutic substitutes, there was no need anymore to carry out an analysis of economic substitutability.²⁰⁶ The geographic market was limited to the national territory, due to different health care policies between countries and various access regimes.²⁰⁷ Since Aspen Pharma was the only producer of the Cosmos drugs, it enjoyed a monopolist position. The judgement points out that although the drugs were not patented anymore, no producers were going to ask for a marketing authorization. The Court also rejected Aspen’s argument holding that the Italian national health service (SSN) enjoyed significant countervailing buyer power. In this respect the Court hold that the national health service would not have stopped buying the Cosmos drugs since they were essential for patients in need of therapeutic continuity. Because of these factors, Aspen Pharma enjoyed a dominant position on the market.²⁰⁸

²⁰⁰ Lanza & Sfasciotti 2017, p. 3-4.

²⁰¹ Autorità Garante della Concorrenza e del Mercato (AGCM), Case A480, *Aspen Pharma* [2016], par. 3.

²⁰² *Ibid*, par. 86.

²⁰³ Angeli 2017, p. 224.

²⁰⁴ *Ibid*, p. 224.

²⁰⁵ *Ibid*, p. 224.

²⁰⁶ *Ibid*, p. 225.

²⁰⁷ Autorità Garante della Concorrenza e del Mercato (AGCM), Case A480, *Aspen Pharma* [2016], par. 87.

²⁰⁸ Angeli 2017, p. 225.

To assess the possible abuse of a dominant position, the AGCM applied the United Brands-test, consisting of two phases: an assessment on both the excessive disproportion between the costs and the price and on the unfairness.²⁰⁹ In the first step, the AGCM assessed whether the prices were excessive by looking at both the margins and the profits made by Aspen. It established that before the price increase of the Cosmos products, these drugs positively contributed to Aspen's profits. Therefore, after the price increase of the five products ranging from 300% to 1500%, Aspen's profits increased proportionally.²¹⁰ Moreover, a 'cost plus' analysis, which included a thorough measure of the costs of Aspen (including the price it paid for acquiring the rights to sell the products) showed the excess of each drug's price ranged from 100% to 300%.²¹¹ With regard to these high percentages the AGCM stated: *"Although there is no regulatory framework that defines the size that the gap between prices and costs has to have in order to be considered an indication of an abusive conduct, the values observed in the case at hand represent multiples of percentages of excess judged indicative of an abusive conduct in various European precedents."*²¹² In the second step, the AGCM assessed whether the prices applied by Aspen were unfair. In this regard, especially the sudden price increase without any justifications was relevant. Furthermore, the AGCM took account of various contextual and behavioural factors, such as the fact that Aspen did not make any qualitative improvement to the Cosmos products or their related service and the fact that Aspen did not have high costs in R&D since Aspen was a generic producer and the Cosmos products had already been on the market for decades.²¹³ Furthermore, the AGCM took the negotiating strategy of Aspen and the influence on the health care budget into account: the public expenditure for Aspen's drugs was about five times higher than before the price increase.²¹⁴ This direct effect on public resources was taken seriously by the AGCM, which stated: *"(...) public resources destined to the pharmaceutical expenditure are limited and determined by the State budget. The dispersion of public funds caused by Aspen's abusive behaviour – with the higher expense born by the SSN for purchasing said drugs – inevitably entailed the reduction of funds available for other purposes falling within public healthcare policies."*²¹⁵

As a result of the foregoing, the AGCM came to the conclusion that Aspen Pharma had abused its dominant position by charging excessive prices and imposed a fine of €5.2 million.²¹⁶ The Court confirmed the amount of the fine imposed by the AGCM in the light of the seriousness of the infringement and its duration.²¹⁷ The current investigation of the Commission looks into the pricing policies of Aspen Pharma with regard to the Cosmos

²⁰⁹ Autorità Garante della Concorrenza e del Mercato (AGCM), Case A480, *Aspen Pharma* [2016], par. 131.

²¹⁰ Angeli 2017, p. 226.

²¹¹ *Ibid*, p. 226.

²¹² Autorità Garante della Concorrenza e del Mercato (AGCM), Case A480, *Aspen Pharma* [2016], par. 327.

²¹³ *Ibid*, par. 339-344.

²¹⁴ *Ibid*, par. 350.

²¹⁵ *Ibid*, par. 351.

²¹⁶ *Ibid*, par. 401.

²¹⁷ Angeli 2017, p. 227.

products as well. Since Aspen Pharma has already been convicted in Italy, the territorial scope of this investigation will be the whole EEA except Italy.²¹⁸

3.3.3 Pfizer/Flynn Pharma case

Two months after the AGCM imposed a fine on Aspen Pharma, the British Competition and Markets Authority (CMA) made a decision in the case *Pfizer/Flynn Pharma*. This case dealt with phenytoin sodium capsules which were manufactured by Pfizer and were used as an anti-epilepsy drug by around 48.000 patients in the United Kingdom.²¹⁹ These capsules were sold under the brand name Epanutin up to and including 23 September 2012. Until that date, the price of Epanutin was regulated under the NHS's Pharmaceutical Price Regulation Scheme (PPRS).²²⁰ During the course of 2012, Pfizer and Flynn entered into agreements under which Pfizer transferred its marketing authorisations for Epanutin to Flynn for a nominal fee, after which Pfizer would continue to manufacture the phenytoin sodium capsules and exclusively supply them to Flynn for distribution in the United Kingdom. According to the CMA, a key feature of the negotiations between Pfizer and Flynn was that the genericization of Epanutin would provide the basis for a significant increase in the prices of phenytoin sodium capsules. Accordingly, evidence would suggest that one of the key reasons why Flynn was introduced into the supply chain was for it to be the focus of any adverse reaction to the price increases. In this way, the risk of Pfizer to suffer reputational damage would be mitigated.²²¹ After this transfer on 24 September 2012, Flynn sold the generic version of Epanutin, which then was withdrawn from the PPRS and no longer subject to any form of price regulation.²²² From that moment on, Pfizer supplied the phenytoin sodium capsules to Flynn for a price which was between 780% and 1.600% higher than previously. Subsequently, Flynn sold these medicines to wholesalers and pharmacies for prices which were between 2.300% and 2.600% higher than before 24 September 2012. As a result, the expenditures of NHS on phenytoin sodium capsules increased from about £2 million a year in 2012 to about £50 million in 2013.²²³

The relevant product markets were defined by the CMA as the market for the manufacture of Pfizer-manufactured phenytoin sodium capsules and the market for the distribution of Pfizer-manufactured phenytoin sodium capsules. The CMA itself acknowledged this was a “*very narrow product market*”.²²⁴ Indeed, defining the relevant product market as a brand-specific market is very notable. According to CMA, this was justified since other products

²¹⁸ European Commission, Press Release of 15 May 2017: *Antitrust: Commission opens formal investigation into Aspen Pharma's pricing practices for cancer medicines* (IP/17/1323).

²¹⁹ UK Consumer and Market Authority (CMA), Case CE/9742-13, *Pfizer/Flynn Pharma* [2016], par. 1.3-1.5.

²²⁰ *Ibid*, par. 1.9-1.11.

²²¹ *Ibid*, par. 1.15.

²²² *Ibid*, par. 1.12-1.13.

²²³ UK Government, Press Release of 7 December 2016: *CMA fines Pfizer and Flynn £90 million for drug hike to NHS*.

²²⁴ UK Consumer and Market Authority (CMA), Case CE/9742-13, *Pfizer/Flynn Pharma* [2016], par. 4.9.

could not serve as substitutes because of a clinical guidance which recommended that epilepsy patients were maintained on specific brands of products.²²⁵ The geographical market was, just as in the foregoing cases, defined as national.²²⁶ The CMA concluded that on these relevant markets, both Pfizer and Flynn Pharma separately hold a dominant position. This was due to the fact that Pfizer and Flynn each had very high market shares in their respective relevant markets: on the market for Pfizer-manufactured phenytoin sodium capsules, Pfizer had a market share of 100%²²⁷ and on the market for the distribution of Pfizer-manufactured phenytoin sodium capsules, Flynn enjoyed a market share between 60% and 90%.²²⁸ Furthermore, there were significant barriers to entry and the NHS did not hold sufficient countervailing buyer power to effectively constrain either Pfizer's or Flynn's conduct.²²⁹

To determine whether the prices charged by Pfizer and Flynn were excessive, the CMA applied the test provided for in *United Brands* to both undertakings. To assess whether the prices were excessive in comparison with the costs, the CMA first assessed what could be qualified as a reasonable margin, which should be added to the costs. In this regard, the CMA used the PPRS as guidance and considered a return of 6% on sales to be reasonable.²³⁰ The prices of Pfizer exceeded the costs (plus the reasonable margin) by 29% to 705%.²³¹ Flynn's prices exceeded these costs by 31% to 133%.²³² Since the Competition Appeal Tribunal previously held prices of 47% above costs to be excessive and the Commission did the same for 25% above costs, the CMA concluded the prices of Pfizer and Flynn were excessive as well. With regard to the costs, Pfizer argued that CMA's assessment should include a reasonable allocation of Pfizer's overall R&D costs. It submitted that the pharmaceutical industry operates on a very high fixed cost base, particularly due to extremely high R&D costs, and that recovering these costs required profitability to be maximised on all products within a portfolio, including established products. Therefore, Pfizer argued it "*needs to recoup its substantial overall R&D expense through a contribution margin on the sales of all its products*".²³³ The CMA did not accept this argument. Although it accepted that pharmaceutical companies may recover substantial R&D costs through higher prices, it considered this to be the role of patent protection, which allows for a period of exclusivity in which supra-competitive margins can be earned as a reward for innovation. However, the CMA did not accept the fact that a manufacturer of an old, non-patented drug can sustain prices significantly above the competitive level to recover overall R&D costs. It stated that when patent exclusivity expires, prices and/or market share should drop as a

²²⁵ UK Consumer and Market Authority (CMA), Case CE/9742-13, *Pfizer/Flynn Pharma* [2016], par. 4.107.

²²⁶ *Ibid*, par. 4.187.

²²⁷ *Ibid*, par. 4.211.

²²⁸ *Ibid*, par. 4.216.

²²⁹ *Ibid*, par. 4.190.

²³⁰ *Ibid*, par. 5.93.

²³¹ *Ibid*, par. 5.125.

²³² *Ibid*, par. 5.218

²³³ *Ibid*, par. 3.

result of competitive entry. Since such entry did not occur in this case, Pfizer and Flynn were able to charge unfairly high prices.²³⁴

Then, the CMA had to determine whether the prices were unfair. The CMA explained that the second test of *United Brands*, whether a price is 'unfair in itself or when compared with competing products' is an alternative and not a cumulative test. Therefore, the CMA stated it was sufficient to prove that one of the limbs is satisfied in order to find an infringement.²³⁵ Accordingly, the CMA concluded the prices of Pfizer and Flynn were unfair in itself. In this regard, several factors played a role. First, the substantial disparity between Pfizer's prices and the economic value of Pfizer's products and between Flynn's prices and the economic value of Flynn's products was taken into account. In this regard it was deemed important that phenytoin sodium capsules were very old drugs which had been off-patent for a long time and that phenytoin sodium capsules had been sold by Pfizer at a much lower price for a number of years prior to the de-branding of Epanutin. The substantial price increases, which followed after the de-branding, were not the result of any change in costs, investments or risks.²³⁶ Secondly, the prices could only be maintained on such a high level because the competitive conditions on the relevant markets did not function properly. This was, inter alia, due to the clinical guidance, which maintained patients on phenytoin sodium capsules produced by a particular manufacturer. For that reason the CMA stated, "*patients who are stabilised on Pfizer-manufactured phenytoin sodium capsules are effectively captive customers.*"²³⁷ A third factor in the assessment of the unfairness was the fact that the prices of Pfizer and Flynn had an adverse effect on the end consumer, in this case the NHS. After the prices of phenytoin sodium capsules were raised, the health service had to commit extra money from their constrained budgets in order to continue to fund. Consequently, the scope of other healthcare services had to be compromised.²³⁸ Additional to these factors, the CMA took evidence into account which showed that Pfizer and Flynn knew that the September 2012 price increases would have an adverse impact on the NHS budget and could give rise to adverse publicity. The mitigation of this exposure and the management of reputational risks was an important reason why Flynn was included into the supply chain.²³⁹ Although the CMA states that in principle the assessment of whether or not a price is unfair is an objective one, the parties' intentions and motives can give information about the way they regarded the price increases themselves.²⁴⁰ On the basis of all foregoing factors, the CMA came to the conclusion that both Pfizer's and Flynn's prices were unfair in itself.²⁴¹ After coming to this conclusion, it was not necessary anymore to determine whether the prices were unfair in comparison with others, according to the CMA. However, for the sake of completeness the

²³⁴ UK Consumer and Market Authority (CMA), Case CE/9742-13, *Pfizer/Flynn Pharma* [2016], annex L, par. 3-6.

²³⁵ *Ibid*, par. 5.244.

²³⁶ *Ibid*, par. 5.356.

²³⁷ *Ibid*, par. 5.391.

²³⁸ *Ibid*, par. 5.399.

²³⁹ *Ibid*, par. 5.426-5.427.

²⁴⁰ *Ibid*, par. 5.428-5.429.

²⁴¹ *Ibid*, par. 5.475.

CMA assessed whether such a comparison could be made as well. In this respect it concluded there were no sufficiently similar products that could allow for a meaningful comparison.²⁴² As a result, the CMA imposed a fine of £84.2 on Pfizer and a fine of £5.2 on Flynn.²⁴³

However, the CAT annulled this decision recently. Although the CAT found that the CMA was correct in holding that both Pfizer and Flynn Pharma held a dominant position, it ruled that CMA did not apply the legal test for finding that prices were unfair correctly. Specifically, it did not appropriately consider what the right economic value for the product at issue was and it did not take sufficiently account of the situation of other, comparable products, in particular of the phenytoin sodium tablet.²⁴⁴ With reference to the case *AKKA/LAA*, the CAT stated that CMA should have selected comparators in accordance with ‘objective, appropriate and verifiable criteria’.²⁴⁵ As a result, the CAT ruled that CMA’s findings on abuse of dominance in this case could not be upheld. For this reason, it referred the case back to the CMA with the order to apply the United Brands-test in a correct way, including all the steps the CAT set out in its judgement, such as the establishment of a benchmark price and an overall judgement on price and economic value.²⁴⁶ According to the CAT, *“The importance of this case for the public interest makes it desirable to rectify the errors we have found. In a matter as important for government, for the public as patients and as taxpayers, as well as for the pharmaceutical industry itself, the law should be clear and any decisions made should be soundly based on proper evidence and analysis.”*²⁴⁷ At the time of writing, CMA is considering to appeal this judgement at the Competition Appeal Court.²⁴⁸ It should be noted that the CAT explicitly did not rule out the possibility for CMA to have a successful case against Pfizer and Flynn Pharma by applying the United Brands-test again in a correct way: *“In overturning the CMA's findings of abuse of dominance we are not saying that no finding of abuse could be made in this case.”*²⁴⁹ In any way, this judgement clearly reflects the inherent difficulties of the assessments regarding the ‘excessiveness’ of prices in the area of competition law.

²⁴² UK Consumer and Market Authority (CMA), Case CE/9742-13, *Pfizer/Flynn Pharma* [2016], par. 5.479.

²⁴³ *Ibid*, par. 7.150

²⁴⁴ UK Competition Appeal Tribunal, Case 1275/1/12/17, *Pfizer/Flynn Pharma* [2018], par. 4.

²⁴⁵ *Ibid*, par. 392.

²⁴⁶ *Ibid*, par. 441-443.

²⁴⁷ *Ibid*, par. 465.

²⁴⁸ UK Government, Press Release of 7 June 2018: *CMA considers appeal in phenytoin case*.

²⁴⁹ UK Competition Appeal Tribunal, Case 1275/1/12/17, *Pfizer/Flynn* [2018], par. 441.

3.3.4 Key findings

By analysing these cases, a few conclusions can be drawn. First, it can be concluded that in all these cases, different methods were used to come to the conclusion that prices were excessive. Especially in *Napp*, the assessment was different than the one used in *Aspen* and *Pfizer & Flynn Pharma*. In *Napp*, the authority made a cost-price comparison and compared the charged prices with the prices of competitors' products and the prices charged in other markets, such as to hospitals and in other Member States. Additionally, the competition authority compared the profits *Napp* made on morphine with profits made on other products. For this reason, this case was mentioned by AG Wahl in the case *AKKA/LAA* as a successful example of a case in which the authorities combined several methods to prove excessive prices.²⁵⁰ It is notable that the authorities did not apply the second limb of the United Brands-test. After coming to the conclusion the prices were excessive, they did not assess whether the prices were also 'unfair in itself or when compared to competing products'. This can be explained by the fact that the abuse was not only seen as an exploitative, but also as an exclusionary form of abuse. In comparison with the methods used in *Napp*, the assessment in the case *Aspen* did not entail a detailed comparison with other prices. First, prices charged by competitors were not compared since these products were not considered valid alternatives. Secondly, prices charged by *Aspen* in other Member States were not assessed due to different conditions in those Member States and because high prices in other Member States could reflect a similar strategy to increase prices.²⁵¹ Instead, the Italian competition authority assessed the excessiveness of the prices by looking at the costs and the margins of *Aspen*, which increased proportionally after the prices increases of 300% to 1500%. To conclude the prices were not only excessive but also unfair, the authority mainly relied on the fact that the prices were increased dramatically without any justification. In the case *Pfizer & Flynn Pharma*, the finding that the prices were excessive was also based on a cost-price comparison. And just as was the case in *Aspen*, the authority concluded the prices were 'unfair in itself' mainly because of the fact that for a long time the medicines had been sold for a much lower price and the price increase happened without any justification such as changes in costs, investments or risks. In this regard, no price comparisons with other products were made. In this way, it becomes clear that the establishment of excessive prices in *Napp* had a different nature than the one in *Aspen* and *Pfizer & Flynn Pharma*. While the excessiveness of *Napp's* prices was proved by a comparison of the prices with prices of competitors and the prices on other markets, the prices of *Aspen* and *Pfizer and Flynn Pharma* were not compared with other prices. Instead, the excessiveness was found by a cost-price comparison which found the new prices to be excessive in comparison with the costs. Thereafter, the prices were found to be unfair, mainly because of the strong price increase without any justification. Later, the CAT rejected CMA's finding that the prices were unfair due to the lack of a price comparison. Regarding

²⁵⁰ Opinion AG Wahl in the Case C-177/16 *AKKA/LAA* [2017], ECLI:EU:C:2017:286, par. 44.

²⁵¹ Faella 2017, slide. 9.

the argument of CMA that no meaningful comparators existed, CAT ruled that *“suitable and meaningful comparators do not have exactly to mimic the features of phenytoin, and if there were prima facie evidence of a meaningful comparator which helped establish a benchmark price for Pfizer-Flynn Capsules in conditions of normal and sufficiently effective competition, it should have been examined carefully”*.²⁵²

A second conclusion is that the circumstances in *Aspen* and *Pfizer/Flynn Pharma* were quite exceptional and provided a lot of evidence for the competition authorities to prove excessive prices. First, the prices of drugs for which there were no alternatives available were suddenly raised by huge percentages. Since the products had been on the market for much lower prices before, it could quite easily be concluded that the new prices did not have any relation with the costs anymore. In this way, the former price could be used easily as a reliable benchmark. However, it should be noted that the CAT did not agree with the CMA in this regard: although it stated that *“large price raises may be indicative of an abuse of a dominant position that needs to be examined, it should not be confused with the test for unfair pricing itself.”*²⁵³ Secondly, in both cases the competition authorities found no justification grounds for these price increases since the product had not been improved and there were no changes in costs, risks of investment. With regard to R&D it could be determined easily that this factor could not justify any price increase as well. In *Aspen*, the products were generic medicines that had been sold for several decades and for which the expenses for R&D had already been sustained by the originator producers. In *Pfizer/Flynn Pharma*, no R&D costs could be justified either since phenytoin sodium capsules had been marketed since 1938, had been off patent for a long time and had been genericised by other producers. Third, in both cases the pharmaceutical companies used tools which were lawful, but at the same time highly questionable from an ethic point of view: *Aspen Pharma* applied an aggressive negotiation strategy towards the Italian Medicines Agency by threatening to suspend the medicines off the market, while *Pfizer* and *Flynn Pharma* applied the de-branding strategy. However, according to the CAT these circumstances were not sufficient to prove the second limb of the United Brands-test. In order for this condition to be satisfied, the CMA should have assessed the ‘unfairness when compared to competing products’ as well.²⁵⁴ This means that according to the CAT such circumstances can play a role in the decision to investigate certain price strategies, but cannot be used as a way to prove the unfairness of the price.

²⁵² UK Competition Appeal Tribunal, Case 1275/1/12/17, *Pfizer/Flynn* [2018], par. 345.

²⁵³ *Ibid*, par. 439.

²⁵⁴ *Ibid*, par. 367.

Chapter 4: The suitability of the prohibition of excessive pricing to prevent high prices of medicines

4.1 Situations in which the concept of excessive pricing is a suitable instrument

In the foregoing paragraph, three cases in which competition authorities successfully imposed fines on pharmaceutical companies for charging excessive prices, were analysed. From these cases, a few characteristics can be derogated which made it possible for the prohibition of excessive pricing to be applied successfully. Although the decision of the CMA in the case *Pfizer/Flynn Pharma* was overturned by the CAT in June 2018, some aspects of the decision were upheld, which makes the case still relevant to see which factors play a role in the probability for a case against a pharmaceutical company to be successful. First, all cases that were dealt with were about non-patented drugs. Consequently, the pharmaceutical companies could not use the argument that they had to earn back their high investments as a justification ground. For this reason, the prohibition of excessive pricing is 'easier' to apply to medicines which are not patented anymore. In situations in which high prices as a result of a patent would be targeted directly, innovation might be impeded since companies are not able anymore to earn back their investments. It is argued by authors that the existence of a patent is not a reason to exclude the enforcement of the excessive pricing prohibition by the authorities.²⁵⁵ Nevertheless, targeting prices of patented products is a path which is far more difficult than targeting prices of non-patented products.

Another important factor that determines the chances of a successful case on excessive pricing, is the existence of substitutes. Especially in the cases *Aspen* and *Pfizer/Flynn Pharma*, the relevant product market was defined extremely narrow. This was due to the fact that for these specific health conditions there were no products of other brands with the same effects for patients available. Because of this very narrow definition of product markets, which was accepted by the CAT²⁵⁶, the pharmaceutical companies could be qualified as dominant undertakings. The consequence is that if substitutes were available and pharmaceutical companies could not be considered dominant, the prohibition of excessive pricing could not have been applied. Therefore, the prohibition of excessive pricing is only sufficient in case a particular company is considered dominant on a particular medicine market.

Moreover, two of the three cases that were discussed in the foregoing chapter involved strong price increases, which happened 'overnight'. For this reason, it was quite easy for the competition authorities to prove the prices were excessive since the products had been on the market for a much lower price for many years. Although these strong price increases

²⁵⁵ See for example Fonteijn, Akker & Sauter 2018, p. 10.

²⁵⁶ UK Competition Appeal Tribunal, Case 1275/1/12/17, *Pfizer/Flynn Pharma* [2018], par. 198.

made it easier to establish a benchmark price, the CAT was very critical about the approach of CMA, which based the finding of the unfairness of the price mainly on these price increases. In this regard, the CAT stated: “(...) *we understand the weight that the CMA placed on this matter. However, whilst this may be a valid reason for a competition authority to investigate a case, it should not be confused with the test for unfair pricing itself.*”²⁵⁷ With regard to the case *Aspen*, the strong price increases are seen as an important reason why the Commission considered it promising to start an investigation. At the announcement of the investigation, Commissioner Vestager stated: “*Companies should be rewarded for producing these pharmaceuticals to ensure that they keep making them into the future. But when the price of a drug suddenly goes up by several hundred percent, this is something the Commission may look at.*”²⁵⁸ This definitely raises the question whether a case against *Aspen Pharma* by the Italian Competition Authority or the Commission could have been made if *Aspen* had not raised its prices suddenly by huge rates, but slowly by smaller percentages over a longer period of time. In such a situation, the authorities would probably have been more hesitant to intervene since they would not have had a starting point from which they could determine what a reasonable price for a certain medicine could be. Therefore, it would have been way more difficult to prove that the prices charged were excessive. However, it is certainly possible that the judgement of CAT regarding the price increases will have implications for the assessment of the Commission in this respect as well.

4.2 Shortcomings of the concept of excessive pricing

To start with, all contraries of the situations which were described in the foregoing paragraph can be regarded as drawbacks of the concept of excessive pricing in this paragraph. This means in case the medicines are patented products, it can be harder for competition authorities to intervene since in such situations, the tension between fair prices and the need for innovation becomes more apparent. Secondly, if substitutes for a medicine are on the market, intervention becomes difficult. In such cases, the relevant market will be broad which means a certain undertaking is less likely to be dominant. Since behaviour such as excessive pricing is only prohibited if an undertaking is dominant, the prohibition of article 102 TFEU cannot be of any help if the undertaking does not hold a dominant position. Thirdly, contrary to strong price increases, there can be situations in which the starting point of the price of a medicine is already too high or the price is slowly increased during years. In such situations, competition authorities will probably be more hesitant to intervene since it is more difficult to prove that the prices are excessive and unfair.

²⁵⁷ UK Competition Appeal Tribunal, Case 1275/1/12/17, *Pfizer/Flynn Pharma* [2018], par. 439.

²⁵⁸ European Commission, Press Release of 15 May 2017: *Antitrust: Commission opens formal investigation into Aspen Pharma's pricing practices for cancer medicines* (IP/17/1323).

Next to these situations, the concept of excessive pricing entails more shortcomings. For example, the concept of excessive pricing is not suitable to tackle situations in which the overall price level of certain groups of medicines is considered to be too high. In such cases, a price comparison with prices of other products of a certain undertaking, prices on other markets or with prices of competitors will not be of any help. Besides, situations exist in which a price comparison is not possible because there are simply no substitutes to compare the price of a medicine with. In these situations, it can be very hard to prove the excessiveness or unfairness of a certain price. For that reason, authors have proposed to use the threshold that has been set as the maximum cost per gained Quality-Adjusted Life Year (QALY). This concept is used by many countries to measure health gains of treatments.²⁵⁹ By using the QALY-threshold in the assessment of excessive prices, comparisons with other drugs and other types of health expenditure would be possible. However, such an approach can raise questions of arbitrariness as well since the prices of medicines designed for different medical conditions would have to be compared.

Another main problem concerning the application of the concept of excessive pricing is the lack of transparency of pharmaceutical companies with regard to their costs. Pharmaceutical companies usually argue their prices are justified since they have to earn back their very high costs in R&D, including the costs of products which do not enter the market in the end. As a result, successful medicines have to cross-subsidize the unsuccessful ones. As already touched upon in the introduction, the call for more transparency by pharmaceutical companies about their real costs has become louder during the last years in the European Union. But until now, pharmaceutical companies have not disclosed such information. As a consequence, in many situations, the assessment of whether a price is excessive will be very hard to make, due to incomplete information about the cost structure. This lack of transparency becomes even more apparent when it is taken into account that public funding contributes significantly to R&D costs: about 30% of direct funding of the industry is public money.²⁶⁰ Additionally, 25% of new drugs originate in university laboratories and this proportion is even higher if treatments addressing unmet medical needs are considered.²⁶¹ As long as pharmaceutical companies cannot be obliged to open up about their costs, assessments about excessive prices will be hard to make.

²⁵⁹ Canoy & Tichem 2018, p. 2.

²⁶⁰ Reid & Balasegaram 2016, p. 656.

²⁶¹ *Ibid*, p. 656.

4.3 Evaluation and conclusion

On the basis of the foregoing paragraphs, the suitability of the concept of excessive pricing in the pharmaceutical sector can be evaluated. Generally, it can be said the prohibition of excessive pricing can be very useful to address situations in which pharmaceutical companies charge excessive prices, but only in certain circumstances. First, for the prohibition to be applied successfully, the pharmaceutical undertaking must have a dominant position on the relevant market. The definition of the relevant market depends on the existence of substitutes, which means that if alternative medicines are available, the market will be defined broadly and the undertaking will not have a dominant position. In such situations, excessive prices cannot be addressed. Secondly, the analysed cases show the determination of excessive prices can be made easier in case the prices were suddenly increased strongly without any justification. Although the CAT ruled that strong price increases are not sufficient to prove the unfairness of the price, they can definitely help competition authorities by providing a benchmark price. If sudden price increases do not occur, the excessiveness of prices is harder to prove. In such situations, the excessiveness of the prices can be proved by price comparisons. However, in case the overall price level of a medicine on different markets or of a certain group of medicines made by competitors is high, a price comparison cannot be of any help. Next to that, price comparisons are not possible in some situations due to the lack of substitutes. Especially in dynamic, R&D intensive sectors, there are often no effective comparators.²⁶² Thirdly, the prohibition of excessive pricing is mainly suitable to be applied with regard to non-patented products. In case the product is still patented, companies are basically allowed to charge very high prices since they should be able to earn back their investments. Although patent rights do not make the application of the prohibition of excessive pricing impossible, they make it way more difficult since companies can strongly argue the prices are needed to earn their R&D costs back. This is related to the fourth issue: transparency. Nowadays, the cost-structure of pharmaceutical companies is not transparent, which makes it hard to determine the validity of the arguments relating to investment that were made, especially when it is taken into account that public funding plays an important role in the development of medicines.

For these reasons, the conclusion can be drawn that the prohibition of excessive pricing can be helpful to prevent extreme prices under certain circumstances, but it has several shortcomings which make it hard to apply successfully. Concluding, the prohibition of excessive pricing can only be applied in special circumstances, in which prices can truly be considered to be excessive and unfair. In case the prohibition of excessive pricing is applied to non-patented medicines, for which there are no substitutes available and the prices were suddenly strongly increased, competition law seems to be a suitable instrument. In such a situation, the prohibition of excessive pricing can help to guarantee access to certain

²⁶² De Sousa 2017, 'Excessive Pricing in the Pharma Sector – Recent OECD Developments', slide 9.

medicines for patients at a reasonable price. It also safeguards the incentive to innovate for pharmaceutical companies, since it is about non-patented products for which R&D costs have been earned back by the originator during the patent period. For this reason, if the foregoing circumstances are present, competition law is a suitable instrument to prevent extreme prices of medicines and at the same time balancing the interests of patients, the society and pharmaceutical companies. With regard to the remaining circumstances, it is useful to analyse which other options are available to prevent extreme prices of pharmaceuticals.

Chapter 5: Alternative remedies to prevent high prices of medicines

As was explained in the foregoing chapter, competition law is not always a suitable instrument to prevent high prices of medicines. In the words of Abbott, the ‘fixing the market’ approach of competition law is problematic with regard to patented products since in the conventional antitrust sense, the mechanical aspects of the market are not broken at all. Rather, the market has been designed “*without adequate control mechanisms or ‘limiters’ that act to constrain exploitative behaviour.*”²⁶³ Therefore, other remedies, some of which are more political than legal, can provide better tools to prevent excessive prices and should be considered as well.

5.1 Price regulation

A first remedy could be the use of a more stringent form of price regulation by setting maximum prices. This would mean that if the costs of a medicine are higher than the maximum price that is laid down, the medicine would not be reimbursed anymore. Nowadays, most European countries apply some form of price regulation to medicines, although these policies differ to a large extent.²⁶⁴ In general, maximum prices are set either by referencing pricing or by value-based pricing policies.²⁶⁵

The most common regulatory practice in the EU is external pricing referencing (EPR), which is used by all EU Member States except Sweden and the UK. However, the scope, relevance and methodological design vary across the countries.²⁶⁶ External pricing referencing means that countries refer to the prices of other countries to set the price of medicines in their own country. In this way, the international price comparison offers a reference or a benchmark for policymakers to understand where the prices proposed by the pharmaceutical industry are ranked relatively to other countries. Practically, the price information achieved through EPR is mostly seen as a starting point of further negotiating in order to conclude agreements which set prices at a more affordable price.²⁶⁷ For example in the Netherlands prices are set by using the prices of certain medicines in Belgium, Germany, France and the United Kingdom as references prices.²⁶⁸ These ERP policies have raised quite some criticism: it has been argued by, inter alia, the OECD that EPR policies cause incentives for pharmaceutical companies to launch medicines first in countries with higher prices and delay, or not launch at all, medicines in countries with lower prices, in order not to reduce the international

²⁶³ Abbott 2016, p. 284.

²⁶⁴ Vogler et al. 2017 p. 2

²⁶⁵ Ben-Aharon, Shavit & Magnezi 2016, p. 859.

²⁶⁶ Vogler et al. 2017, p. 4.

²⁶⁷ Ibid, p. 4.

²⁶⁸ Article 2 par. 2 Wet Geneesmiddelenprijzen 1996 (Dutch Act regarding prices of medicines).

reference price of a certain medicine.²⁶⁹ This is one of the reasons why countries increasingly use confidential arrangements: they keep a high 'list price' and subsequently get confidential discounts after negotiations. These practices allow pharmaceutical companies to provide medicines at lower prices to low-income countries, while the reference price is not affected negatively.²⁷⁰ These confidential agreements are another important reason why the ERP policy is much criticized: the prices referred to, which form the basis for maximum prices, do not reflect the final price in other countries after the confidential negotiations. Additionally, the ERP policy could increase the inequality between high and low-income countries. Especially high GDP countries have greater negotiation powers because of their size and revenue and therefore, these countries can obtain confidential rebates that can be as high as 60% of the official 'list price'. These rebates, being confidential, will not be integrated into ERP rules. As a consequence, lower GDP countries end up referencing inaccurately higher prices, adding burden to already higher relative costs.²⁷¹

Secondly, countries regulate the prices of medicines by using value-based pricing (VBP), which consists of setting a price according to the added therapeutic value of a new product through comparison with existing treatments.²⁷² Accordingly, this pricing policy relies on a cost-effectiveness analysis and the setting of a threshold beyond which a new medicine is not funded.²⁷³ In the European Union, VBP is applied on a regular basis in the UK, Germany and Sweden to decide which medicines should be reimbursed. In Sweden, a new cost-regulating mechanism characterized by cost benefit analyses for new drugs as well as generic substitutes was introduced in 2002. In 2011, Germany launched new legislation, which determines maximum prices of reimbursed products by assessing their added medical value.²⁷⁴ In the UK, VBP applies to all new branded medicines introduced from 2014.²⁷⁵ The majority of costs of branded medicines in the UK is regulated by the voluntarily Pharmaceutical Price Regulation Scheme (PPRS). Manufactures and suppliers who do not sign up for the PPRS are regulated by a statutory scheme. This 'Statutory scheme to control costs of branded health services', which was recently revised, can also provide for maximum prices which may be charged by a manufacturer or supplier.²⁷⁶ Under the PPRS, the government agency National Institute for Health and Care Excellence (NICE) makes a cost-effectiveness assessment and advises directly to the NHS about which medicines should be available for reimbursement.²⁷⁷ In this assessment, the QALY-threshold is used, which is nowadays set between £20.000 to £30.000.²⁷⁸ Also in other countries, such as the

²⁶⁹ Vogler et al. 2017, p. 4.

²⁷⁰ Vogler et al. 2017, p. 4.

²⁷¹ Young, Soussi & Toumi 2017, p. 8.

²⁷² Vogler et al., p. 7.

²⁷³ Ibid, p. 5.

²⁷⁴ Ben-Aharon, Shavit & Magnezi 2016, p. 863.

²⁷⁵ Parliamentary Office of Science and Technology 2015, p. 2.

²⁷⁶ Article 8 Branded Health Service Medicines (Costs) Regulation 2018.

²⁷⁷ Appleby 2016, p. 1.

²⁷⁸ Paulden 2017, p. 239.

Netherlands, the QALY-threshold is often proposed to serve as a benchmark to determine the maximum price, which can possibly be corrected for a variety of ethical and other considerations.²⁷⁹ Since the QALY value represents the amount of money the society is willing to pay, it is argued that medicines with a price above this threshold are welfare decreasing rather than welfare increasing.²⁸⁰ In this respect, Canoy and Tichem argue that the use of this QALY-threshold would not decrease innovation, as is often argued, but would rather stimulate innovation. They claim that when the pharmaceutical industry anticipates on charging drug prices which exceed the QALY-threshold, and in this way, gain more than the benefit of the drug to society, this creates inefficiencies in innovation. The reason for this is that companies will overinvest in medicines for which there is no competition and for which they can charge such prices. According to these authors, this is an important reason for the fact that many medicines for very rare diseases (the so-called orphan drugs) were developed during the last years. Due to this perverse price incentive, pharmaceutical companies invest too much in these orphan drugs, at the expense of drugs which are of more benefit to the society. As a result, high drug prices lead to crowding out of valuable drug development projects. Therefore, Canoy and Tichem claim that enforcing lower prices by referring to the QALY-threshold will lead to an improvement of innovation because as a result, future investments will be geared towards projects that are more desirable for society.²⁸¹ This view is supported by Vogler et al., which state that a major argument in favour of using a value-based pricing policy is that it might create an incentive for the development of products that generate more added value.²⁸² Despite these possible positive consequences, value-based pricing has been proven difficult to implement, especially in therapeutic areas where no alternative treatments are available and patients suffer from severe life-threatening diseases. In such cases, there is a lot of public pressure which often makes payers accept high prices for limited clinical benefits.²⁸³ An example of this occurred in the UK, where after the NICE rejected the funding of certain cancer drugs, public pressure made the government decide to establish the Cancer Drug Fund, which would reimburse certain medicines the NICE had not yet reviewed or rejected.²⁸⁴ This example shows the difficulties which arise when it is decided not to fund a certain medicine based on cost-effectiveness. Although it is expected that the factor of cost effectiveness will remain important and will maybe even play a bigger role in the future, the discussion about what the maximum costs should be per gained Quality-Adjusted Life Year is a very difficult one and touches upon many ethical questions.

Because of the difficulties of setting maximum prices, either by reference pricing or by value based pricing, these methods are probably not sufficient to prevent excessive prices.

²⁷⁹ Canoy & Tichem 2018, p. 21

²⁸⁰ Fonteijn, Akker & Sauter 2018, p. 13.

²⁸¹ Canoy & Tichem 2018, p. 2-3.

²⁸² Vogler et al. 2017, p. 9.

²⁸³ Ibid, p. 9.

²⁸⁴ The Economist Intelligence Unit 2016, p. 10.

However, by improving these methods, for example by looking more critically at the 'list prices' which is referred to or by launching a real societal debate about what society is willing to pay for certain medicines, stronger price regulation can help to decrease prices of medicines.

5.2 Adjustment of the patent system

A second remedy which is often mentioned is to adjust the patent system. Many experts have criticized the current regulatory framework on pharmaceutical patents, especially regarding the question whether it is still fit for public purposes and needs.²⁸⁵ In this respect, it has been proposed to exclude medicines from patents entirely. Although this sounds like a radical option, still in 1987, 43 countries did not grant patents to pharmaceuticals, of which seven developed countries.²⁸⁶ Moreover, for example French patent law excluded medicines from patentability until 1960 for two public health reasons. The first one was the fight against charlatanism and to ensure that patents were not used for purely commercial purposes. The second reason concerned the prevention of monopolies in the medical field. In both reasons, the particular status of health products was crucial: they were considered to be goods unlike any others.²⁸⁷ One could indeed say that medicines are goods which are so essential for public health that they cannot fall under regular patent law. However, totally excluding medicines from patent law and in this way take away the possibility for pharmaceutical companies to earn back their investments would mean that new drugs would have to be developed mainly by using public resources. Since this is a quite radical and risky solution, many authors focus on other, less far reaching remedies. In this respect, it has been proposed to limit the length of the patent period for medicines. Generally, this could be done in two ways.

The first way would be to amend the TRIPS Agreement and to shorten the current patent period of twenty years. However, two third of the countries have to accept such an amendment, which is quite unlikely at this moment. A second way in which countries could limit the length of the patent period is to rely on the exception of article 30 of the TRIPS Agreement. This article states: *"Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties"*. Since this article was only once interpreted by a dispute panel and has not been subject to further interpretation, its effects are not entirely clear. However, on the basis of the broad drafting of the article, authors argue this article could be used to allow exceptions to the

²⁸⁵ Garattini & Padula 2017, p. 1.

²⁸⁶ Davis 2014, p. 186.

²⁸⁷ Cassier 2008, p. 1.

patent rights, such as shortening the patent period.²⁸⁸ For this to be allowed, the ‘legitimate interests of third parties’ must be at stake, which is quite a high burden. Normally, it is argued that this threshold is only passed if the health interests of people are really endangered. Even if this threshold is passed, the extent to which the patent could be shortened is uncertain: at some point, shortening would probably cross the line of the ‘unreasonably prejudice’ of the interest of the patent owner.²⁸⁹

Furthermore, a lot of attention is paid to the patent protection of the so-called ‘orphan-drugs’, the medications for rare conditions that occur in less than 5 out of 10.000 inhabitants. The increasing prices of these orphan drugs raise many concerns. For example in the Netherlands the costs for orphan drugs raised from € 173 million in 2012 to € 226 million in 2015: an increase of 31%.²⁹⁰ Interestingly, the development of these drugs was strongly encouraged in both the EU and the US, where legislative acts were introduced to provide for additional protection of these drugs.²⁹¹ For example in the EU, in addition to protection by intellectual property law, a company that manufactures an orphan drug is granted ten years market exclusivity, which means that no medicines based on the same mechanism of operation for the disease in question are allowed to be put on the market.²⁹² Recently, the Dutch Council for Public Health and Society criticised this additional protection. It stated that although the Regulation has strongly encouraged the development of new orphan drugs, it has also had the perverse effect of medicines being investigated and licensed for narrow and restricted indications in order to obtain the status of an orphan drug, while the study results indicate that its efficacy is broader.²⁹³ Because of these strategies, stricter control on the registration of a drug as an ‘orphan drug’ is necessary. Besides, one can question whether the period of ten years market exclusivity is really necessary, especially when it is taken into account that after the expiry of this period, the prices do not decrease (significantly) and competition does not seem to be arising.²⁹⁴

Next to the length of the patent period and the patent protection of orphan drugs, attention should be paid to the fact that pharmaceutical companies have developed a practice in which minor improvements to medicines are made just before the expiry of the patent period, after which a new patent can be applied for. In the pharmaceutical trade, this procedure, where slight modifications of old drugs are claimed to be ‘new inventions’ is known as ‘evergreening’.²⁹⁵ With this strategy, the patent period of medicines is stretched beyond the term of twenty years, which enables pharmaceutical companies to keep the prices high. The difficulty with these practices lies in the fact that they are not illegal: the

²⁸⁸ McBeth 2010, p. 141.

²⁸⁹ McBeth 2010, p. 141.

²⁹⁰ *Monitor Weesgeneesmiddelen* 2017, p. 6.

²⁹¹ Orphan Regulation (EC) No. 141/1200 and the US Orphan Drug Act 1983.

²⁹² Article 8 Orphan Regulation (EC) No. 141/1200.

²⁹³ *Development of new medicines – Better, faster, cheaper* 2017, p. 23.

²⁹⁴ *Monitor Weesgeneesmiddelen* 2017, p. 6.

²⁹⁵ Collier 2013, p. 1.

current patent laws allow companies to apply for a new patent after every little improvement of the formula. In India, much attention has been paid to this problem. As a result, it is laid down in Indian patent law that a new version of an old drug must demonstrate 'improved efficacy' to merit a patent monopoly. However, this criterion can also raise difficulties, according to authors, which argue that one should also look at, for example, whether the new product improves patient safety, reduces adverse effects or increases adherence.²⁹⁶ In any way, this provision in Indian patent law shows that it is important to pay attention to possible abuse of the current patent law by pharmaceutical companies. For that reason, it could be useful to raise the bar for patentability by setting criteria and in this way, to assess strictly whether or not the granting of a new patent is justified.

To conclude, adjusting the patent system could be a solution in order to decrease the prices of medicines. The limiting of the patent period in general could be an option, but is rather unlikely at this moment since it requires an amendment to the TRIPS Agreement for which two third of WTO members should agree. Therefore, it seems more promising to look critically at the current strong patent protection for orphan drugs. Furthermore, the practice of 'evergreening' should be assessed critically and raising the bar for a patent to be registered could be considered. Especially this last measure will not affect the incentive for companies to innovate, since companies have had the possibility to recoup their R&D costs during the patent period. Therefore, this measure secures a balance between the interests of patients, society and the pharmaceutical industry and can be considered a suitable tool to prevent excessive prices.

²⁹⁶ Collier 2013, p. 2.

5.3 Compulsory licensing

A third remedy to avoid high prices of pharmaceuticals can be the option of compulsory licensing. Essentially, a compulsory license is an involuntary contract between an unwilling patent holder and a willing licensee, imposed and enforced by the State. Generally, the aim of a compulsory license is to improve access to a patented product or process. This can be done either by reducing prices through increased competition, or by increasing supply where the patent holder's production is insufficient for the needs of the domestic market.²⁹⁷ In this way, compulsory licenses emphasize the public benefit that flows from enabling access to an otherwise inaccessible invention.²⁹⁸ In contrast to compulsory licenses, voluntary licenses exist, which emphasize the need for the licensee to be provided with reasonable terms. Such voluntary licenses are made between the holder of a standard-essential patent and a standard-setting organisation²⁹⁹ in order to establish standard systems which facilitate operability or compatibility between products.³⁰⁰ In the telecommunications sector, these licenses are most common. Since such standard essential patents confer significant market power on their holders, standard setting organisations often require the owners of these patents to license their patents only on FRAND-terms, which stands for 'Fair, Reasonable and Non-Discriminatory'.³⁰¹ These FRAND commitments are designed to ensure that the technology incorporated in a standard is accessible to the manufacturers of standard-compliant products and at the same time, patent holders are rewarded financially.³⁰² In this sense, the determination of the remuneration is negotiated on a more equal basis compared to compulsory licenses, where essentially, the government dictates the price.³⁰³

In the pharmaceutical sector, the issuing of a compulsory license would mean that the government buys the license of a pharmaceutical company in exchange for a certain amount of remuneration, after which the licence can be given to other companies that can produce the specific medicine at a lower price. Compulsory licensing is a quite radical option since it circumvents a company's patent, and has not been applied often, especially not in developed countries. However, it seems that this option is becoming more and more realistic in some European countries. Recently, the Dutch Minister of Health stated that compulsory licensing could be considered a possible option in case a pharmaceutical company keeps asking a very high price for an important medicine.³⁰⁴

²⁹⁷ McBeth 2010, p. 143.

²⁹⁸ Ragavan, Murphy & Davé 2016, p. 83.

²⁹⁹ An example of an important standard-setting organization is the European Telecommunications Standards Institute (ETSI).

³⁰⁰ Ragavan, Murphy & Davé 2016, p. 86.

³⁰¹ European Commission 2014, p. 3.

³⁰² *Ibid*, p. 3.

³⁰³ Ragavan, Murphy & Davé 2016, p. 116.

³⁰⁴ Translated from the Letter of 16 November 2017 from the Dutch Minister of Health (Bruins) to Parliament, 'RVS-advies over ontwikkeling nieuwe geneesmiddelen', 16 November 2017, p. 5.

Article 31 of the TRIPS Agreement offers the possibility to make use of compulsory licenses. Such use is only permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and such efforts have not been successful within a reasonable period of time. This requirement can be waived in case of a national emergency or other circumstances of extreme urgency or in cases of public non commercial use.³⁰⁵ Furthermore, the right holder shall be paid an adequate remuneration, taking into account the economic value of the authorization.³⁰⁶ Another important condition is the fact that the scope and duration of the license must be limited to the purpose for which it was granted³⁰⁷ and issuing of the license should be subject to judicial review or other independent review by a distinct higher authority in that state.³⁰⁸ Further guidance on the possibility to use compulsory licences was given by the Doha Declaration, which the WTO adopted in 2001. This declaration was adopted to clarify several uncertainties of governments between the need to protect public health and the terms of the TRIPS Agreement.³⁰⁹ In this Declaration, it was explicitly stated that each party to the agreement has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.³¹⁰ Furthermore, it was laid down that states have the right to determine what constitutes a national emergency or other circumstances of extreme urgency.³¹¹ In 2017 an amendment was adopted after many years, which provided for an additional type of compulsory licensing. Before the amendment, article 31(f) TRIPS Agreement stated that compulsory licences could only be granted in case they mainly served the domestic market. This provision was heavily criticized because medicine production is mainly located in high-income countries and many developing countries lack pharmaceutical production capacity all together. Therefore, this provision acted like a barrier for developing countries to issue compulsory licenses.³¹² With the amendment, which inserted a new article 31 bis in the Agreement, it became possible for WTO members to grant special compulsory licenses exclusively for the production and export of affordable generic medicines to other members that cannot domestically produce the needed medicines in sufficient quantities for their patients themselves.³¹³ In this way, it became easier for less developed countries with limited or no manufacturing capacity to declare a compulsory license to import generic drugs from other countries.³¹⁴

³⁰⁵ Art. 31(b) TRIPS Agreement.

³⁰⁶ Art. 31(h) TRIPS Agreement.

³⁰⁷ Art. 31(c) TRIPS Agreement.

³⁰⁸ Art. 31(i) TRIPS Agreement.

³⁰⁹ WTO, 'The Doha Declaration on the TRIPS Agreement and Public Health', <who.int/medicines/areas/policy/doha_declaration/en/> [20 May 2018].

³¹⁰ Art. 5b Doha Declaration, 14 November 2001.

³¹¹ Art. 5c Doha Declaration, 14 November 2001.

³¹² Feldman 2009, p. 147.

³¹³ WTO, 'TRIPS Agreement' (as amended on 23 January 2017), <wto.org/english/docs_e/legal_e/31bis_trips_01_e.htm> [21 May 2017].

³¹⁴ Verma 2011, p. 94.

Apart from the WTO rules, compulsory licenses can be granted in the European Union under article 102(b) TFEU which prohibits the refusal to supply for dominant undertakings in certain situations. A very important judgement in this regard, which dealt with the balancing act that should be done between on the one hand, giving access to a patent's product and on the other hand, intellectual property rights, was made in the case *Microsoft*. This case started with a request of Sun Microsystems to Microsoft to provide the information and technology which was necessary to allow the work group server operating systems of Sun to interoperate with the Windows client PC operating system.³¹⁵ After Microsoft declined this request, Sun lodged a complaint at the European Commission, claiming, inter alia, that Microsoft was abusing its dominant position. In March 2004, the Commission adopted a decision which found that Microsoft had indeed abused its dominant position by refusing to supply its competitors with interoperability information and by authorising the use of that information for the purpose of developing and distributing products competing with Microsoft's own products on the work group server operating systems market.³¹⁶ Besides that, Microsoft had abused its dominant position by making the availability of the Windows client PC operating system conditional on the simultaneous acquisition of the Windows Media Player software.³¹⁷ In the appeal procedure of this decision, the Court of First Instance (CFI) made clear that Microsoft's argument holding that a refusal to supply interoperability information cannot constitute an abuse of its dominant position because this information is protected by IP rights or otherwise constitutes a trade secret, was not valid: in case a product is protected by intellectual property rights, this does not prevent competition law to apply. However, only under exceptional circumstances the refusal to supply by the holder of an IP right can be considered abuse of a dominant position, which is the case if three conditions, the so-called *Magill* criteria, are fulfilled. First, the refusal should relate to a product or service indispensable to the exercise of a particular activity on a neighbouring market. Secondly, the refusal must be of such a kind as to exclude any effective competition on that neighbouring market. Thirdly, the refusal must prevent the appearance of a new product for which there is potential consumer demand. Once these conditions are fulfilled, the refusal by the holder of a dominant position to grant a licence will be considered an abuse of a dominant position unless the refusal is objectively justified.³¹⁸ Since the CFI concluded these conditions were satisfied, it upheld the Commission's decision and obliged Microsoft to disclose its information.

During the years, several countries have issued compulsory licenses for medicines, such as Thailand, Brazil, Mozambique, Zimbabwe, Zambia, Rwanda, Malaysia, Indonesia and recently India.³¹⁹ The latter quite recently issued a compulsory license over Bayer's anticancer drug Navaxer to generic company Natco Pharma Ltd, on the ground that the drugs were not

³¹⁵ Case T-201/04 *Microsoft v. Commission* [2007], ECLI:EU:T:2007:289, par. 7.

³¹⁶ *Ibid*, par. 36.

³¹⁷ *Ibid*, 43.

³¹⁸ *Ibid*, 331-333.

³¹⁹ Saroha, Kaushik & Nanda 2015, p. 89.

available to the public at a reasonably affordable price.³²⁰ But still, compulsory licenses have rarely been used by developing countries for a number of reasons, such as the strict conditions which apply, the absence of an administrative and legal infrastructure and the fear of sanctions.³²¹ Moreover, threats and political pressure, especially from countries with a big pharmaceutical industry, kept many governments from actually invoking or using the legal rights they had.³²² Besides developing countries also developed countries have issued compulsory licenses in the past, such as the United States, Canada, Germany, Italy, and Israel.³²³ However, the issuing of compulsory licenses is generally only accepted under extraordinary circumstances which seriously threaten health interests. For instance, the United States tried to issue a compulsory license for Bayer's medicine Ciprofloxacin, an anthrax antibiotic, following the attacks of 11 September 2001. This was considered since the United States wanted to treat 10 million people in case of a mass anthrax attack. Eventually, a compulsory license was not issued because the United States and Bayer came to an agreement.³²⁴ This example shows that the instrument of compulsory licensing is mainly used for other purposes than to combat excessive prices, especially in developed countries.

Next to issuing compulsory licenses to produce a specific medicine, one can think of issuing compulsory licenses for certain types of data which are necessary for the development of new medicines. In this regard, it is interesting to note that the CFI accepted the interpretation of the Commission of the third criteria regarding the prevention of the appearance of a 'new product' for which there is potential consumer demand. The Commission reasoned that for this criterion to be fulfilled, it was not necessary to identify a specific new product for which there was actual or potential consumer demand: it was enough that the refusal limited 'technical developments to the prejudice of consumers'. The CFI accepted this reasoning and ruled that the appearance of a 'new product' cannot be the only parameter to determine whether a refusal to license an intellectual property right is capable of causing prejudice to consumers: such prejudice can also arise when there is limitation of technical development.³²⁵ In this way, the CFI endorsed the Commission's view that a refusal to supply may be abusive not only because it prevents competitors from developing a new product but also because it is likely to hinder future innovation. Furthermore, Microsoft's argument that it would have less incentive to develop new technologies if it was required to grant compulsory licenses to competitors was of no relevance with regard to the third condition, according to the CFI, since this condition was concerned only with the competitors' incentives to innovate.³²⁶ The argument of Microsoft

³²⁰ Davis 2014, p. 191.

³²¹ Verma 2011, p. 84.

³²² Reichmann 2009, p. 5.

³²³ Feldman 2009, p. 149.

³²⁴ Reichmann 2009, p. 6.

³²⁵ Case T-201/04 *Microsoft v. Commission* [2007], ECLI:EU:T:2007:289, par. 647.

³²⁶ Jones & Sufrin 2016, p. 531.

relating to innovation could therefore only be examined under the question of whether or not there was an objective justification, which was not accepted by the CFI.³²⁷

The fact that this condition was interpreted in such a manner, raises the question whether compulsory licensing could also be a way to stimulate the innovation of new medicines. This is a relevant question since many authors argue that patents are stifling biomedical research, for example by preventing researchers from accessing patented materials or methods they need for their studies.³²⁸ In this way, an existing patent can block further research on a certain product or method, which can eventually have a negative effect on the development of medicines. Especially with regard to pharmaceutical test data which are necessary for market approval, this is problematic: if the generic entrant does not get permission of the originator company to use this test data, it will have to re-conduct the test, which can take several years, or wait until the data exclusivity period has expired.³²⁹ In this regard, article 39.3 of the TRIPS Agreement on data exclusivity is relevant: *“Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.”* The consequence of this provision is that WTO members are not prevented from refusing to disclose any relevant test data. Consequently, this article prevents generic drug companies from using, for example, clinical trial data for a specific period of time, such as a period of 5 to 7 years of exclusivity in the United States depending on the type of drug.³³⁰ In this way, the entry of generics on the market is significantly delayed, which eventually impedes access to cheaper versions of medicines.

To conclude, the use of compulsory licenses is an option, but has only been issued in specific situations in which health interests were really at stake. Compulsory licenses have not often been used in other circumstances, and especially in developed countries, the rights of the patent owner probably outweigh the interest of a government to use compulsory licenses. Moreover, compulsory licenses do not offer a lasting solution because of the limited scope and limited duration of the use of the license. For this reason, compulsory licenses to produce medicine are generally not considered to be a suitable tool in order to prevent high prices. However, issuing a compulsory license to grant certain data to generic companies which are essential to bring a cheaper product on the market without unnecessary delays, could be a solution to increase competition on the market and in this way, decrease prices. In order to safeguard the interests of pharmaceutical companies, next to those of patients and society, they should be provided a fair and reasonable remuneration. With regard to the

³²⁷ Case T-201/04 *Microsoft v. Commission* [2007], ECLI:EU:T:2007:289, par. 701.

³²⁸ Gold et al. 2009, p. 1.

³²⁹ Sanjuan, Love & Weissman 2006, p. 1-2.

³³⁰ Ragavan 2017, p. 133.

question what a 'fair and reasonable' remuneration is, the voluntary licenses based on FRAND terms could be used as guidelines.

5.4 Increasing transparency

Another remedy that could help to prevent excessive prices and is often discussed nowadays, is to oblige pharmaceutical companies to be transparent about their costs. As already mentioned, calls for more transparency have been raised on both the national and European level. It is expected that as soon as pharmaceuticals have to disclose information about their costs and profits, the prices of medicines will become more proportional with the actual R&D costs made.

In 2015, the European Parliament adopted a resolution in which it requested the European Council to *"oblige pharmaceutical companies to ensure absolute transparency regarding the real costs of research and development, particularly in relation to the public research portion."*³²⁹ In the Netherlands, the Dutch Minister of Health stated recently: *"I would like to see the social responsibility pharmaceutical companies have – and claim to have – reflected in the prices of medicines and transparency they offer about the structure of this price. I aim for maximal transparency."*³³¹ Although in these statements it is not made explicit to whom pharmaceutical companies should be transparent exactly, this is an important question since, due to competitive reasons, companies can normally not be expected to provide all information about their cost structure to the public. Therefore, it would probably be reasonable to oblige companies to provide this information to the institutes which have to decide about the reimbursement of a certain medicine. Also in the US, the call for transparency is growing: during the last years, nineteen states have tried to introduce legislation that requires pharmaceutical companies to be more transparent about their costs.³³² A state with one of the most far reaching legislation which was successfully introduced is Nevada. In this state, legislation has passed which requires manufacturers of drugs essential for the treatment of diabetes to report annually information about the costs of producing the drug, the marketing and advertising costs, the profit the manufacturer has earned from the drug, information about patient assistance programs, the wholesale acquisition cost of the drug over the last several years and the aggregate amount of rebates provided. The law requires the Department of Health and Human Services to compile an annual report based on this information. Furthermore, manufacturers are required to submit information to the state about price increases. In this regard, manufacturers must disclose any factor, without limitation, that has contributed to the price increase and explain the role of each factor in the increase.³³³

³³¹ Translated quote from the Letter of 15 January 2018 from the Dutch Minister of Health (Bruins) to Parliament, p. 1.

³³² Berman et al. 2017, p. 18-19.

³³³ Ibid, p. 7.

Proponents of transparency legislation argue that payers have the right to know how the price of a medicine relates to such factors as its development, manufacturing and marketing costs.³³⁴ It is argued that this information would assist, for example, health institutions in determining whether the price of a certain medicine should be reimbursed. Furthermore, it could help to identify cases in which the development of certain drugs was heavily subsidized by public resources. While these are valid arguments, several factors could limit the effectiveness of transparency instruments. A first difficulty arises with regard to the question which costs should be calculated with respect to a specific medicine. Normally, it is argued that these costs should also entail the R&D costs of failed products, since without those costs, no investments would be made anymore (the so-called cross subsidizing argument). Besides that, it is almost impossible to determine the actual R&D costs of a medicine, since not every cost can be traced back to that specific chemical: costs are normally made for a whole range of possible medicines, of which only a few go into a next developing phase.³³⁵ However, the question is how far the possibility to include costs of failed medicines should go. In this regard, authors ask the question whether “*companies should be allowed to recoup the costs of a failed drug for, for instance, Alzheimer’s disease by raising the price of a new drug for diabetes?*”³³⁶ A complicating factor is that the information provided by the pharmaceutical companies has to be checked by an independent institution, which can be a very difficult task since only the companies itself have access to certain information. Besides that, it is argued that the focus should not lie on R&D costs only. Also many other costs play a role in the drug developing process, such as costs of meeting regulatory requirements and the overhead costs of a business with tens of thousands of employees. By focusing only on R&D costs, many other costs that influence the eventual price will not be taken into consideration. But besides these possible pitfalls, increasing transparency could be a realistic measure which would make it easier for the authorities to assess whether or not certain prices are reasonable.

Another possibility, besides introducing legislation which requires total transparency from pharmaceutical companies about their costs, could be to demand transparency with regard to concrete costs in case of a reasonable suspicion of excessive prices. If competition authorities have reasons to think that the prices charged are excessive, pharmaceutical companies could be asked to provide information about their cost structure and in this way, justify their prices. In a sense, this would mean a shift of the burden of proof which could ease the determination of excessive prices to a considerable extent. This shift of the burden of proof occurred in the case *Napp*, where the Competition Appeal Tribunal ruled: “*Napp has provided no figures as to what that initial investment was. In the absence of any indication to the contrary, we would expect that initial investment to have been recouped*

³³⁴ Sarpatwari, Avorn & Kesselheim 2016, p. 2303.

³³⁵ S. Gavura, ‘Legislators want “pharmaceutical cost transparency”. Are they asking the wrong question?’, *Science-Based Medicine* 21 May 2015.

³³⁶ Sarpatwari, Avorn & Kesselheim 2016, p. 2303.

*long ago.*³³⁷ This line of argumentation can be applied to R&D costs as well: if there are reasonable grounds to believe the prices charged are excessive and pharmaceutical companies do not want to disclose their R&D costs, the prices could be considered to be disproportionate in relation to the R&D costs. Accordingly, pharmaceutical companies would have to justify their prices by giving information about their cost structure. In this regard, Abbott states it would be a major contribution of competition litigation directed towards excessive pricing to require the originator industry to provide concrete data regarding the costs of R&D on individual drugs that are subject to assessment.³³⁸

Concluding, an obligation for pharmaceutical companies to be transparent about their R&D costs could be a way to decrease prices, since it enables the authorities to assess whether prices are reasonable. Next to preserving the interests of patients and of society, this measure preserves innovation because companies are still able to earn back their investments. However, this measure includes difficulties relating to the question what exactly should be included into R&D costs for a specific medicine. Therefore, another possibility could be to demand transparency in case competition authorities have a reasonable suspicion of excessive prices. If the pharmaceutical company does not want to disclose information in such a situation, it should be assumed that the prices were excessive.

5.5 Increasing countervailing buying power

The fact that countervailing buying power is an important factor to assess market power of undertakings, was already touched upon in paragraph 2.2.3. In case there is sufficient bargaining strength on the side of the consumers, undertakings, even those with very high market shares, will not be able to behave to an appreciable extent independently. As explained, bargaining strength can result from, inter alia, the customers' size, their commercial significance for the dominant undertaking or their ability to switch easily to competing undertakings.³³⁹ With regard to medicines, there are many situations in which there is no sufficient alternative available, which decreases countervailing buying power significantly. However, other measures could be taken to increase the countervailing buying power and in this way, impede the possibilities for pharmaceutical undertakings to determine their prices independently. In this regard, the most important measure that could be taken to increase countervailing buying power is to cooperate in the bargaining process. On the national level, there have already been attempts to make several organizations work together. For example, last year in the Netherlands a pilot was started in which hospitals and health insurances purchase medicines together. Instead of individual hospitals trying to get a

³³⁷ UK Competition Appeal Tribunal (CAT), Case No. 1001/1/1/01, *Napp Pharmaceuticals Holdings Ltd and Subsidiaries* [2002], par. 538.

³³⁸ Abbott 2016, p. 307-308.

³³⁹ Communication from the Commission (2009/C 45/02), *Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings*, par. 18.

fair price for a certain medicine, now all actors cooperate and pharmaceutical undertakings only have one negotiation partner. Especially when alternative medicines exist and hospitals are able to switch, this creates a significantly stronger position. This joint purchase project was encouraged by the national competition authority, which published a guideline in which it explained the possibilities for hospitals and health insurances to cooperate in this regard.³⁴⁰ With this guideline, the competition authority wanted to “clarify to purchasing agents what they can and cannot do collectively. (...) The goal is to give market initiatives a boost, thereby strengthening the position of the purchasing agents on the drugs market vis-à-vis the pharmaceutical companies.”³⁴¹

However, in order to really create a strong negotiation position, cooperation on the European level seems necessary. In 2015, the ‘BeNeLuxA Initiative on Pharmaceutical Policy’ was established by Belgium, the Netherlands, Luxemburg and Austria and later joined by Ireland. These countries wanted to cooperate in several areas and started joint price negotiations with pharmaceutical undertakings, beginning with orphan drugs which are very expensive. Next to this, Spain, Malta, Cyprus, Greece, Italy, Portugal, Ireland, Romania and Slovenia signed the ‘Valetta Declaration’ in May 2017, which also aims to explore strategies to jointly negotiate prices with the pharmaceutical industry.³⁴² Furthermore, Poland, Hungary, Slovakia and Lithuania have organised themselves in the ‘Fair Pricing Coalition.’³⁴³ These joint purchasing tactics can have considerable consequences in the future. At the moment, pharmaceutical undertakings are used to negotiate bilaterally with national governments, which puts them in a favourable position by having an overview of each of the 28 EU Member States’ pharmaceutical policies, purchasing power and willingness to pay. It is said that “in contrast, national governments are prevented from knowing what is happening in neighbouring countries, due to market fragmentation and the cloak of secrecy that covers the pharmaceutical negotiating process.”³⁴⁴ As a consequence, the pharmaceutical companies do have a much stronger position in the negotiating process. If Member States act together during the negotiations, this power imbalance can be corrected. However, these initiatives are still in the starting phase: the Valetta Declaration and the Fair Pricing Coalition have barely started work. It turns out that cooperation can be challenged by the number of countries in a group, their languages and legal differences which exist in each

³⁴⁰ Dutch Competition Authority, *Guidelines on collective procurement of prescription drugs for medical specialist care*, June 2016.

³⁴¹ Dutch Competition Authority 2016, ‘Sterkere positie voor ziekenhuizen en zorgverzekeraars bij inkopen geneesmiddelen’, <acm.nl/nl/publicaties/publicatie/15727/Sterkere-positie-voor-ziekenhuizen-en-zorgverzekeraars-bij-inkoop-geneesmiddelen> [1 June 2018].

³⁴² Michalopoulos 2017.

³⁴³ Paun 2018.

³⁴⁴ Natsis 2017, p. 49.

state. Furthermore, countries differ to an appreciable extent in the way decisions about medicine prices are made and timelines about when these decisions should be made.³⁴⁵

Concluding, increasing countervailing buying power by cooperation in the bargaining process can possibly help Member States to be more successful in the negotiating process and in this way, decrease prices of medicines. On the national level, this could for example be established by cooperation between hospital organizations and insurers. On an international level, governments could work together more intensively and start joint price negotiations with the pharmaceutical industry. While there are no concrete results of this cooperation forms yet because the initiatives are still in the starting phase, this form of cooperation could become a remedy to prevent excessive prices. This is especially the case in situations where possibilities to switch exist. However, also in situations where there is no alternative medicine available, joint purchasing can help since the pharmaceutical undertakings certainly do not want to lose a market consisting of several states. If states stand together in the negotiations, they can be able to put a lot more pressure on pharmaceutical undertakings than they were able to do before.

³⁴⁵ Paun 2018.

5.6 Conclusion

In the foregoing paragraphs five alternative solutions were presented which could be possible remedies to prevent excessive prices of medicines. All these options would be legally possible, although some of them, such as the adjustment of the patent system, would be more challenging in a legal sense than others, such as increasing countervailing buying power. Subsequently, all these options can be divided into variants which all have suitable features and drawbacks when it comes to the question how they can prevent excessive prices of medicines and at the same time guarantee the interests of patients, society and pharmaceutical companies.

With regard to price regulating mechanisms, both methods which are used often in the EU nowadays have their shortcomings: the external pricing mechanism often refers to prices which are unreliable, while value based pricing raises difficult questions which are more of an ethical nature. By trying to improve these methods, for example by assessing the listed prices more critically and by opening the discussion about what society is willing to pay for certain medicines, these price regulating mechanism can contribute to lower prices, while the interests of patients, society and pharmaceutical companies are taken care of. The second option, the adjustment of the patent system, could offer a solution to decrease prices as well. Since limiting the patent period is a quite radical option, it seems more promising to look at other peculiarities of the patent system which could be adjusted. An example is the current strong patent protection for orphan drugs which, according to critics, has the perverse effect of medicines being investigated and licensed very narrowly in order to obtain the orphan drug status. Besides this, it seems necessary to assess the practice of 'evergreening' critically and to see whether the bar for a patent to be registered can be raised. Thirdly, the option of compulsory licensing was described. However, this option is quite radical and does not seem to be fairly balanced with regard to the interests of pharmaceutical companies. If this option was applied more regularly, it would create uncertainty for pharmaceutical companies about the question whether they will be able to earn back their investments. Besides that, the WTO rules only offer the possibility to grant such licenses in case of extraordinary circumstances. However, issuing a compulsory license with regard to intellectual property rights is an option that should be considered. If data which is necessary for generic companies to bring medicines on the market is protected by intellectual property rights, could become available, this could help to increase competition on the market and in this way, decrease prices. As a fourth option transparency legislation was discussed. Especially in the US, much legislation is being developed to require pharmaceutical to be transparent about their R&D costs. It is expected that such legislation will be developed in the EU such legislation as well. However, it should be assessed critically what falls under the relevant costs exactly and which institutions could be able to verify these figures. Another feasible option could be to demand transparency of pharmaceutical companies if there is a reasonable suspicion of excessive prices. This shift of the burden of

proof, as was applied in the case *Napp*, could help competition authorities to prove the excessiveness of prices in case pharmaceutical companies refuse to provide information about their costs. As a final remedy, countervailing buying power could be increased if institutions cooperate in the bargaining process. First of all, internal cooperation is a way to have a stronger position against pharmaceutical companies during price negotiations. An even stronger position could be created if several countries act together in the negotiating process and in this way are able to put more pressure on pharmaceutical undertakings. Furthermore, this form of cooperation can prevent market fragmentation and the confidential agreements, which are price increasing factors. The current initiatives are still in the starting phase, but it is probably worth it to invest in these cooperation forms in the future and to see whether a stronger negotiation position will eventually lead to decreasing prices.

Chapter 6: Conclusion

In this research, an answer was sought to the question whether the concept of excessive pricing in competition law is a suitable instrument to prevent high prices of medicines and if not, which other remedies can be considered. Since for competition law to apply, the company should have a dominant position, chapter 2 investigated what the concept of dominance entails and how this concept is applied, especially in the pharmaceutical sector. Furthermore, chapter 2 described the different forms of abuse of a dominant position and investigated how these types of abuse appeared with regard to medicines and how they were dealt with by the authorities. In chapter 3, the concept of excessive pricing was described by giving an overview of the historical development of this concept and by describing which methods are used to assess 'excessiveness'. Subsequently, this chapter explored in which way the concept of excessive pricing was applied in the cases *Napp*, *Aspen* and *Pfizer/Flynn Pharma*, where pharmaceutical companies were eventually convicted for charging excessive prices. By analysing these cases, it became clear that there were quite some similarities between those cases, especially with regard to the cases *Aspen* and *Pfizer/Flynn Pharma*, which contributed to the fact that the competition authorities were able to prove that the prices charged were excessive. Although the decision *Pfizer/Flynn Pharma* was annulled by the CAT recently, some findings of the decision are still relevant to consider. On the basis of the similarities that were found, chapter 4 described in which situations it is likely that the application of the concept of excessive pricing will be successful, and in which situations a successful application will be less likely.

Generally, the probability that the prohibition of excessive prices is applied successfully is the highest in case the medicines are not covered by a patent anymore, (almost) no substitutes of the medicine exist and the prices were increased suddenly by large percentages. In such a situation, it will be very hard for the pharmaceutical company to justify the prices. However, the concept of excessive pricing is not suitable to tackle situations in which the overall price level of certain groups of medicines is considered too high, since in such a situation a price comparison cannot be of any help. The same holds for a situation in which there are no substitutes to compare the price of a medicine with. Another drawback of the concept of excessive pricing is the fact that because of the lack of transparency, pharmaceutical companies have good chances to justify their prices by arguing these are necessary to earn back their investments. Only if the price suddenly goes up without any reason for the R&D costs to have increased or in case the burden of proof is shifted, this argument cannot be made. Based on this, the conclusion was drawn that only under specific circumstances it is likely that competition authorities will be able to apply the prohibition of excessive pricing successfully. Therefore, the prohibition of excessive pricing is definitely not always a suitable instrument to prevent high prices of medicines.

This conclusion is due to the fact that in general, the difficulties relating to high prices of medicines are not always related to competition problems. With regard to the pharmaceutical market, there is definitely not always a situation of a classical 'market failure' in which a dominant undertaking exploits its customers. The pharmaceutical market has several characteristics which distinguish it from other markets. First of all, this is due to the fact that people are dependent on medicines, sometimes even for their lives. This very fact makes the determination of what the concrete value of a medicine is and what a reasonable price could be, very hard to make. Another important characteristic of the pharmaceutical market is the fact that the costs for innovation are very high: huge investments have to be made in order to develop a certain medicine. Besides that, the market is characterized by very low price elasticity due to the high willingness to pay and the fact that doctors who prescribe medicines and the private individuals which use them, do typically not contribute to the costs of the medication themselves. Next to this, the pharmaceutical market is characterized by a lack of transparency: often the ultimate prices of medicines are decided on during confidential negotiations between state officials and pharmaceutical companies, of which the results are not made public. Furthermore, the pharmaceutical companies do not want to be transparent about their R&D costs. These specific characteristics of the pharmaceutical market lead to the fact that medicines cannot be considered 'goods' just as on other markets. Although in some specific situations the instrument of competition law can help to prevent situations which are really exploitative, this instrument cannot be used to improve the general problem of very high prices of medicines. Besides the fact that in many situations competition law cannot be of any help, the application can sometimes also be quite inefficient: very complicated investigations should be started and only sometimes it is possible to come to an actual enforcement of the prohibition of excessive pricing which leads to a fine for the pharmaceutical company. Furthermore, the prices that have been paid by society for many years, can normally not be compensated in a sufficient way. Therefore, it could be more promising to try to lower the prices of medicines in an earlier stage. To some extent, this finding was reflected in the judgement of CAT in the case *Pfizer/Flynn Pharma*, where it stated: "*Generally, price control is better left to sectoral regulators, where they exist, and operated prospectively; ex post price regulation through the medium of competition law presents many problems*".³⁴⁶ Concluding, the prohibition of excessive pricing is necessary to have and should be enforced in clearly exploitative situations, but cannot be used to prevent high prices more generally. For this reason, the goals of ensuring availability of medicines for a reasonable price for society, while preserving the interest of innovation, can better be reached by other instruments.

In chapter 5, some of those other instruments were discussed. These instruments, some of them having a more political than legal nature, included price regulating mechanisms, the adjustment of the patent system, compulsory licenses, increasing transparency and

³⁴⁶ UK Competition Appeal Tribunal, Case 1275/1/12/17, *Pfizer/Flynn Pharma* [2018], par. 462.

increasing countervailing buying power. Although these alternatives have some drawbacks too, some variants can be considered suitable instruments to decrease the price level of medicines. Specifically the adjustment of the patent system with regard to orphan drugs and the practice of 'evergreening', compulsory licenses regarding intellectual property rights, increasing cost transparency, either by legislation or by shifting the burden of proof and cooperation in the bargaining process between states seem to be suitable instruments which balance the interests of patients, the society and pharmaceutical companies in a fair manner. In this way, these instruments could help to prevent excessive prices, while at the same time preserving the incentive of pharmaceutical companies to innovate. As a concluding remark, it should be said that except for situations in which pharmaceutical companies really abuse their dominant position, they have developed several strategies which are maybe doubtful from an ethical point of view, but are legally allowed. Examples in this regard are renewing patents because of minor improvements, medicines being investigated and licensed very narrowly in order to obtain the orphan drug status, not being transparent about R&D costs, refusing disclosure of data which is essential for generics to enter the market and closing confidential agreements with states. Under the current legislation, these strategies are legally allowed. Therefore, if society is of the opinion that this behaviour should not be allowed anymore, it is necessary to adjust the legal framework. The application of the prohibition of excessive pricing is a suitable instrument in some specific situations, but in order to really improve the functioning of the pharmaceutical market, also in the long term, other instruments should be employed as well.

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