Amsterdam District Court
Cause list date: 21 June 2023

SUMMONS

Stichting Farma ter Verantwoording

Counsel
Mr. J.J.M. Sluijs
Mr R. Meijer

versus

AbbVie Inc,
AbbVie B.V.,
AbbVie Deutschland GmbH Co KG

Today, ... two thousand and twenty-three, at the request of **Stichting Farma ter Verantwoording (**hereinafter called: **FTV**), with its registered office in AMSTERDAM, electing domicile in this matter at Sarphatikade 14, (1017 WV) Amsterdam, at the offices of Hausfeld Advocaten, of which mr. R. Meijer is appointed as counsel, and also electing domicile at Carnegieplein 5, (2517 KJ) the Hague at the offices of Coupry, of which mr. J.J.M. Sluijs is appointed as counsel.

HAVE SUMMONED:

1) **AbbVie Inc.,** a company incorporated under the laws of the United States of America, having no known domicile or place of business in the Netherlands, with its registered office and principal place of business at (60064) **North Chicago, IL, United States of America,** at **1 North Waukegan Road**, thereunto depositing my writ at the office of the public prosecutor of the District Court of Amsterdam at **IJdok 163 in Amsterdam**, and leaving two copies of this writ and two translations thereof in the English language to

employed there

- With the request that this writ together with the English translation thereof, be served on the company incorporated under US law **AbbVie Inc**, located at 1 North Waukegan Road, North Chicago, IL 60064, United States of America, to be served in accordance with Articles 3 to 6 of the Convention on the Service Abroad of Judicial and Extrajudicial Documents in Civil or Commercial Matters of 15 November 1965 (the "Convention") and by service in accordance with the procedures laid down by the law of the Member State addressed for the service of documents drawn up in that country and addressed to persons residing there, requesting the (central) authority referred to in Article 6 of the Convention to return a copy of the document accompanied by the certificate provided for in Article 6 of the Convention.

- Furthermore, a copy of this writ and any document(s) specified below, together with the English translation thereof, shall forthwith be sent by me by registered letter to the address of **AbbVie Inc**, aforementioned.

- A proof of payment attached to this writ shows that in the meantime the costs of (USD) $95.00 payable in connection with the issuance of the writ have been transferred to the bank account of Process Forwarding International, Seattle, 633 Yesler Way, Seattle, WA 98104 (United States of America) into its account at Wells Fargo Bank, Seattle, Account No. 2007107119, Swift/IBAN Code: WFBIUS6S with the entry: 'Service of judgment to defendant AbbVie INC'.

- Further, in accordance with Article 10(b) of the Convention, I have today sent a copy of this writ without exhibits, with translation thereof into the English language, to a bailiff, officer or other competent person duly authorised in the State of California (United States of America), requesting that service thereof be made on AbbVie Inc. in accordance with the forms prescribed by the laws of the State of California (United States of America).

2) The private limited liability company **AbbVie B.V.**, with its registered office in **Amstelveen** and its principal place of business at (2132 JD) **Hoofddorp, the Netherlands,** at the address **Wegalaan 9**, at which address I have served my writ and legt a copy hereof with:

3) The company **AbbVie Deutschland GmbH Co. KG,** having no known domicile or place of business in the Netherlands but having its registered office and principal place of business at (65189) **Wiesbaden, Germany**, at **Mainzer Str. 81**,

I Bailiff, therefore, have today, pursuant to Article 56 of the Code of Civil Procedure and in my capacity as Transmitting Agent within the meaning of EC Regulation No. 23020/1784 of the Council of the European Union of 25 November 2020 (EU Service Regulation), served two copies of this writ of summons on the person entitled to receive payment. 23020/1784 of the Council of the European Union of 25 November 2020 (EU Service of Documents Regulation), sent two copies of this writ, with translation into English, to the receiving agency in Germany, namely:

Wiesbaden District Court
Mainzer Strasse 124
D-65189 Wiesbaden

Germany

that shipment has taken place by UPS courier with acknowledgement of receipt;

the application form referred to in the Council of European Union Regulation (EC) No 2020/1784 of 25 November 2020, completed in the German language.

I have requested the receiving agency to serve this document and the aforementioned copy on the appellant in the manner described under 5. in the form "request for service of documents", namely: service in accordance with the law of the requested State (Article 5.1. form);

IN ADDITION, FOR THE PURPOSE OF SERVING ABBVIE DEUTSCHLAND GMBH CO. KG, PRESENTED,

today a third copy accompanied by a translation into the English language will be sent by me, in accordance
with Section 56(3) of the Code of Civil Procedure and Section 18 of the said Regulation, by ups courier to the address of **ABBVIE DEUTSCHLAND GMBH CO. KG**, aforesaid, provided with the form l referred to in Article 12 of the Regulation, set out in Annex i to the Regulation, with the notice that the defendant may refuse to accept this document if it is not set out in or not accompanied by a translation as referred to in Article 12(1) of the Regulation, and that for this purpose the defendant may return either the said form l or a written statement to that effect to the receiving agency within the time limit set out in Article 12(3) of the Regulation;

hereinafter defendants 1 to 3 are collectively referred to as "**Defendants**" or "**AbbVie**",

IN ORDER TO:

appear on Wednesday the twenty-first of June two thousand and twenty-three (21/06/2023), in the morning at 10:00 a.m., not in person but represented by counsel, at the hearing of the District Court of Amsterdam, then and there to be held in the court building at the Parnassusweg 280 in (1076 AV) Amsterdam

WITH NOTIFICATION THAT:

(1) if a defendant fails to appoint counsel or fails to timely pay the court fee to be mentioned below, and the prescribed time limits and formalities have been complied with, the Court will default against such defendant and grant the claim described below, unless it appears to it to be unlawful or unfounded;

(2) if at least one of the Defendants appears in the proceedings and has timely paid the court fee, a single judgment shall be rendered between all parties, which shall be deemed to be an judgment in a defended action;

(3) on appearance in the proceedings, a court registry fee will be levied on each of the Defendants, payable within four weeks from the time of appearance;

(4) the amount of court fees is set out in the most recent annex to the Civil Registration Fees Act, which can be found, inter alia, on the website: www.kbvg.nl/griffierechtentabel;

(5) a person who is insolvent shall be charged a court fee for insolvent persons established by or under the Act, if he has produced at the time the court fee is charged:

   (i) a copy of the decision to grant an addition, as referred to in Article 29 of the Legal Aid Act, or if this is not possible due to circumstances that cannot reasonably be attributed to him, a copy of the application, as referred to in Article 24(2) of the Legal Aid Act, or
   (ii) a statement from the Board of the Legal Aid Board, as referred to in Article 7(3)(e) of the Legal Aid Act, showing that his income does not exceed the income referred to in the general order under Article 35(2) of that Act;

(6) of Defendants who appear before the same attorney and make identical submissions, a joint court fee is levied only once on the basis of Article 15 of the Civil Cases (Court Fees) Act;

(7) the Foundation is obliged, on pain of inadmissibility, to register this summons in the central register for collective actions as referred to in Article 3:305a(7) of the Civil Code;

(8) the effect of this entry is that - unless the Court declares the Foundation inadmissible forthwith - the Court will stay the case until a period of three months has elapsed from the entry in the Central Register;

(9) after the expiry of this time limit, the hearing of the case shall be continued at the stage it is at, unless pursuant to Article 1018d paragraph 2 of the Dutch Code of Civil Procedure, this time limit has been extended or another collective claim for the same event has been instituted; that the court date referred to in Article 128 paragraph 2 of the Dutch Code of Civil Procedure for the delivery of the statement of reply shall be set by the District Court at a period of six weeks after the time limit referred to in Article 1018c paragraph 3 of the Dutch Code of Civil Procedure has expired.

AND STATING THAT

the claimant is obliged, on pain of inadmissibility, to file the writ of summons at the court registry within two days after service of the summons and simultaneously make a note of the summons in the central register for collective actions as referred to in Article 3:305a paragraph 7 of the Civil Code (www.rechtspraak.nl/Registers/centraal-register-voor-collectieve-vorderingen). The annotation will be accompanied by a copy of the writ of summons;

IN ORDER TO:

hear claims on behalf of the claimant and conclude as follows:

Content

1 Introduction and crux of the matter

1.1 The present proceedings concern the fundamental question of the extent to which pharmaceutical companies, or a drug manufacturer like AbbVie, are completely free to set and maintain the prices of the drugs they offer or whether there are limits that must be respected under either written or unwritten law. FTV's position is that these limits exist and, moreover, that these limits have also been crossed by AbbVie.

1.2 Specifically, the case involves the drug Humira. This drug works for rheumatoid arthritis (rheumatism), but also for many other indications, giving it the nickname 'the Swiss army knife among medicines'.

1.3 The number of Dutch patients using Humira increased more than nine times between 2004 and 2018, and the price remained almost unchanged during that period when it enjoyed patent protection in the Netherlands (about EUR 460 per injection and about EUR 11,000 per patient per year). After the expiry of patent protection in the EU, the price decreased by about 80% on average. From 2009 to 2018, Humira was the drug with the highest annual sales in the Netherlands.

1.4 In FTV's view, AbbVie abused its dominant position during the patent period and the price of Humira was excessive. In doing so, FTV notes that the present proceedings do not seek monetary compensation for the damages suffered as a result of the excessive prices. FTV is concerned with the general interest that excessively expensive drugs should not lead to unnecessary displacement of care resulting in years of life in good health being lost in the Netherlands (this will be explained and substantiated in more detail later in this summons). It is this social problem that FTV stands up for in these proceedings.

1.5 Besides this social problem that concerns the health damage suffered collectively as a result of excessive drug prices resulting in the displacement of care, the issue also has a more purely property-law component. This consists, in short, of health insurers and hospitals having overpaid for drugs (in the present case, Humira).

1.6 There are thus two dimensions to the issue: on the one hand, the general interest of not unnecessarily displacing care resulting in the loss of life years in good health and, on the other, the problem of overpaying for medicines. Although these problems are closely related, FTV is primarily defending the general interest concerning the unnecessary displacement of care in these proceedings and not the aforementioned

property interest. It is in principle up to health insurers and/or hospitals to look after the latter interest.

1.7 FTV therefore seeks a declaratory judgment only. By doing so, it aims to set a precedent on the (un)legality of excessive pricing for a drug protected by patents. FTV is not concerned with limiting patent protection on drugs or minimizing the profit-seeking of drug manufacturers. Thus, FTV also does not detract from perhaps the most important objective of profit-seeking, namely: ensuring the continuity of the business. Which in the case of drug manufacturers also means that new drugs will and can always be brought to the market. AbbVie has also brought new drugs to the market. Only the number is small when set against the profit achieved on Humira after deducting costs and a reasonable profit for a drug manufacturer. FTV will show that AbbVie did not spend an excessive portion of the profit earned on Humira on drug development.

1.8 AbbVie drastically reduced the price for the drug after the patent period of Humira, so the issue of displacement related to the price of Humira has not arisen since then. FTV is bringing this case to establish wrongfulness in the so-called patent period and because the government is not (and has not) made any moves to take enforcement action against AbbVie over the excessive price AbbVie charged for Humira during that period.

1.9 In view of the above, FTV serves a social interest, because an unfairly (unlawfully) high price for medicines leads to avoidable displacement of legally insured basic care - that is: care that has not been/is not being provided, or has been/is being postponed, and has thereby caused health damage to the person who would otherwise have received that care or would have received it directly. Consequently, the (collective) interests of residents in the Netherlands who are or may be entitled to statutory basic care are thus promoted.

1.10 In this introductory chapter, FTV will first set out the gist of the case, which will then be further developed and explained in the chapters that follow.

A. The Dutch healthcare market

1.11 The healthcare market is a growth market par excellence. For every available healthcare service and/or healthcare product, there is a demand for care. Ageing, a growing population and medical progress contribute to this. Because the (potentially) available care supply and the expenditure on it are insufficiently limited by normal

market mechanisms,[1] the government plays an important role in this by determining, on the one hand, what belongs to the legally insured basic care package (so-called package management) and, on the other hand, by setting the collective expenditure (the available budget) for it. Both package management and the available budget are determined and controlled in a democratically legitimised process, thus safeguarding both elements as public interests.

1.12 The available budget consists of public funds and statutory and nominal health insurance premiums which, with the exception of nominal premiums,[2] are set at a level such that care is available to citizens for an 'affordable' premium. These collective expenditures are budgeted annually.

1.13 In 2021, collective total net healthcare spending amounted to EUR 76.2 billion, almost EUR 2 billion more than the previous year. EUR 48.1 billion was spent on care aimed at healing, so-called curative care (Zvw care), and EUR 26.1 billion was spent on long-term care (Wlz care).[3] Spending on intramural expensive medicines and extramural medicines amounted to over EUR 2.6 billion and 4.8 billion respectively in 2021,[4] almost half a billion more than was spent on first-line care and more than one-fourth of spending on second-line care. [5]

1.14 The largest expenditure items in the national budget for years have been social security and healthcare. Since 2006, the development of *real collective spending* has been highest in healthcare.[6]

1.15 To control collective spending on healthcare, various measures are being taken by the government and agreements on cost growth are being made between the Ministry of Health, Welfare and Sport and the sector. For instance, it has been agreed that costs under the Health Insurance Act may grow by EUR 8 billion in the period 2019-2022.

[1] When we become (seriously) ill, treatment is usually necessary. Because the cost of this for individuals is usually so high and unpredictable, the Netherlands has statutory health insurance. This fact (need for treatment and obligation to pay premiums for its cost) as well as the fact that often only one or a few healthcare treatments are available, means that 'voting with your feet' by switching to another treatment out of dissatisfaction with the price is not possible in practice. Market forces are complex and do not run directly between care user and provider.

[2] The nominal premium is the healthcare premium that everyone in the Netherlands aged 18 and over pays to their health insurer for basic insurance.

[3] Resp. https://www.staatvenz.nl/zorguitgaven-en-ontvangsten-zvw and https://www.staatvenz.nl/zorguitgaven-en-ontvangsten-wlz.

[4] https://www.staatvenz.nl/kerncijfers/geneesmiddelen-uitgaven-dure-geneesmiddelen-intramuraal and https://www.staatvenz.nl/kerncijfers/geneesmiddelen-uitgaven-extramuraal.

[5] https://www.staatvenz.nl/zorguitgaven-en-ontvangsten-zvw.

[6] Parliamentary Paper II 2017/18, 34 775, 1, p 62 and 63 and Parliamentary Paper II 2021/22, 35 925, 1, p 42.

1.16 In short, the care available annually is determined by what is collectively financially available for it.[7] The care available to Dutch society can therefore be imagined as a pie to be divided among those who provide care and/or offer their services and products to the care sector. The provision of care is thus essentially a distribution issue: what is reimbursed to one cannot be spent on another. This means that - if the demand for care exceeds the available care budget - there is, by definition, displacement of care.

B. Fair prices versus unnecessary displacement of care

1.17 Given the aforementioned distribution issue and the necessary limits to the care budget, displacement of care is to some extent unavoidable. However, this displacement should be limited as much as possible; avoidable displacement should be avoided. In FTV's view, this implies that the prices paid for the benefit of our care, and in particular to parties holding key positions in the healthcare system - such as drug manufacturers - must be justifiable. At least, if we consider access to legally insured basic care as a public interest. Only then can that 'public pie' be distributed fairly and equitably, avoid displacement of care as much as possible and maximise access to potentially available care. Drug manufacturers should also comply with competition law, including the prohibition of abuse of a position of economic power.

1.18 FTV defines *displacement of care by the price of a drug* as the care that, given that the demand for care is greater than the available budget, could have been provided for the excess over the fair price[8] of the drug in question.

C. Social duty of care for drug manufacturers

1.19 FTV is committed to fair, or at least non-unreasonable, drug prices. By an unreasonable price, FTV defines this as a price whose level cannot be explained on the basis of the efforts and/or investments made by the drug manufacturer and/or a price that - excluding a reasonable profit margin - is higher than necessary to recoup investments made within a reasonable period of time. Such prices promote displacement of care and unacceptably impede access to other care.

1.20 To avoid misunderstanding: FTV does not herewith argue the application of the *iustum-pretium* doctrine, but it does argue that drug manufacturers may in

[7] The government determines the size of what is collectively financially available, or what the collective burden of care is.

[8] WHO's definition is: "A fair price is one that is affordable for health systems and patients and that at the same time provides sufficient market incentive for industry to invest in innovation and the production of medicines."

circumstances be subject to a duty of care which means that the price that can be asked for drugs is not unlimited.

1.21 Drug manufacturers play a crucial role in the health system. After all, they ensure the development and availability of medicines. This makes the pharmaceutical industry an indispensable link in the healthcare system. In doing so, there should of course be reasonable remuneration for the development and production of (new) medicines, so that the investments made - with their inherent risks - can be recouped. In that context, it is relevant that drug manufacturers in principle enjoy patent protection for the drugs they develop so that they enjoy exclusivity during the patent period.

1.22 The level of price that drug manufacturers can charge for their products is not imposed on them by the government. In principle, the price for medicines is established in a process of price negotiations. While these price negotiations take place within certain legal and financial frameworks as determined by the government (see section 3.2), in essence, drug manufacturers are free to set their own prices for the drugs. At first sight, this is also the normal state of affairs in a free-market economy. However, on closer inspection and taking into account the social issues surrounding unsustainable healthcare costs, FTV believes this is more nuanced.

1.23 Given their key position in the healthcare market and the dominant position they may enjoy as a result of patented drugs, drug manufacturers have a special position in society. This also entails responsibilities which, according to FTV, at least consist of ensuring that drug manufacturers should not in all circumstances be guided purely by shareholder interests (read: mere profit motives), but should also consider the adverse consequences of their actions.

1.24 This applies in particular in the situation where there are extremely high profit margins - which cannot be explained by the efforts and/or investments made - while, as a result of the high price charged for the medicine in question, foreseeable health damage occurs as a result of displacement of care. In that situation, according to FTV, there is a breach of a social duty of care in which international standards also play a role in the fulfilment of this duty of care (see sections 4.2.2 and 4.2.3).

D. Unlawful conduct of AbbVie with Humira

1.25 Defendants (hereinafter jointly and singularly **AbbVie**) have been selling Humira® (adalimumab) (hereinafter **Humira**) on the Dutch market since 2004. Between 2004 and the end of 2018, AbbVie offered Humira on the Dutch market under patent

protection. After the patent protection expired, AbbVie offered Humira at a significantly lower price: in the EU, the price fell by around 80% on average.

1.26 FTV is of the opinion that AbbVie acted unlawfully in the period 2004 to 2018 because it requested and received a price for Humira at that time, thereby promoting the displacement of legally insured basic care and, consequently, unacceptably impeding access to legally insured basic care, except for the care for which Humira was used.

1.27 Assessed in the light of the facts and circumstances and internationally widely accepted standards relating to corporate responsibility[9] and human rights, AbbVie thus acted in breach of an unwritten standard of care applicable to it, as referred to in Section 6:162 of the Dutch Civil Code. FTV is also of the opinion that AbbVie abused its dominant economic position in the relevant period with the pricing of Humira and therefore acted in breach of Article 24 of the Competition Act (hereafter: **Mw**) and/or Article 102 of the Treaty on the Functioning of the European Union (hereafter: **TFEU**).

1.28 Legal action against a drug manufacturer because of the price it charges (or has charged) for a drug is unusual, but not new.[10] Usually, however, the discussion focuses only on whether there has been an abuse of an economic dominant position and thus unlawful conduct. Although FTV's claim in the present proceedings is also partly based on excessive pricing in violation of the prohibition on abuse of a dominant economic position, FTV's primary contention is that a drug manufacturer - in this case AbbVie - has a social (enforceable) duty of care, which it breached in this case.

1.29 FTV will substantiate that *access to care* and *right to life* are fundamental rights (or human rights) that AbbVie must respect, or at least which fundamental rights should not be compromised as a result of AbbVie's actions. In this regard, FTV will substantiate that AbbVie charged a price for Humira during the patent period that was unlawful given the circumstances of the case.

1.30 In this context, FTV reiterates that it does not dispute that it is in principle at the discretion of a company to set prices for its products. Nor does FTV dispute that companies like AbbVie are allowed to generate profits. FTV also recognises that

[9] In the context of (international) corporate social responsibility is also often referred to as corporate social responsibility. The OECD Guidelines for Multinational Enterprises, which are authoritative in relation to international corporate social responsibility, generally speaks of corporate responsibility.

[10] For example, by decision of 1 July 2021 (case number ACM/20/041239), the ACM fined manufacturer Leadiant over EUR 19.5 million for abusing its economic dominance by charging an excessive price for its drug CDCA-Leadiant. Lawsuits are also filed against drug manufacturers that perpetuate their (high) price by abusing their market or economic position or by cartel agreements, such as cases on evergreening and pay for delay.

research and development costs for drug development are generally substantial and should be taken into account when justifying the pricing of the drug in question.

1.31 However, even taking into account the aforementioned perspectives, there is no justification for the price AbbVie charged for Humira during the patent period. As will be explained, AbbVie's research and development costs have been marginal compared to the sales and profits generated by AbbVie with Humira. The much-heard argument that high prices are necessary for the sake of drug (further) development therefore does not apply to AbbVie. As AbbVie occupies a key position in society, it also has a special responsibility. This responsibility is also determined by fundamental rights, such as the right of access to care, for which AbbVie has an independent obligation of compliance.

1.32 AbbVie failed to recognise this particular responsibility, or recognised it insufficiently, by pricing Humira solely on the shareholder interest of profit optimisation without considering its negative consequences for the fundamental right to access to care.

1.33 In doing so, AbbVie acted in breach of its social duty of care and also in breach of competition law by abusing its dominant economic position due to excessive prices (Article 24 Mw and/or Article 102 TFEU). AbbVie is also liable for this competition law infringement.

E. Statement for justice

1.34 In these proceedings, FTV seeks a declaratory judgment that AbbVie acted unlawfully. It is - as stated above - expressly not seeking damages. For a proper understanding of this case, it is important to distinguish between the health damage caused by AbbVie's conduct and the pure pecuniary damage resulting from this conduct. Health damage refers to damage caused by non-provided or delayed care. Health damage can be expressed in the number of life years lost due to the unnecessary displacement of care by AbbVie's actions. The fact that the drug Humira also produced health benefit does not detract from the (foreseeable) health damage caused. Any lower price for Humira, that would be assessed as not unfair by legal standards, would have generated the same health benefit, unless AbbVie had chosen not to offer the drug on the Dutch market.

1.35 Pure financial loss mainly concerns the damage consisting of the excessive price paid for Humira. In the Dutch healthcare system, these costs are primarily paid by health insurers. While it is obviously problematic that too much was paid for Humira - and, as

mentioned above, also closely related to the issue of unnecessary (and thus unlawful) displacement and lost life years - this pure financial loss is not what FTV is primarily focusing on in these proceedings as this is primarily up to the health insurers themselves to address.

1.36 Thus, what FTV is defending in these proceedings is the health damage caused by AbbVie's actions in charging excessive prices for the drug Humira, with the foreseeable consequence of unnecessary displacement of care. Commissioned by FTV, healthcare economists from Zorgvuldig Advies calculated that this health damage expressed in lost life years amounts to 7,200 to 16,300 healthy life years lost (in the period when Humira enjoyed patent protection in the Netherlands). This is damage suffered by Dutch society as a collective.

1.37 In these proceedings, FTV seeks a declaratory judgment to the effect that AbbVie acted unlawfully for (primarily) breaching its duty of care and (alternatively) abusing its dominant economic position by charging excessive prices.

1.38 With these proceedings, FTV aims to clarify the (un)lawfulness of pricing for a medicine that is protected by patents. In doing so, FTV serves a social interest, because an unfairly (unlawfully) high price for medicines leads to avoidable displacement of legally insured basic care - i.e.: care that is not/will not be provided, or is/will be postponed, and therefore has caused health damage to the person who would otherwise have received that care or would have received it directly. Consequently, the (collective) interests of residents in the Netherlands who are or may be entitled to statutory basic care are thus safeguarded.

1.39 FTV requests the court, taking into account all that will be stated and reasoned in this summons, to award what FTV claims from AbbVie.

2 Parties addressed

2.1 AbbVie Inc.

2.1 AbbVie is one of the largest biopharmaceutical companies in the world. AbbVie Inc is the parent company of AbbVie headquartered in Chicago, United States of America.

2.2 AbbVie B.V.

2.2 AbbVie B.V. is an (indirect) subsidiary of AbbVie Inc. According to the trade register, AbbVie B.V. is engaged in the business of buying, selling, importing, exporting, manufacturing, distributing, and utilising pharmaceutical, hospital, nutritional, chemical, diagnostic medicine and related products.

2.3 AbbVie Deutschland GmbH Co. KG

2.3 AbbVie Deutschland GmbH Co. KG is an (indirect) subsidiary of AbbVie Inc and is the brand owner of Humira in Europe.

3 Facts relating to the issues at stake in this case

3.1 Introduction

3.1 The cost of all healthcare has increased significantly in recent years. Reasons for this include an ageing population and rapid medical-technological developments.[11] To prevent unrestrained collective spending on healthcare, it is estimated and budgeted annually. These are set in a democratically legitimised process; the financial resources available for healthcare are thus safeguarded as a public good.

3.2 The issue now, is this: AbbVie, during the period it offered the patented Humira on the Dutch market, demanded and received an excessive price for this drug, thereby promoting the displacement of legally insured basic care and, consequently, unacceptably impeded access to legally insured basic care, except for the care for which Humira was used.

3.3 That a displacement effect like the above can also occur as a consequence of increases in other cost items in healthcare does not detract from what is said in these

[11] M. Buijsen, *Further erosion of the healthcare system threatens*, NJB 2009/1605, para 32.

proceedings about displacement. All the more so because the prices of medicines cannot be regulated in a way that the supply of care by healthcare providers can be regulated. Indeed, a drug manufacturer is not classified as a healthcare provider in the Dutch healthcare system, but as an regular company (see section 3.2.5). As a result, the products and services they offer fall outside the main market regulation rules of the Dutch healthcare system.

3.4 To understand how AbbVie's actions led to these consequences, this chapter first discusses the design of the Dutch healthcare system (section 3.2), to the extent relevant to the assessment of this case. It then discusses the history and success of Humira (section 3.3). It then turns to AbbVie as a Big Pharma entrepreneur in the in Dutch healthcare system (section 3.4).

3.2 The Dutch healthcare system

3.2.1 LEGAL FRAMEWORK

3.5 The Dutch healthcare system has two system laws that are important for medicine care: the Healthcare Insurance Act (hereinafter: **Zvw**) and the Long-term Care Act (hereinafter: **Wlz**).[12] Both laws ensure the so-called basic package; the minimum but high-quality standard of healthcare that should be available to every resident in the Netherlands.

3.6 The Zvw covers curative care (care aimed at healing): the care provided by medical specialists, general practitioners and hospitals, medicines and paramedical care. Only those forms of care for which insurance is necessary according to the government are covered by insurance coverage. Article 10 of the Zvw specifies the risk to be insured functionally as the need for, among other things: medical care, oral care, pharmaceutical care, auxiliary care, nursing and care. The insurance coverage is further specified in the Health Insurance Decree.[13] This states (sometimes explicitly and sometimes implicitly) in which cases the form of care concerned is reimbursed. The content and extent of the insured care is partly determined by the state of science and practice and, in the absence of such a criterion, by what the profession considers adequate and responsible care.[14] This criterion is referred to as 'state of science and practice' for short.

[12] K. Wessels & I.D. van Troostwijk, *Zó werkt de geneesmiddelenzorg,* s.p.: De Argumentenfabriek 2019, pp. 77-79.
[13] Decree of 28 June 2005, Stb. 2005, 389, p. 35.
[14] Article 2.1(2) Health Insurance Decree.

3.7 The Wlz covers long-term care and support for the elderly and people with a mental, sensory, physical or psychological disability.[15] Article 3.1.1 Wlz defines the insured services, which include: stay in an institution, personal care, guidance and nursing. As with the Zvw, some forms of care are only reimbursed in certain cases.

3.8 Both the Zvw and the Wlz have two performance forms of care: care in kind and restitution. With an in-kind policy, the insurer chooses the healthcare provider the insured person can go to. With a restitution policy, the insured is free to choose which healthcare provider to use.

3.2.2 FINANCING OF MEDICINES

3.9 The Ministry of Health, Welfare and Sport's Care Expenditure Ceiling budgets the maximum annual level of expenditure for the entire care sector for the cabinet period.[16] The healthcare expenditure under the Healthcare Expenditure Ceiling is composed of the estimated premium-financed expenditure under the Zvw and Wlz and the budget-financed healthcare expenditure (e.g. Wmo Protected Housing).[17] The level of the expenditure ceiling for the year 2023 was EUR 89.4 billion. Of this, EUR 55.6 billion was reserved for the Health Insurance Act and EUR 31.3 billion was reserved for the Wlz. EUR 4.794 billion was set aside for pharmacy care.[18]

3.10 How do drug prices - and their reimbursement - come about? To get a picture of this, it is first necessary to distinguish between extramural and intramural medicines.

3.11 Extramural medicines are medicines that are dispensed in pharmacies (community pharmacies or outpatient pharmacies) and may or may not be reimbursed as a separate performance via the statutory health insurance system. In addition, the health insurer has the option of applying a so-called preference policy with regard to active ingredients that are eligible for reimbursement under the Health Insurance Act. In that case, the health insurer can choose which versions of medicines from the basic package are eligible for reimbursement. The insured is then not entitled to reimbursement of a medicine if it is not designated by the insurer, unless it is medically irresponsible to use the designated medicine.[19]

[15] Parliamentary Papers II 2013/14, 33 891, 3, p. 2.
[16] K. Wessels & I.D. van Troostwijk, *Zó werkt de geneesmiddelenzorg,* s.p.: De Argumentenfabriek 2019, p. 111.
[17] Parliamentary Papers II 2022/23, 36 200 XVI, no. 2, p. 165.
[18] Parliamentary Papers II 2022/23, 36 200 XVI, no 2, p. 205 (Adoption of the budget statement of the Ministry of Health, Welfare and Sport for the year 2023). See www.gipdatabank.nl for annual total expenditure on medicines.
[19] Section 2.8 paragraph 1 paragraph 3 and paragraph 4 Health Insurance Decree.

3.12 Intramural medicines are medicines used in specialist medical care and are usually dispensed to patients in hospitals. Intramural medicines fall within the overall financing of the institutions, which means that the institutions bear financial risk when purchasing and dispensing these medicines and that this also affects the total care that the institution can offer and that it contracts with the health insurer. Hospitals negotiate contracts with health insurers on an annual basis where, in practice, they do not add up individual products and prices, but often agree on a contract sum or budget ceiling. This means that spending on intramural drugs (with the exception of 'add-on' drugs, see below) directly reduces the budget elsewhere in the hospital. Hospitals can try to exert some influence on this by adopting a preference policy on which drugs to prescribe, for example to prescribe biosimilars instead of original biologicals.[20]

3.13 Having said this, the starting point is that the drug manufacturer itself determines the price at which it wants to market the drug (the so-called pharmacy purchasing price, AIP). In doing so, he focuses, as an entrepreneur, on numerous factors, including the profit he wants to make and the costs incurred (including failed R&D projects). However, the asking price must not exceed the maximum price set by the Minister of Health, Welfare and Sport under the Medicines Pricing Act (**Wgp**).[21] This is established by looking at the amount charged for the same or similar medicine in the reference countries Belgium, France, Norway and the United Kingdom. The average of these is the maximum price charged in the Netherlands.[22] Note that the level of the maximum price is therefore not set by the government, but is determined by the average market price, i.e. the price at which the manufacturer(s) puts the medicine on the market. In the case of patented drugs, the manufacturer has full influence on the level of this maximum price, as it determines the asking price, the timing and the order of market introduction in the reference countries. [23]

[20] Biosimilars are 'copies', at least alternative biologics with no clinically meaningful differences from the original reference product - the biological (originator) whose patent has expired.

[21] K. Wessels & I.D. van Troostwijk, *Zó werkt de geneesmiddelenzorg,* s.p.: De Argumentenfabriek 2019, pp. 119-120.

[22] Act of 4 December 2019 amending the Medicines Pricing Act in connection with an adjustment of the reference countries, Official Gazette 2019, 479.

[23] See also Commission 10 February 2021, Case AT.40394 - Aspen. Drug manufacturer Aspen pursued the strategy of implementing price increases first in Germany so that other Member States used that (high) list price as the reference price. Pt. 98: "Aspen started the price increase process in Germany because, under German law, Aspen had the freedom to unilaterally set new, increased list prices for the Products. A statutory claw-back applied in Germany with the aim of preventing increases of real net prices in Germany. However, these regulatory measures did not prevent Aspen from using the increased German list prices in its price increase applications in other Member States. As [Aspen employee] pointed out, the *"beauty about this is that the official German price is significantly (sic) higher and can be used as reference in many other countries at this level."* In 2013, 17 Member States actually used the German official list price as reference in their external reference pricing system."

3.14 If extramural medicines are involved and the maximum price is not exceeded, the Netherlands Healthcare Institute (hereafter: **ZIN**) almost always advises positively on inclusion in the basic package, making the medicine eligible for reimbursement under the Zvw or Wlz.

3.15 In principle, intramural medicines flow into the basic package as soon as the 'state of science and practice' criterion is met and the maximum price under the Wgp is not exceeded. Intramural medicines that cost more than an average of EUR 1,000 per patient per year qualify for so-called 'add-on' status. Such medicines are charged by the hospital separately from the treatment (DOT)[24] to the insured or the insured's health insurer. To obtain this status and the amount that may be charged for reimbursement, a health insurer and a hospital must jointly request permission from the NZa, after which the add-on medicine becomes available to all Dutch insured persons.

3.16 All new (intramural and extramural) drugs are initially assessed by ZIN for effectiveness; this determines whether a drug is eligible for reimbursement from the basic health insurance package. ZIN then advises on the cost-effectiveness of the medicine. If this raises questions, it usually advises the Minister of VWS to negotiate a lower price.

3.17 The standard used by ZIN for cost-effectiveness is based, on the one hand, on the therapeutic added value of the medicine and, on the other hand, on the reference value used in the Netherlands of one life year gained in good health (**QALY**: Quality Adjusted Life Year), i.e. a maximum of EUR 80,000. This reference value is relatively high, by the way. There is research that estimates the average price of one QALY in all Dutch care at less than EUR 20,000. And for cardiovascular hospital care, it is estimated at EUR 41,000. This means, according to the Court of Audit in 2020, that reimbursing (new) care at a reference value of EUR 80,000 per QALY increases the risk of crowding out other care.[25]

3.18 New (intramural) medicines with an expected high macro cost impact per year, whether or not in combination with high costs per treatment, do not automatically flow into the basic health insurance package. The macro cost impact refers to the expected total annual cost of dispensing the medicine for treatment. These costs should not

[24] DOT stands for DBC on the road to transparency. A DBC, diagnosis treatment combination, is the total care process from diagnosis to treatment (if any) and its declaration. DOT, DBCs on the road to transparency, is the process to improve the hospital billing system, which has been in place since January 2012.

[25] Netherlands Court of Audit, *Horse remedy or emergency bandage, Results of drug price negotiations*, The Hague: 2020, p. 12 and sources cited therein. See **Production 1**.

exceed EUR 40 million. The expected cost per treatment may not exceed EUR 50,000. Cost per treatment refers to the expected cost per treatment of a patient per year. This cap only applies if the macro cost impact is EUR 10 million or more.[26]

3.19 The minister of VWS can exempt medicines that exceed the above thresholds from the influx and place them in the lock-in.[27] Patients will then not be reimbursed for the medicine until there is an agreement between the minister and the medicine manufacturer on the price. If the minister and the drug manufacturer have agreed on a price, the drug in question will be reimbursed in the basic package, but in such a way that the negotiated price, due to its supposed business confidentiality, will not be known to either the hospital or the health insurer.

3.20 Along the ways described above, the aim is to curb drug expenditure to some extent. How much the patient ultimately has to pay for the medicine himself depends on several factors, such as: the drug manufacturer's pricing, the insured package, the reimbursement limit, the health insurer's preference policy, the amount of the deductible and the form of performance (in-kind / reimbursement) the insured has chosen.

3.2.3 Role of the government

3.21 In the healthcare system, the government performs the important role of 'package manager'. In this capacity, it determines which care is included in the basic package. Furthermore, given the size and fluctuations of the basic package, the government has the important task of monitoring and maintaining the financial balance of the entire healthcare system.[28]

3.22 In the case of effective medicines that lend themselves to admission to the basic package, it follows from the above, the government can only rudimentarily influence the price of medicines. This is because drug manufacturers are not classified as healthcare providers within the meaning of the Wmg and for this reason fall outside the main market regulation rules of the Dutch healthcare system (see below section 3.2.5)

[26] Decree of 23 April 2018, amending the Healthcare Insurance Decree in connection with rules for the admission of medicines to the basic package, Stb. 2018, 131, p. 13-14.
[27] Decree of 23 April 2018, amending the Healthcare Insurance Decree in connection with rules for the admission of medicines to the basic package, Stb. 2018, 131, p. 7-8.
[28] For a historical overview of (government) measures to control drug costs, see: K.-P. Companje et. al, *Fifty years of cost control in healthcare. Part II: 1995-2022*, Sdu: 2021.

3.23 However, the government can influence cost increases of drug care through a 'budget right'. This is because in the Healthcare Expenditure Ceiling (formerly: the Healthcare Budgetary Framework), the government sets the annually available 'budget' for healthcare during the cabinet period.[29] And the so-called macro management instrument sets specific expenditure ceilings at the national level. The NZa sets macro budgetary frameworks for sectors designated by the Minister of Health, Welfare and Sport. If the minister finds that the framework has been exceeded, he can determine that the excess is recovered from the healthcare providers.[30] In practice, the macro management instrument serves mainly as a means of pressure for industry associations of health insurers and healthcare providers to conclude healthcare agreements aimed at curbing collective expenditure growth.[31]

3.2.4 ROLE OF THE INSURER

3.24 The health insurer acts as a director of care in the basic package. In that role, it has a number of freedoms that allow it to exert a certain influence on the price of medicines. For instance, as mentioned above, it can pursue a preference policy: with regard to extramural medicines designated by the Minister of Health, Welfare and Sport, the health insurer may choose which versions of medicines to include in the package it insures so that only these are eligible for reimbursement.[32] In addition, the health insurer chooses with which healthcare provider it wants to enter into a contract and at what price it wants to purchase the care.[33]

3.25 In addition to freedoms, restrictions apply to the health insurer. The restrictions are laid down in the Wmg and are not relevant for the assessment of the present case. Among other things, the health insurer must comply with obligations relating to tariff regulation,[34] the payment system[35] and product information.[36]

3.2.5 DRUG MANUFACTURER IS NOT A HEALTHCARE PROVIDER

3.26 In Article 1, paragraph 1 under c (1), the Wmg defines 'care provider' as the natural person or legal person who provides care professionally or commercially. In brief, the

[29] H.J.J. Leenen et al, *Handboek gezondheidsrecht,* The Hague: Boom Juridisch 2020, p. 813.
[30] Parliamentary Papers II 2009/10, 32 393, 3, p. 30.
[31] H.J.J. Leenen et al, *Handboek* gezondheidsrecht*,* The Hague: Boom Juridisch 2020, p. 873.
[32] K. Wessels & I.D. van Troostwijk, *Zó werkt de geneesmiddelenzorg,* s.p.: De Argumentenfabriek 2019, p. 86.
[33] K. Wessels & I.D. van Troostwijk, *Zó werkt de geneesmiddelenzorg,* s.p.: De Argumentenfabriek 2019, p. 122.
[34] Article 35(3) Wmg.
[35] Article 37 Wmg.
[36] Article 40 Wmg.

term 'care' refers to care within the meaning of the Zvw and Wlz (i.e. basic package care) as well as care in the so-called 'third compartment' (supplementary insurable care) insofar as it is provided by a professional within the meaning of Section 3 of the Individual Healthcare Professions Act.[37] Like the healthcare insurer, the healthcare provider must comply with the obligations of the Wmg with regard to (among other things) tariff regulation,[38] the payment system,[39] and consumer information.[40]

3.27 However, a drug manufacturer does not provide healthcare within the meaning of the Wmg and does not fall under the concept of healthcare provider as referred to in that Act. As a result, the products and services they offer fall outside the main market regulation rules of the Dutch healthcare system. At the same time, it should be noted that drug manufacturers fulfil an important role in our healthcare system: after all, their products cure and/or help patients. This fact means that drug manufacturers can participate in the healthcare system as regular companies acting on the basis of business and market economy principles.

3.28 Because drug manufacturers are not parties in the regulated triangle (patient/care provider/health insurer) of the healthcare system, government influence is only *indirectly* felt by them, namely as the possible new result of negotiations between healthcare provider and/or health insurer on the one hand and the manufacturer on the other. However, it should be borne in mind that, in principle, a drug manufacturer may continue to charge the price for its medicines at which it obtained admission to the basic package, and that, for prudential reasons, it may choose to stop marketing its medicines on the Dutch market. This usually gives drug manufacturers a strong negotiating position.

3.29 The bargaining power of drug manufacturers is often strengthened by the various exclusivity rights the manufacturer has established over its drugs, such as patent rights and data exclusivity rights. These rights assure the manufacturer the long-standing exclusive right to market the drug. The fact that, in practice, drug manufacturers also give discounts on their products that healthcare providers buy from them does not affect their strong legal and economic bargaining power.

3.2.6 CONCLUSION

[37] Article 1(1)(b) Wmg and MoT, Parliamentary Papers II 2004/05, 30 186, 3, p. 50-51.
[38] Article 35(2) Wmg.
[39] Article 37 Wmg.
[40] Article 38 Wmg.

3.30 The cost of all health care has increased substantially in recent years. To prevent unrestrained collective spending on health care, it is budgeted and set annually. These are set in a democratically legitimised process; the financial resources available for healthcare are thus safeguarded as a public good.

3.31 The amount of the collective expenditure ceiling in favour of legally insured basic care for the year 2021 was EUR 77.1 billion. Of this, EUR 49.7 billion was for curative care, EUR 24.9 billion for long-term care and EUR 4.765 billion for drug care.

3.32 The starting point is that a drug manufacturer itself determines the price at which it wants to market the drug (the so-called pharmacy purchasing price, AIP). However, that asking price may not exceed the maximum price set by the Minister of Health. This maximum price is related and is established by looking at the amount charged for the same or similar medicine in the reference countries Belgium, France, Norway and the United Kingdom. The average of these is the maximum price charged in the Netherlands. The level of the maximum price is therefore not set by the government, but is determined by the average market price, i.e. the price at which the manufacturer(s) puts the medicine on the market. In the case of patented drugs, the manufacturer has full influence on the level of this maximum price, as it determines the asking price, the time and the order of market introduction in the reference countries.

3.33 New (especially intramural) drugs with an expected high macro cost impact per year, whether or not combined with high costs per treatment, do not automatically flow into the basic package. This situation does not arise in the present Humira case.

3.34 Drug manufacturers are not parties in the regulated triangle (patient/care provider/health insurer) of the healthcare system. As a result, government influence on a drug manufacturer's 'pricing policy' is felt only *indirectly*, namely as the possible outcome of negotiations between healthcare provider and/or health insurer on the one hand and the manufacturer on the other. However, it should be borne in mind that, in principle, a drug manufacturer may continue to charge the price for its medicines at which it obtained admission to the basic package, and that, for prudential reasons, it may choose to stop marketing its medicines on the Dutch market. This usually gives drug manufacturers a strong negotiating position, which is further strengthened if a manufacturer has been able to establish various exclusivity rights on its drug, such as patent rights and data exclusivity rights. These rights assure the manufacturer the long-standing exclusive right to market the drug. The fact that drug manufacturers in

practice also give discounts on their products that healthcare providers buy from them does not affect their strong legal and economic bargaining power.

3.35 The government/state can only rudimentarily influence the price of drugs and has no effective tool to force a manufacturer to charge a lower price for its patented drugs for which there are no or few substitutes.

3.3 Blockbuster Humira

3.3. 1INTRODUCTION

3.36 The brand name Humira (Human Monoclonal antibody In Rheumatoid Arthritis) stands for the first human monoclonal antibody Adalimumab. This makes Adalimumab an early example of a biopharmaceutical drug, based on a biological source. It is also known as a 'biological'. Adalimumab is a product derived from white blood cells; it works against an overactive immune system. It was first developed as a treatment for sepsis, but this was abandoned. Adalimumab was then developed for rheumatoid arthritis (rheumatism), but also works for many other indications, earning it the nickname 'the Swiss army knife among medicines'.

3.37 The number of Dutch patients using Humira increased more than nine times between 2004 and 2018, and the price remained almost unchanged during the period it enjoyed patent protection in the Netherlands (around EUR 460 per injection and about EUR 11,000 per patient per year). After the expiry of patent protection in the EU, the price fell about 80% on average. From 2009 to 2018, Humira was the drug with the highest annual sales in the Netherlands.

3.38 In 2012, a change in the Dutch healthcare system was introduced that made hospitals financially responsible for purchasing expensive drugs, such as Humira.[41] Since then, these drugs could only be dispensed by hospital pharmacies and were thus paid for with the hospital budget.

3.3.2 TIMELINE AND RETURNS

[41] 'Expensive medicines' here means and follows the definition as used by the ZIN (GIPdatabank.nl), which read: Extramural expensive medicines are medicines for which the reimbursement exceeds EUR 15 million and the average reimbursement per user of this medicine exceeds EUR 1,000. Intramural expensive medicines are medicines for which an add-on performance with a maximum fee has been set by the NZa.

3.39 In 2002, AbbVie, or at least its legal predecessor Abbott Laboratories (**Abbott**), acquired Knoll Pharmaceuticals (**Knoll**) from BASF Pharma for US$6.9 billion in cash.[42]

3.40 An important part of the acquisition was obtaining the monoclonal antibody, Adalimumab, then referred to as D2E7. Research with this antibody was in its final phase and the clinical trial results were promising. Abbott CEO Miles D. White said of the acquisition at the time:

> "Importantly, the acquisition will also bring leading monoclonal antibody technology, and a strong research presence in immunology with a high-potential product, D2E7, for rheumatoid arthritis."[43]

3.41 Adalimumab was discovered as a result of a collaboration between BASF Bioresearch Corporation and Cambridge Antibody Technology, which was a collaboration of the government (UK) funded Medical Research Council and three academics.[44]

3.42 In summary, the successful development of Humira, the trade name of Adalimumab (a so-called TNF-alpha inhibitor) proceeded as follows.[45]

- 1998: Preliminary results of early clinical trials (phase 1) with the fully human anti-TNFα monoclonal antibody D2E7.
- 2001 (June): One of the results in a double-blind, placebo-controlled clinical trial with 271 patients suffering from active rheumatoid arthritis is that 50% of the patients show an improvement in the American College of Rheumatology (ACR) score.
- 2002: Adalimumab results from five separate studies show that it is effective in reducing signs and symptoms of rheumatoid arthritis. In these studies, adalimumab had a rapid onset of action and sustained efficacy. Moreover, Adalimumab was safe and effective when given alone or in combination with Methotrexate as a subcutaneous injection.
- 2002 (Dec 31): Humira approved by the US Food and Drug Administration (FDA) for the treatment of rheumatoid arthritis.
- 2003: Market launch in the US for treatment of rheumatoid arthritis and continuation of clinical trials for additional indications.

[42] Knoll's projected annual revenue at the time of the purchase was over $2 billion.
[43] Forbes, Focus On The Forbes 500s: Abbott Buys Knoll, 15 December 2000.
[44] Dr David Chiswell, (Nobel laureate) Sir Greg Winter and Dr John McCafferty.
[45] Humira stands for: human monoclonal antibody in rheumatoid arthritis.

- 2005: Market launch for treatment of psoriatic arthritis and 'early rheumatoid arthritis'. Annual sales of Humira exceed US$1 billion.
- 2006: Application for approval for treatment of Crohn's disease and market launch for ankylosing spondylitis (AS). Introduction of the Humira injection pen. Annual sales of Humira exceed US$2 billion.
- 2007: Market launch for treatment of Crohn's disease in the US, and application for global approval for treatment of plaque psoriasis. Annual sales of Humira exceed US$3 billion.
- 2008: Market launch for the treatment of plaque psoriasis.
- 2009: Five-year data show that initial use of Humira with Methotrexate can prevent further joint damage in patients with early rheumatoid arthritis

3.43 The above leaves no doubt that AbbVie had bought a goose with golden eggs by acquiring Knoll. In seven years, Humira was registered and marketed for five disease indications. In 2005, Humira's annual (net) sales were already more than US$1 billion and those (net) sales increased steadily every year: in 2015, net sales were already more than US$14 billion and in 2018 almost US$20 billion. In 2019, net sales fell slightly, but climbed back to US$19.8 billion in 2020.[46]

3.44 Some nuance on the success of Humira, FTV would also like to make at this point. When the drug was introduced to the market in 2003, it could not have been predicted with 100% certainty that its success would be so large in scale. Indeed, at that time there were already two other biological products on the market, which potentially competed with Humira. These were Remicade (from manufacturer MSD) which had been on the Dutch market since 1999, and Enbrel (from Manufacturer Pfizer) which had been on offer since 2001.

3.45 Remicade had the disadvantage that it had to be administered by infusion ('intravenous') and thus in a hospital. This did not apply to Enbrel and Humira, which has to be administered subcutaneously ('subcutaneously') and patients can do it themselves (at home) using a disposable injection pen.

3.46 Humira had the advantage over Enbrel that it could usually be administered every other week instead of weekly. The prices of Humira and Enbrel were about the same per administration per year: both manufacturers did not compete on price in the Dutch market.

[46] https://www.statista.com/statistics/318206/revenue-of-humira/. See also AbbVie website for its financials: https://investors.abbvie.com/financial-releases.

3.47 While Pfizer had a two-year 'head start' with Enbrel, AbbVie managed to get more indications approved for Humira than Pfizer did for Enbrel. Both drugs can be used in rheumatoid arthritis, juvenile idiopathic arthritis (JIA), psoriatic arthritis (PsA), ankylosing spondylitis (AS) and plaque psoriasis. In addition, Humira can still be used in Crohn's bowel disease, ulcerative colitis (UC), the skin disease hidradenitis suppurativa, and the eye disease uveitis. Partly for this reason, Humira sales in the Netherlands outpaced Enbrel in 2009. In 2011, Enbrel reached its peak sales of EUR 160 million; Humira peaked at EUR 223 million in 2014.

3.48 After the patents expired, manufacturers faced biosimilar competition. For MSD (Remicade), that moment came in 2015, for Pfizer (Enbrel) in 2016, and for AbbVie (Humira) in October 2018.

3.49 Therapeutic competitors Cimzia (UCB) and Simponi (Janssen), which entered the market in 2009, captured little market share. In 2016, these drugs were used by only 1,157 and 2,071 patients, respectively. By comparison, in 2016 Remicade was used by 11,578 patients, Enbrel by 15,469 and Humira by 19,763 patients. Enbrel remained at this number while the use of Humira and competing biosimilars still increased to 28,091 patients in 2020.

3.4 AbbVie as Big Pharma company in Dutch healthcare system

3.4.1 INTRODUCTION

3.50 AbbVie is an international drug manufacturer; one of the largest biopharmaceutical companies in the world, founded in 2013.[47] AbbVie is headquartered in Chicago. In the Netherlands, a total of 330 people work in Hoofddorp and Zwolle. From the Zwolle facility, AbbVie handles distribution (and 'supply chain planning') for all its drugs worldwide except for the US market.

3.51 On its Dutch-language website, AbbVie lists the following key figures: [48]
- around 48,000 employees work in more than 70 countries worldwide;
- 57 million patients in more than 175 countries are treated with AbbVie drugs every year;
- 22 production and development facilities worldwide;

[47] AbbVie is an offshoot of Abbott Laboratories, which was founded by Dr Wallace C. Abbott in 1888 under the then name Abbott Alkaloidal Company.
[48] https://www.abbvie.nl/over-abbvie/in-een-oogopslag.html.

- more than 1.37 million patients worldwide are supported by AbbVie's patient programmes;
- 125 years of patient care.

3.52 AbbVie offers relatively few medicines in the Dutch market. In 2020, AbbVie achieved sales of over EUR 95 million with its medicines in the Netherlands, representing about 3.9% of what was spent on intramural medicines in total in the Netherlands in 2020 (this was: EUR 2.452 million). [49]

3.53 In the last year that AbbVie still benefited from the patent on its blockbuster Humira - this was 2018 - it still achieved sales in the Netherlands of over EUR 245 million, or 11% of what was spent on intramural medicines in the Netherlands in total in 2018 (this was: 2.224 million).[50] As mentioned, in the period 2009 to 2018, Humira was the drug with the highest annual turnover in the Netherlands.

3.54 The following first discusses the codes of conduct to which AbbVie is committed (section 3.4.2). It then discusses AbbVie's conduct in practice with respect to Humira (section 3.4.3). It then discusses the attributable costs to Humira (section 3.4.4) and compares Humira sales in the Netherlands with collective healthcare spending (section 3.4.5).

3.4.2 CODES OF CONDUCT TO WHICH ABBVIE IS COMMITTED

3.55 AbbVie presents itself as a responsible and passionate company.[51] Thus, it states on its website: "We focus on complex, hard-to-treat conditions and seek to improve access to healthcare." And on its corporate culture, it states, among other things, "Helping people, we like nothing better." AbbVie claims to adhere to various (international) standards of conduct in its business operations. Some of these are dwelt upon below. AbbVie also stands for, in its own words: "sustainable affordable care; responsible deployment and use of medicines contribute [to this]."[52]

3.56 AbbVie's international website provides more information on its ethical pledge.[53]

[49] BIP database: https://www.gipdatabank.nl/databank?infotype=g&label=00-totaal&tabel_g_00-totaal=R_03_factsheet3&geg=vg&spec=&item=bijlage.
[50] BIP database: https://www.gipdatabank.nl/databank?infotype=g&label=00-totaal&tabel_g_00-totaal=R_03_factsheet3&geg=vg&spec=&item=bijlage.
[51] https://www.abbvie.nl/over-abbvie/wie-we-zijn.html.
[52] https://www.abbvie.nl/over-abbvie/transparantie-regelgeving.html.
[53] https://www.abbvie.com/our-company/positions-views.html.

3.57 The following first discusses the 'Dutch code of conduct' to which AbbVie subscribes, then looks at its own internationally applicable AbbVie company code and its commitment to human rights.

3.4.2.1 VIG code

3.58 As a member of the Association for Innovative Medicines (hereinafter: **VIG**), AbbVie is bound by the *Integrity, Transparency, Social Responsibility and Quality* Code (hereinafter: **VIG Code**), which is intended to clarify the principles from which the industry operates and what the industry stands for (**Production 2**). The VIG code describes the values and standards from which members operate, these relate to: integrity, transparency, social responsibility and quality.

3.59 The VIG code aims to complement existing laws and regulations and align with international guidelines. The introduction on page 5 articulates this as follows:

> "We are bound by existing laws and regulations and committed to further industry self-regulation. This Code complements this and is in line with international guidelines."

3.60 In the Integrity chapter, a normative rule on "fair market conduct" is included (rule 1.7). It follows from this that AbbVie "dissociates itself from anti-competitive actions through irresponsible pricing and improper use of (legal) exclusivity rights." The notes include:

> "Besides the prohibition of anti-competitive agreements, fair market behaviour also concerns the importance of preventing abuse of market power. We recognise our special responsibility that market power with a medicine on the Dutch market may entail. We distance ourselves from abuse of market power, such as excessive prices and improper use of (legal) rights and procedures."

3.61 With regard to 'corporate social responsibility', AbbVie is in line with international standards on this.[54] In this regard, the VIG code states with regard to "responsible pricing" (rule 3.11):

> "We want to ensure social acceptability of our new drugs through responsible pricing that takes into account the value of the new drug for patients and society, as well as a reasonable contribution to our (future) innovation."

[54] VIG code, p. 24, introduction.

3.62 The explanatory statement notes:

> "[...] Responsible pricing takes into account the value of the medicine for patients and society. [...] The price may reflect the level of demand and include an appreciation of innovation. Moreover, it is highly desirable for society to find room in the price to encourage the development of new drugs. [...]"

3.4.2.2 The AbbVie Code of Business

3.63 "The AbbVie Code of Business, Inspired by Integrity", is a 67-page code of conduct that addresses various aspects of integrity (**Production 3**). In the foreword, the CEO, Richard A. Gonzales, writes: "The Code reflects The AbbVie Way and is essentially an outline that sets clear expectations about how to do the right thing, the right way." And: "The Code provides guidance and direction for our efforts. It describes what we believe in and what we strive to deliver to those we serve: patients, health care providers, shareholders, business partners and our fellow employees."

3.64 In the code of conduct, AbbVie mainly and repeatedly emphasises that it complies and will comply with all laws and regulations applicable to its 'business'. A concrete definition or standard with regard to acting ethically and with integrity is not given in the code of conduct. For AbbVie, acting ethically and with integrity seems to mean above all not breaking laws and regulations. Nevertheless, in the context of fair competition, it speaks that "the fair pricing of their products is essential to their commitment to improving health worldwide.

3.4.2.3 Commitment to Human Rights

3.65 AbbVie wholeheartedly endorses that as a company it must respect human rights. In its "Commitment to Human Rights" (**Production 4),** it states on page 1, among other things:

> "AbbVie believes in the inherent dignity of every human being and respects individual rights as set out in the Universal Declaration of Human Rights. We reflect these precepts in our company's fundamental principles and in our mission to address serious health challenges.
>
> AbbVie supports the Universal Declaration of Human Rights and key tenets of the United Nations Guiding Principles on Business and Human Rights. While governments have a key role to respect, protect, promote and fulfil the human rights of their citizens, we recognize that companies share this responsibility to respect human rights within their own operations and through business relationships. AbbVie is committed to preventing, mitigating and remedying any adverse human rights impacts across our value chain."
>
> "[...] Four aspects of our business and operations as a biopharmaceutical company are particularly relevant: workplace, access to health care, clinical trials and supply chain."

3.66 Under the heading "Access to Healthcare" (p. 2), AbbVie notes:

> "We believe patients need access to quality and affordable medicines. Using our expertise to improve health is one of AbbVie's corporate responsibility commitments and is integral to our core business strategy. As detailed in Our Commitment to Access to Medicines, we use a variety of strategies to support patients and enhance access to healthcare. AbbVie is committed to the highest quality products for patients who use them.
>
> AbbVie works to increase access to healthcare services and to our medicines. We do this by: collaborating with local stakeholders to provide tailored solutions that meet specific needs for pricing and access; partnering with stakeholders on interventions to help build healthcare capacity; and advancing patient and provider education globally."

3.67 While AbbVie seems to link its role with regard to 'access to healthcare' mainly to the affordability of its products, it recognises that it is also linked to increasing access to healthcare services in general.[55]

3.4.3 ABBVIE'S CONDUCT IN PRACTICE REGARDING HUMIRA

3.68 AbbVie's behaviour in practice regarding Humira stands in stark contrast to its ethical pledge. Much about this behaviour has been made public by a US Congressional investigation into AbbVie's pricing in relation to two blockbusters, including Humira.[56] The investigation reveals many relevant facts. The results were made public on 18 May 2021 in the U.S. House of Representatives, Committee on Oversight and Reform, Staff Report, *Drug Pricing Investigation, AbbVie - Humira and Imbruvica*, May 2021 (hereinafter **Staff Report**) (**Production 5**).

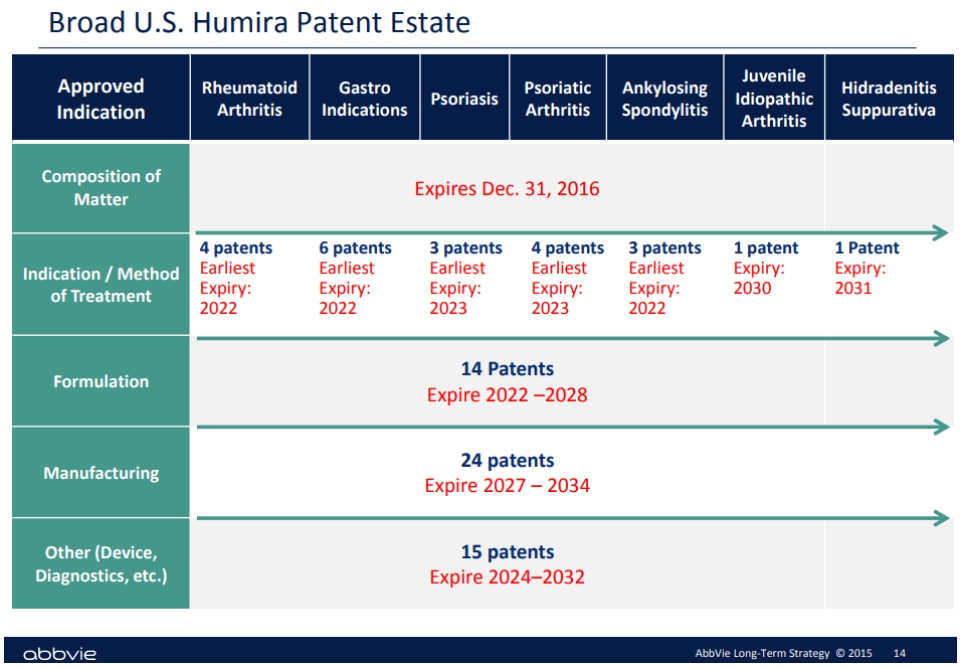
3.69 The investigation led to a formal request to the US competition authority, the Federal Trade Commission (FTC), to investigate whether AbbVie exploited the US patent system and engaged in anti-competitive practices to extend its monopoly prices.[57]

3.70 The Staff Report states and notes the following about AbbVie's conduct, among others.

3.71 The patent on the active ingredient "Adalimumab" expired on 31 December 2016. It was then expected that competitors with biosimilars would enter the market and the price of the product would fall. However, that did not happen, as AbbVie cleverly exploited the patent system and thereby managed to obtain, or apply for, more than 200 additional patents on Humira, thereby blocking biosimilar competition at that time.[58]

3.72 In a presentation to investors on 30 October 2015, AbbVie CEO Richard Gonzalez used the following slide to tout AbbVie's "Broad U.S. Humira Patent Estate".[59]

[55] See also https://www.abbvie.com/our-company/positions-views.html, under "Our Commitment to Access to Medicines".
[56] Initially , this was an investigation into 12 drug manufacturers offering expensive drugs in the US market, see: https://oversight.house.gov/news/press-releases/oversight-committee-to-issue-subpoena-to-abbvie-inc.
[57] https://oversight.house.gov/news/press-releases/oversight-committee-held-hearing-with-abbvie-ceo-and-experts-on-pricing.
[58] Production 5, p. 23.
[59] Production 5, p. 24.



3.73 The slide shows AbbVie's patents on a range of alleged inventions related to Humira, including Humira's use to treat certain conditions, Humira's formulation, Humira's manufacturing process and devices used to inject Humira. In the five years since that presentation, AbbVie's patent portfolio has continued to grow. By 2020, the company owned or has at least 257 Humira-related patents pending, the last of which will expire in 2037, 21 years after the original Humira patent expired.[60]

3.74 Not all patents relating to Humira have held up. For instance, the U.S. Patent Trial and Appeal Board invalidated three additional Humira patents that related to dosage for the treatment of rheumatoid arthritis because the dosage was "obvious" and therefore unpatentable.[61]

3.75 The Staff Report states that AbbVie's patent strategy is particularly illegitimate because it tries to overwhelm potential competitors with the large number of patents on Humira, regardless of whether individual patents are properly granted under US law. If a patent is invalidated, AbbVie has another patent ready to go. So if a competitor wants to enter the market, it has to work its way through the entire patent thicket -a process that is both expensive and slow. [62]

[60] Production 5, p. 24.
[61] Production 5, p. 25.
[62] Production 5, p. 25.

3.76 AbbVie CEO Gonzalez's equally frank and disconcerting words to investors in 2017, after the above dosage patents were overturned, confirm this conclusion. In the so-called AbbVie Q1 2017 Earnings Conference Call, (27 April 2017), Gonzalez lectures his listeners:[63]

> "Okay. Jeff [one of the analysts], this is Rick [Gonzalez]. On the IPR [Intellectual Property Rights], as we've said in previous calls, I mean we're in active litigation now, so we're not going to talk a lot about specifics around this. What I would say to you is, if you look at our level of confidence in what we've described to the market about our ability to protect Humira, it remains the same. And that confidence was built around a large portfolio of IP [IP], it was never contingent upon any one set of IP or any single set of patents or individual patents. We have a large portfolio of formulation patents that have come under challenge and have been successful and successfully navigated through those challenges. We now have the beginning of these dosing patents, we have a large portfolio of dosing patents. We have dosing patents beyond '135 [one of the nullified patents] in RA [rheumatoid arthritis], so beyond the ones being challenged. And so I'd say our level of confidence in the outcome, the overall outcome that we anticipated remains the same, and it remains high."

3.77 The Staff Report concludes that most patent applications relating to Humira were not necessary to drive the company's development of the drug. About 90% of the applications were filed after Humira was already approved and marketed. Almost half of the patent applications related to Humira date from 2014 or later - more than a decade after Humira was launched on the market. Furthermore, internal company documents revealed that AbbVie views the US patent system as much more lenient than patent systems in the rest of the world. For example, an internal white paper noted that Europe's patent system excluded many of the same patents it obtained in the US, including a subset of its so-called formulation patents and at least one of its patents relating to the use of Humira to treat psoriasis. Consequently, in October 2018, AbbVie began to face competition in Europe from five different biosimilars. As a result, AbbVie reduced its price of Humira by as much as 80%. As a result of this biosimilar competition, AbbVie's non-US sales of Humira fell 31% in 2019, while its US sales rose 8.6%.[64]

[63] https://seekingalpha.com/article/4066300-abbvie-abbv-q1-2017-results-earnings-call-transcript. See also Production 5, pp. 25-26.

[64] Production 5, p. 26.

3.78 In one of the hearings on the *Drug Pricing Investigation, AbbVie - Humira and Imbruvica*, Katie Porter questioned AbbVie CEO Gonzales about the spending the company has done from 2013 to 2018. AbbVie then spent as a company: [65]

(i) US$2.45 billion in R&D to Imbruvica
(ii) US$1.6 billion in lawsuit settlements,
(iii) an annual amount of US$4.71 billion on *marketing and advertising,*
(iv) US$334 million in *executive compensation*, and
(v) US$50 billion in share buybacks and dividend payments.

3.4.4 ATTRIBUTABLE COSTS TO HUMIRA

3.79 As mentioned, AbbVie, at least its legal predecessor Abbott, managed to acquire Humira in 2001 with the acquisition of Knoll. The acquisition price was US$6.9 billion for the company, which then had US$2 billion in sales. This acquisition price was (possibly) determined to a significant extent by the value of Humira and a large part of the acquisition price could therefore be considered an investment made by AbbVie for the benefit of Humira. Furthermore, AbbVie incurred costs related to the drug's further development.

3.80 It follows from the Staff Report that AbbVie claims to have spent a total of US$5.19 billion in "Humira Research & Development" in the period 2009 to 2018,[66] representing about 4.2% of global net sales in that period. It follows from AbbVie internal documents that much of this research spending was spent on expanding its market monopoly by limiting biosimilar competition for Humira.

3.81 The Staff Report states on the above:

> "AbbVie's total research and development expenditures for Humira represented only a small fraction of its net revenue from this drug. In response to the Committee's request, AbbVie identified a total of $5.19 billion in "Humira Research & Development" between 2009 and 2018 - approximately 7.4% of its Humira U.S. net revenue and 4.2% of its Humira worldwide net revenue over that period. Even this research and development spending may be overstated, as AbbVie initially identified only $2.17 billion in Humira-specific research and development costs in response to the Committee's requests-and identified an

[65] https://www.youtube.com/watch?v=7axjk-9poKc.

[66] It is not always clear whether the Staff Report refers to the period 2009 to 2018, or the period 2009 to 2018. The subpoena assumes the period 2009 to 2018, making the figures presented a possible overestimation of the actual situation.

additional $3.03 billion in spending more than eight months later, just prior to the publication of this report."[67]

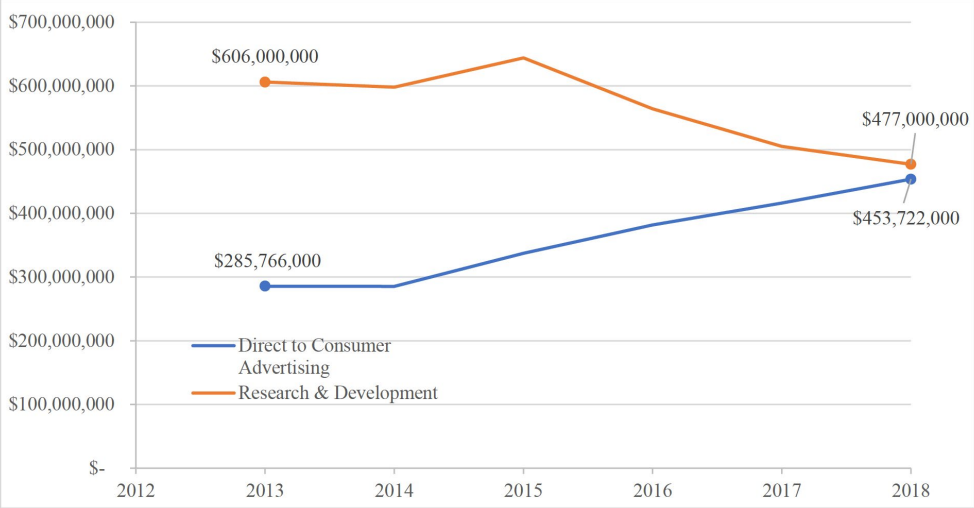
"AbbVie's internal documents and data show that a large portion of AbbVie's research expenditures on Humira were dedicated to extending its market monopoly by limiting biosimilar competition through "enhancements" to Humira. One internal presentation emphasised that one objective of the "enhancement" strategy was to "raise barriers to competitor ability to replicate." The presentation also identified the "Humira High concentration" and "Sustained Release" formulations as furthering AbbVie's goal of "Biosimilar defence."[68]

"Since spinning off from Abbott in 2013, AbbVie's Humira research and development decreased over time, while its expenditures on direct-to-consumer advertising grew significantly. Figure 15 below shows AbbVie's expenditures on direct-to-consumer advertising compared to Humira-specific research and development."

[67] Production 5, p. 43.

[68] Production 5, p. vi and pp. 37 to 39.

Figure 15: Humira Direct-to-Consumer Advertising Compared to R&D



3.82 In this context, the Staff Report further notes that from AbbVie's own perspective, the research expenditure was relatively low-risk and highly valuable, as it was predicted to result in significant returns even after adjusting for the risk of clinical trial failure. The Staff Report put it as follows: [69]

> "AbbVie has also argued that its clinical trial expenditures are made with "low odds of success," and that this risk must be considered when evaluating the price of Humira. However, the Committee's investigation found that AbbVie internally estimated that its expenditures were relatively low-risk and highly valuable, as they were predicted to result in substantial returns even after adjusting for the risk that the clinical trial would fail. For example, a July 16, 2010, slide deck on Humira's global development plan and life cycle management strategy detailed AbbVie's expected return on investment for clinical studies evaluating Humira as a treatment for gastroenterological conditions. The projected cost of clinical studies to evaluate Humira as a treatment for mild to moderate Crohn's disease was estimated to be $34.63 million with a 60% probability of success, and the company projected a risk-adjusted net present value of the project to be $923 million. Another clinical study to evaluate the optimal use of Humira for treating Crohn's disease was projected to cost approximately $13.8 million with a 90% probability of success, and the project had a risk-adjusted net present value of $750 million."

[69] Production 5, p. 44.

3.83 'Attributable costs' to Humira include costs of manufacturing and selling Humira. It follows from the Staff Report that AbbVie claims to have spent a total of US$13.9 billion (globally, that is) on manufacturing and selling costs in the period 2009 to 2018, representing 11% of net sales in that period.[70]

3.84 In summary, in the period 2009 to 2018, attributable costs to Humira against global net sales were as follows:

Net sales and attributable costs Humira from 2009 to 2018 (9 years)[71]

Global net sales	US$ 121,190,000,000	*completed*
Production and selling costs	US$ 13,938,000,000	11% of net turnover
R&D costs	US$5,192,000,000	4% of net turnover

3.85 For the period 2003 (first market launch of Humira) to 2009, the Staff Report does not share any financial data. What is known is that AbbVie, or at least its legal predecessor Abbott, acquired Humira with the acquisition of Knoll - for US$6.9 - billion.

3.4.5 Sales of Humira in the Netherlands and these sales compared with expenditure expensive medicines

3.86 AbbVie acquired a marketing authorisation for the sale of Humira in 2003 and has actually offered the drug on the Dutch market since 2004.[72] In April 2018, the basic patent on Humira expired, but by registering an indication for children, AbbVie was granted patent extension until 15 October 2018. Incidentally, this applied to the entire EU.[73] Since the expiry of the patent, the price of Humira has fallen sharply. The Authority Consumer and Market (hereafter **ACM**) concluded in its Report, *Sector investigation TNF-alpha inhibitors - Competition before and after entry of biosimilars*, September 2019 (hereafter **ACM Sector investigation**) (**Production 6**) that even in the run-up to the expiry date of the patent, the price of Humira was already 10% to 15% cheaper. The ACM stated, "With the lower price of the originator drug Humira,

[70] Production 5, p. 47.

[71] Production 5, p. 48 Figure 18.

[72] Registration number EU/1/03/256. Date of marketing authorisation granted: 8 September 2003. See: https://www.geneesmiddeleninformatiebank.nl/ords/f?p=111:3::SEARCH:::P0_DOMAIN,P0_LANG,P3_RVG1:H,NL,71656.

[73] https://www.horizonscangeneesmiddelen.nl/binaries/content/assets/horizonscan/overzicht-patentverloop-dure-geneesmiddelen.pdf.

AbbVie may already be anticipating in its pricing the entry of biosimilars for its active ingredient (adalimumab) in 2019."[74]

3.87 FTV commissioned research into the displacement of legally insured basic care in the Netherlands due to the pricing of Humira in the period 2004 to 2018. This study was conducted by Consultantbureau Zorgvuldig Advies (hereinafter: **ZA**) and is submitted as **Production 7**. It follows from this research that AbbVie (and its legal predecessor Abbott) is estimated to have achieved net sales of (rounded) EUR 2.3 billion with Humira in the Netherlands in the (patent) period 2004 to 2018 (Production 7, p. 22). How much the production and sales costs of Humira were in that period is not precisely known and also not disclosed by AbbVie, but these are estimated in patent period 2004 to 2018 in the research report to be between (rounded) EUR 248 million and EUR 916 million (Production 7, p. 24).[75]

3.88 To the best of FTV's knowledge, there are no specific R&D costs attributable to Humira sales in the Netherlands; AbbVie has also reported global R&D costs to the US Congress. Nevertheless, to calculate the 'net impact' of Humira's price on the available healthcare budget in the Netherlands (in other words, the impact on pie-sharing), FTV relies on global R&D costs. According to AbbVie, these amounted to US$5.192 bln in the period 2009 to 2018. By converting these costs to average annual costs and then allocating them to the period 2003 to 2018 and adding the entire acquisition price (US$6.9 bln) for Knoll,[76] the total global R&D costs in that period would be (converted) over EUR11.6 bln - i.e. 10.7% of Humira's global sales in the period 2004 to 2018 (Production 7, p. 25). This amount is likely to be a significant overestimate, as average R&D costs for new drugs are estimated to be considerably lower than EUR 11.6 billion (see Production 7, p. 25). Converted to the Dutch turnover of EUR 2.3 billion in the period 2004 to 2018, this then amounts to an amount of R&D of EUR 241 million (10.7% of that turnover achieved in the Netherlands), see Production 7, p. 25.

3.89 In 2010, Humira accounted for 24% of total expenditure on expensive medicines. In the following years, expenditure on expensive medicines increased in absolute terms, causing Humira's percentage share in it to decrease ever so slightly. After the expiry of patent protection, Humira's share was only 2% of total expenditure on expensive

[74] Production 6, p. 20/37.

[75] Respectively 11% of EUR 2.251 billion and 40.7% of EUR 2.251 billion.

[76] Allocating the entire acquisition sum is undoubtedly on the high side, as Knoll achieved annual sales of US$2 billion at the time of the acquisition. Cf. also Commission 10 February 2021, Case AT.40394 - Aspen, pt. 157, in which the Commission considered: "[M]oreover, since the acquisition price should be interpreted as largely a transfer of expected future profits from GSK to Aspen, and not as the valuation of specific tangible or intangible assets acquired by Aspen, it would be also conceptually incorrect to treat the acquisition price as a relevant cost of production or cost of supplying the product, within the meaning of Limb 1 of the United Brands judgment."

medicines (Production 7, p. 21 and 22). However, Humira's market share of total Adalimumab expenditure is still estimated at around 60% thereafter;[77] 40% market share is then occupied by biosimilars.

[77] Production 7, p. 15.

4 Legal framework

4.1 Introduction

4.1 In this section, FTV outlines the legal framework against which AbbVie's actions should be assessed and the legal grounds on which FTV bases its claims.

4.2 In section 4.2, FTV discusses that AbbVie's actions constitute an unlawful act due to acting in breach with what is generally accepted according to unwritten law. In that context, FTV will also discuss AbbVie's responsibility with respect to human rights.

4.3 In section 4.3, FTV explains that the prices charged by AbbVie for Humira were excessive and that AbbVie thereby abused its dominant economic position. This breach of competition law (Article 24 Mw and/or Article 102 TFEU) constitutes an independent unlawful act on the part of AbbVie.

4.4 In section 4.4, FTV summarily concludes that AbbVie is liable on tort grounds.

4.2 Unlawful act : breach of social duty of care

4.2.1 INTRODUCTION

4.5 In FTV's view, from 2004 to 2018, AbbVie's pricing of Humira promoted displacement of legally insured basic care and/or unacceptably impeded access to legally insured basic care. Given the dominant position AbbVie enjoyed with its drug Humira - at least during the patent period - and more generally the key position AbbVie occupies as a drug manufacturer within the healthcare system, AbbVie has a duty of care, which is to render an account of the adverse social consequences that the pricing of its drugs (in this case Humira) has for third parties.

4.6 This does not mean that AbbVie should not be rewarded for its efforts and risks taken in drug development - noting in the case of Humira that AbbVie did not develop the drug itself, but bought it (see paragraph 3.32) - and should not generate (high) profits. It does mean, according to FTV, that extreme excess profits (see section 4.2.4.2 on this subject) should not be enjoyed to the extent that they result in health harm through unnecessary displacement of care.

4.7 In the case of Humira, according to FTV, such a situation occurred. AbbVie has enjoyed extremely high profit margins-which cannot be explained by the efforts and/or

investments made-while, as a result of the high price charged for the drug in question, there has been foreseeable health damage in the Netherlands due to displacement of care. According to FTV, there was therefore a breach of a social duty of care and AbbVie acted unlawfully as a result.

4.8 In fulfilling the aforementioned social duty of care, FTV also values human rights standards, including in particular the right to life and the right to health (par. 4.2.2.3). AbbVie, as a company, also has its own responsibility in complying with these international standards (par. 4.2.3). However, AbbVie's conduct has disregarded this.

4.9 In section 4.2.7, FTV therefore concludes, in summary, that AbbVie is in breach of a rule of unwritten law pertaining to proper social conduct.

4.10 The following begins with an overview of the relevant human rights relevant to the present proceedings (section 4.2.2) and AbbVie's independent responsibility to respect these human rights (section 4.2.3). It then specifically discusses AbbVie's displacement of care (para 4.2.4), briefly considers AbbVie's special position in social and economic life (para 4.2.5) and concludes with a conclusion on AbbVie's actions in breach of its social duty of care (para 4.2.6).

4.2.2 HUMAN RIGHTS

4.2.2.1 Introduction

4.11 In the concepts of Corporate Responsibility and Business Human Rights to be discussed below, human rights play an important role. Indeed, the OECD Guidelines and the UNGP instruct companies that where their business activities have negative effects on human rights, they must eliminate those effects or take measures to reduce those effects as much as possible. In this section, FTV considers relevant human rights issues involved in this case.

4.12 It follows from section 3.2 that the Dutch healthcare system consists of a complex of regulations that regulate the scope of healthcare provision, including the provision of medicines, both functionally and financially. In this complex of regulations, AbbVie acts as an internationally operating company on the Dutch market and not as a healthcare provider in the sense of Article 1 Wmg and (thus) falls outside the regulatory framework of the Wmg. The Minister of Health, Welfare and Sport has no adequate, guiding influence on the setting of prices for medicines. All national regulations and

regulatory instruments notwithstanding, drug manufacturers retain a significant influence on being able to set drug prices to their advantage.

4.13 Given the cost price of Humira, on the one hand, and the displacement of legally insured basic care and/or obstruction of access to legally insured basic care as a result of the demand price in question, on the other hand (see section 4.2.6 below), AbbVie's actions should be classified as a violation of fundamental rights - in the sense of human rights - for which AbbVie, in FTV's view, bears a duty of care to protect them or limit the adverse impact on them.

4.14 Before discussing the various human rights violations and what legal protection these human rights provide, the general concept of human rights is briefly considered.

4.2.2.2 Human rights: general

4.15 Human rights protect the dignity of every human being. *Every* human being can claim them. By their nature, human rights are personal/individual rights that are presumed to be universal and - with the exception of property rights - independent of assets. While human rights guarantee individual rights, they can be claimed collectively in the Netherlands by interest groups. If individuals subject to the jurisdiction of the Dutch state can invoke human rights provisions that have direct effect in the Netherlands, an interest organisation may also do so on their behalf on the basis of Article 3:305a of the Civil Code, provided that the interests of those residents at issue are sufficiently similar and lend themselves to bundling, so as to promote efficient and effective legal protection on their behalf.[78]

4.16 Human rights are enshrined in various international treaties and our Constitution. The basis for all international agreements on human rights is the Universal Declaration of Human Rights (**UDHR**), adopted by the United Nations on 10 December 1948. The UDHR does not include legally enforceable provisions, but its 30 provisions are largely assigned 'customary law'. The drafters also intended a broad scope of the Declaration to include imposing obligations on non-state actors. Thus, Article 29(1) UDHR reads, "Everyone has duties towards the community, without which the free and full development of his personality is not possible."

4.17 Human rights are often divided into two categories, namely: 'civil and political rights' and 'economic, social and cultural rights'. Despite this dichotomy, all human rights are

[78] HR 20 December 2019, Urgenda, ECLI:NL:HR:2019:2006, para 5.9.2.

equally important and there is no hierarchy between human rights.[79] Through case law, the open formulations of human rights provisions have been and are being fleshed out.

4.18 In the classical conception of public international law, human rights impose obligations on states in their relationship with (their) residents. States become parties to human rights treaties by ratification and are then legally bound by the relevant provisions. Thereby, a dogmatic distinction is made between three types of obligations, namely: respect, protect and realise human rights. The first type is a negative obligation (i.e. refrain from acting in violation of human rights), the other two types are positive obligations and therefore require active action by the state to ensure the exercise of human rights by citizens.[80] The European Court of Human Rights (**ECHR**) does not use this tripartite typology but its own doctrine on positive and negative obligations. [81]

4.19 Although it follows from the classical conception of public international law that human rights in principle have no horizontal effect between private parties, i.e. private parties cannot invoke human rights against each other, there are rulings by UN bodies in which individuals/private parties have invoked human rights violations by non-state actors against states, with the legal consequence that the state has to remedy those violations.[82] And in Union law, there is case law in which private parties have been able to invoke fundamental treaty rights, including civil rights, against non-state actors. See section 4.2.4.

4.20 The above threefold division into types of obligations (respect, protect, realise) applicable to states is in principle irrelevant for assessing whether and to what extent a company should eliminate or mitigate the negative collective effects of its actions - which infringe a human right. Indeed, if the externality can be classified as a violation

[79] Vienna Declaration and Programme of Action (Adopted by the World Conference on Human Rights in Vienna on 25 June 1993), para. 5: "All human rights are universal, indivisible and interdependent and interrelated. The international community must treat human rights globally in a fair and equal manner, on the same footing, and with the same emphasis. While the significance of national and regional particularities and various historical, cultural and religious backgrounds must be borne in mind, it is the duty of States, regardless of their political, economic and cultural systems, to promote and protect all human rights and fundamental freedoms."

[80] UN Special Rapporteur on the Right to Food, Asbjørn Eide, *The Human Right to Adequate Food and Freedom from Hunger* (1987) E/CN.4/Sub.2/1987/23, para. 66-69.

[81] I.E. Koch, *Dichotomies, Trichotomies or Waves of Duties?*, Human Rights Law Review, Vol. 5, No. 1, 2005, pp. 81-103.

[82] L. Lane, *The Horizontal Effect of International Human Rights Law*, diss. RUG, 2018, Chapter 5. In the case of torture, the CAT (Convention against Torture), in the Elmi case, effectively classified a non-state actor as a state in its assessment. It concerned the deportation of a Somali who was in danger of falling into the hands of an armed group that effectively controlled Somalia rather than the central state authority (CAT 25 May 1999, Sadiq Shek Elmi v Australia, CAT/C/22/D/120/1998). As a result, the state could not be held responsible for preventing a human rights violation (on the applicant), but that responsibility was deemed to exist with the armed group (a non-state actor).

of a human right, that violation should be remedied in the interest of a state's residents. And when remedying the breach is now taken as the starting point and goal, the question of who is able to do so is at least as relevant as who, under currently applicable law, is responsible for it.

4.21 In the classical conception of public international law, corporations do not have legal positive obligations to protect and realise human rights, as is assumed for states under circumstances. Nevertheless, it has been authoritatively established internationally that companies have a responsibility to respect human rights.[83] This means that in the conduct of their business, they must not only not violate human rights, but also eliminate the negative impact of their actions on human rights.[84] In this context, FTV also reiterates Article 29(1) UDHR, from which it follows that non-state actors also have (human rights) duties towards the community. With regard to the (human) right to health specifically, the Committee on Economic, Social and Cultural Rights (hereinafter: **CESCR**) has endorsed in an authoritative interpretation of this right that in addition to states, the private business sector also has responsibilities for the realisation of the right to health.[85]

4.22 The following section discusses the various (written) human rights norms at stake in the present case.

4.2.2.3 Relevant human rights standards

4.23 AbbVie's actions, in particular with regard to the provision of Humira on the Dutch market, caused externalities in the period 2004 to 2018. Indeed, AbbVie asked such a price for Humira in that period that it thereby promoted displacement of legally insured basic care and/or unacceptably impeded access to legally insured basic care, with the exception of the care for which Humira was used.

4.24 With the onset of externality - i.e. 'promoting displacement of care and/or unacceptably impeding access to other care' - some human rights are violated, namely: the right to life (and, where appropriate, the right to respect for private and family life) and the right to the best possible standard of health. The scope and application of these human rights are discussed separately below.

[83] See UN Guiding Principles on Business and Human Rights ('Ruggie Principles'). Section 4.2.3.3 discusses this framework of standards in detail.
[84] See also laid down in the proposal for the Responsible and Sustainable International Business Act (Parliamentary Papers II 2020-2021, 35 761, no. 2).
[85] CESCR, General comment No. 14, para. 42.

4.25 It should be noted beforehand that the provisions discussed below have almost without exception been invoked in a legal relationship between citizen(s) and the state. In that case-law, the (positive law) obligations of the state are almost always central, i.e. the question to what extent an active action of the state is necessary to guarantee the exercise of human rights by citizens. That case-law also gives a clear indication of how far the protection of human rights extends in individual cases.

a) Right to life

4.26 The right to life is enshrined in several international human rights treaties, such as Article 6 of the International Covenant on Civil and Political Rights (**ICCPR**), Article 6 International Convention on the Rights of the Child (**CRC**), Article 2 of the European Convention on Human Rights (**ECHR**) and Article 2 of the Charter of Fundamental Rights of the European Union (**Charter**).

4.27 The right to life is closely linked to the core principle of human dignity, which is the basis of all rights.[86]

4.28 The UN Human Rights Committee (the so-called Human Rights Committee, hereinafter **HRC**) takes the view - see General comment No. 36 (2019) (**Production 8**)[87] - that states must take measures that respect (respect) access to health care in order for citizens to be able to exercise their fundamental right, i.e. enjoy a dignified life.[88] States should protect their citizens from (reasonably foreseeable) threats emanating from private entities.[89]

4.29 The ECtHR has consistently held that Article 2 ECHR, which enshrines the right to life, includes the positive obligation of a State party to the Convention to take appropriate steps to safeguard the lives of everyone within its jurisdiction ("to take appropriate steps to safeguard the lives of those within its jurisdiction").[90] According to that case-law, this obligation applies, inter alia, in the health care context. For example, in Sentürk v Turkey, the ECtHR held that the state must take appropriate steps to ensure that the patient's life is protected by the hospital that refused healthcare to the patient

[86] UN General Assembly, *International Covenant on Civil and Political Rights*, 16 December 1966, United Nations, Treaty Series, vol. 999, Preamble.

[87] HRC, General comment No. 36 - Article 6: right to life. This General comment replaces General comment No. 6 (1982) and General comment No. 14 (1984).

[88] HRC, General comment No 36 (2019), para 26.

[89] HRC, General comment No 36 (2019), para 26.

[90] HR 20 December 2019, Urgenda, ECLI:NL:HR:2019:2006, para 5.2.2 and, inter alia, ECHR 9 June 1998, no 23413/94 (L.C.B.v the United Kingdom) para 36, ECHR 28 March 2000, no 22492/93 (Kiliç v Turkey), para 62, and ECHR 17 July 2014, no 47848/08 (Centre for Legal Resources on behalf of Valentin Câmpeanu v Romania), para 130.

concerned without prior payment.[91] And in Vasileva v. Bulgaria, the ECtHR held that governments have a positive obligation to ensure regulation that obliges public and private hospitals to take measures to protect their patients.[92] Furthermore, in Asiye Genç v. Turkey, the ECtHR ruled that the state must ensure the proper organisation and functioning of the public hospital service and, more generally, the health protection system.[93]

4.30 The obligation to take appropriate measures exists if there is a 'real and immediate risk' to persons and the state concerned is aware of that danger. 'Real and immediate risk' in this context means a danger that is real and immediate. The term 'immediate' does not refer to the immediacy of the danger in the sense that there must be a short lapse of time until its realisation, but in the sense that there must be a danger that directly threatens the persons concerned. The protection of Article 2 ECHR also covers dangers that may materialise only in the longer term.[94] In the case of waiting lists, it can be argued that the danger is already present.

4.31 The protection of Article 2 ECHR does not only concern specific individuals but also society or population as a whole. [95]

b) Right to health

4.32 The right to health or healthcare exists as an 'economic and social right' and, as such, is enshrined in Article 12 ICESCR, Article 11 of the European Social Charter (hereafter: **ESC**), Article 24 CRC and Article 35 Charter. The right to health is also enshrined in Article 25 of the UDHR.[96]

[91] ECHR 9 April 2013, no 13423/09 (Mehmet Şentürk and Bekir Şentürk v Turkey), para 97.

[92] ECHR 17 March 2016, no 23796/10 (Vasileva v Bulgaria), para 63.

[93] ECHR 27 January 2015, no 24109/07 (Asiye Genç v Turkey), para 80.

[94] HR 20 December 2019, Urgenda, ECLI:NL:HR:2019:2006, para 5.2.2 jo 5.8. And cf, inter alia, ECHR 30 November 2004, no 48939/99 (Öneryildiz v Turkey), para 98-101 (gas explosion at rubbish dump; the risk that it might occur at any time had existed for years and had been known to the authorities for years), ECHR 20 March 2008, no 15339/02 (Budayeva and others v Russia), para. 147-158 (life-threatening mudslide; the authorities knew of the danger of mudslides at the site and were aware of the possibility that they could occur at some point on the scale if they actually occurred), and ECHR 28 February 2012, no. 17423/05 (Kolyadenko and others v Russia), paras 165 and 174-180 (outflow from reservoir made necessary by exceptionally abundant rain; the authorities knew that in the event of exceptionally heavy rain, necessity for outflow could occur). See in this sense also ABRvS 18 November 2015, ECLI:NL:RVS:2015:3578 (Gas extraction in Groningen), para 39.3.

[95] HR 20 December 2019, Urgenda, ECLI:NL:HR:2019:2006, para 5.3.1. And see, inter alia, ECHR 12 January 2012, no 36146/05 (Gorovenky and Bugara v Ukraine), para 32, and ECHR 13 April 2017, no 26562/07 (Tagayeva and others v Russia), para 482.

[96] Despite the fact that the ECHR does not provide for a right to health or health care as a 'civil and political right', an analysis of the ECtHR's jurisprudence suggests that the ECHR imposes several (particularly positive) obligations on States Parties that are relevant to the protection of health, the provision of health care and the protection of patients'

4.33 In 1946, the World Health Organisation (**WHO**) stated in its constitution that "the enjoyment of the best possible state of health is one of the fundamental rights of every human being without distinction of race, religion, political creed, economic or social position." [97]

4.34 In 2000, the 'right to health' enshrined in Article 12 IVESCR was further elaborated in General comment No. 14 (**Production 9**),[98] which sets out in detail the obligations of member states to this convention to ensure 'the right to health' for all - the General comments of UN bodies are authoritative.[99] The wording 'the right to the highest attainable standard of health' in Article 12(1) IVESCR[100] means that this must take into account the biological and socio-economic conditions of the individual as well as the financial possibilities of the state.[101] The 'right to health' should thus be understood as a right to the enjoyment of a variety of facilities, goods, services and conditions necessary for the realisation of the highest attainable standard of health.[102] This includes both access to (literal) health care and access to health care services.

4.35 The right to health in all its forms and at all levels contains the following four interrelated and essential elements, the precise application of which will depend on the circumstances in a given State Party: (i) availability, (ii) accessibility, (iii) acceptability and (iv) quality.[103]

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rights. These obligations are not limited to vertical relations, but also include obligations for horizontal relations. See on this: A. Hendriks, *The Council of Europe and Health Rights*, (Chapter 5), in B.C.A. Toebes et. al, *Health and Human Rights: Global and European Perspectives*, Intersentia: 2022.

[97] See Statute of the World Health Organisation, New York, 22 July 1946, preamble. See also Article 35 Charter which assumes similar standard: "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. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities."

[98] CESCR, General comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12).

[99] See, e.g., ICJ 30 November 2010, Case *Ahmadou Sadio Diallo (Republic of Guinea v. Democratic Republic of the Congo),* para 66: [...] "Although the Court is in no way obliged, in the exercise of its judicial functions, to model its own interpretation of the Covenant on that of the Committee, it believes that it should ascribe great weight to the interpretation adopted by this independent body that was established specifically to supervise the application of that treaty. The point here is to achieve the necessary clarity and the essential consistency of international law, as well as legal security, to which both the individuals with guaranteed rights and the States obliged to comply with treaty obligations are entitled." The ICJ has also referred to the practice of the CESCR, see International Court of Justice 9 July 2004, *Advisory Opinion on the Legal Consequences of the Construction of a Wall in the Occupied Palestinian Territory,* (9 July 2004), para 112.

[100] Article 12(1) ICESCR: "The States Parties to the present Covenant recognise the right of everyone to the enjoyment of the highest attainable standard of physical and mental health."
Article 12(1) IVESCR (translated): "The States Parties to this Convention recognise the right of everyone to the highest attainable standard of physical and mental health."

[101] CESCR, General comment No. 14, para. 9.

[102] CESCR, General comment No. 14, para. 9.

[103] CESCR, General comment No. 14, para. 12. This paragraph explains the AAAQ criteria.

4.36 Availability of health care is related to diversity and quantity of facilities, goods, services and health programs. The level of availability depends heavily on the development/welfare level of a state.

4.37 Accessibility concerns both physical accessibility to care within safe distance for all, as well as financial accessibility and according to the principle of non-discrimination. Also, everyone should have access to understandable health-related information.

4.38 Acceptability of healthcare means that healthcare respects medical ethics and confidentiality and takes into account the culture and needs of specific groups such as minorities, communities, gender and age groups.

4.39 Quality of healthcare refers to the scientific and medical appropriateness of care. Good quality requires, among other things, competent medical staff and approved drugs and equipment.

4.40 General comment No. 14 states that states must respect, protect and fulfil the right to health. The obligation to *respect* means that the state must not violate the right to health. The state must not deny care to people or discriminate in who has access to care. The obligation to *protect means that* the state should prevent violations of the right to health by others. Thus, a state should take measures that prevent this right from being violated by the actions of third parties.[104] The obligation to *realise means* that the state should take measures to ensure that rights can be enjoyed. Thus, a state should take appropriate legal, administrative and budgetary decisions, and concretely provide various different facilities, goods, services and conditions, with the aim of achieving the best possible standard of health.

4.41 With regard to the enforceability of the above responsibilities, it is relevant that the State is under an obligation of effort,[105] see Article 2(1) IVESCR which reads, "Every State Party to the present Convention undertakes to take measures, both independently and within the framework of international assistance and cooperation, particularly in the economic and technical fields, and making full use of the resources available to it, with a view to achieving, by all appropriate means, in particular the

[104] CESCR, General comment No. 14, para. 35.

[105] Indeed, CESCR, General Comment No. 3 (1990) notes in paragraph 1: "Those obligations include both what may be termed (following the work of the International Law Commission) *obligations of conduct* and *obligations of result*." (emphasis added)

introduction of legislative measures, ever closer to the full realisation of the rights recognised in the present Convention."

4.2.2.4 Conclusion

4.42 The right to life, in the sense of protecting life and/or being able to enjoy a dignified life, has been recognised in case law as a human right in the context of healthcare. The right to health is also a recognised human right. In that case, it concerns the right to access (literally) health care as well as health care services at the highest attainable standard of health. In this context, four elements are essential: (i) availability, (ii) accessibility, (iii) acceptability and (iv) quality of healthcare.

4.43 It follows from case law that these human rights are usually invoked in a legal relationship between citizen(s) and the state, and that almost always (positive law) obligations of the state are central. This case law gives a clear indication of how far the protection of human rights extends in individual cases.

4.2.3 Corporate Responsibility and Business and Human Rights

4.2.3.1 Introduction

4.44 This section discusses the standards of conduct on 'corporate responsibility' and 'business and human rights'.

4.45 Both concepts are references to 'responsible business' in a broad (international) sense and are also sometimes referred to as IMVO (international corporate social responsibility). This means that a company should not only pursue the goal of creating shareholder value, but also aim to protect other interests that may be directly or indirectly affected by the company's actions. These may include the interests of workers in the production chain or consumer or environmental interests. In those cases, making profit is a means to achieve those other (socially responsible) goals as well.

4.46 That companies, especially multinational companies, could and should behave more socially is not something of yesterday. The OECD recognised this as early as 1976 and the United Nations in 2011. Both organisations provide a set of principles and standards for responsible corporate behaviour in a global context. The OECD Guidelines for Multinational Enterprises in particular are clear and provide guidance for companies to deal with issues such as chain responsibility, human rights, child labour,

environment and corruption. Although these international guidelines are not legally binding as yet, they have been given a place in the EU SRI Framework Regulation, among others. This has made the guidelines legally enforceable for the purposes of that regulation. Also, if companies themselves state that they comply with these international guidelines, they can be held accountable for it in civilibus.

4.47 In this context, it is also relevant that at Union level, on 23 February 2022, a proposal was published for a Directive on Corporate Sustainability Due Diligence and amending Directive (EU) 2019/1937, the so-called Corporate Sustainability Due Diligence Directive.[106] The proposal provides an EU legal framework for sustainable corporate governance, including due diligence obligations for companies that looks at their global supply chain(s). The European Council also called on member states, in line with their competences and national circumstances, to step up their efforts to effectively implement the UN Guiding Principles on Business and Human Rights, including through new or updated national action plans containing a mix of voluntary and mandatory measures.[107] Several countries, including the Netherlands, are implementing this through legislation.[108]

4.48 These developments underline that not only the government is responsible for protecting public interests, but that companies have an independent responsibility to do so as well. A parallel responsibility is increasingly clearly emerging and 'civil society' is actually enforcing the fulfilment of those responsibilities in court.[109]

4.49 The following, to the extent relevant to this case, discusses the the above-mentioned OECD guidelines and UN guidelines. It concludes with a conclusion.

4.2.3.2 OECD guidelines for multinational enterprises

4.50 The OECD Guidelines for Multinational Enterprises (hereinafter **OECD Guidelines**, **Production 10**), as mentioned, date back to 1976 and have been updated a number of times, most recently in 2011 when the United Nations published its Guiding Principles on Business and Human Rights, about which more below in section 4.2.3.3.

[106] COM(2022) 71 final.

[107] Council of the EU, *Council of the European Union, Council Conclusions on Human Rights and Decent Work in Global Supply Chains*, Brussels, 1 December 2020.

[108] Netherlands, Proposal for a Responsible Sustainable and International Business Act (Parliamentary Papers II 2020-2021, 35 761, no. 2), the Explanatory Memorandum refers to an overview of international legislation and legislative initiatives, Parliamentary Papers II 2020-2021, 35 761, no. 3, p. 12 and 13.

[109] Examples are that of Stichting Urgenda v State (ECLI:NL:HR:2019:2006) and Milieudefensie c.s. v Royal Dutch Shell (ECLI:NL:RBDHA:2021:5337).

4.51 The OECD guidelines aim to ensure that the activities of multinational enterprises are consistent with government policies, strengthen mutual trust between enterprises and the societies in which they operate, improve the investment climate for foreign companies and enhance the contribution of multinational enterprises to sustainable development. While the guidelines contain legally non-binding principles and standards for corporate responsibility, they are authoritative and countries that subscribe to the guidelines enter into a binding obligation to implement them. In that context, the guidelines provide, among other things, a dispute resolution system; so-called National Contact Points provide information on the guidelines on the one hand, and handle reports from individuals, civil society organisations and companies that have a disagreement on the application of the guidelines on the other.

4.52 The OECD guidelines contain a chapter of general principles for corporate policy and nine thematic chapters, namely: Disclosure, Human rights, Employment and industrial relations, Environment, Combating corruption, bribery solicitation and extortion, Consumer interests, Science and technology, Competition, and Taxation.

4.53 Central to the OECD Guidelines is the concept of due diligence. Due diligence is an ongoing process that commands companies to identify and then address or prevent risks in areas such as human rights.

4.54 With regard to human rights, companies belong to the OECD Guidelines (Chapter IV):

(1) Respect human rights, which means that they should prevent violations of third parties' human rights and address adverse effects involving them.
(2) In the course of their own activities, prevent causing or contributing to adverse human rights impacts and address such impacts when they occur.
(3) Seek ways to prevent or reduce adverse human rights impacts when these impacts are directly linked to their business activities, products or services through a business relationship, even if they themselves do not contribute to these impacts.
(4) Have a policy on ensuring respect for human rights.
(5) Conduct human rights due diligence as appropriate in light of their size, the nature and context of activities and the severity of risks of adverse effects on human rights.
(6) Through legitimate procedures, provide for, or cooperate in, addressing adverse human rights impacts where they determine that they have caused or contributed to such impacts.

4.55 It follows from Chapter III (disclosure) that companies that claim to comply voluntarily with codes of conduct and make declarations about their ethical values should also disclose the results in relation to those codes and declarations.[110]

4.2.3.3UN Guiding Principles on Business and Human Rights (UNGP)

4.56 The UN Guiding Principles on Business and Human Rights are more commonly known under the English-language title *UN Guiding Principles on Business and Human Rights* (hereafter **UNGP**) (**Production 11**). They are also sometimes referred to as the 'Ruggie Principles', named after the UN rapporteur concerned, John Ruggie.

4.57 The UNGP describes the duty of governments to protect human rights and the responsibility of businesses to respect human rights.[111] The UNGP introduced the term *Business and Human Rights* and established international recognition that companies have a concrete responsibility towards human rights. The UNGP does not state that companies, like states, must protect human rights, but the due diligence obligations in the UNGP do extend beyond a mere negative obligation for companies to respect human rights.[112]

4.58 The UNGP, like the OECD guidelines, are not binding, but authoritative and not non-binding. The principles are based on internationally recognised guidelines and treaties. In addition, the principles were unanimously adopted by the UN Human Rights Council and apply to all UN countries. This gives the UNGP a high standing. The principles are expected to be incorporated into more and more national and international regulations in the coming years (see above section 4.2.3.1).

4.59 The UNGP states that companies must respect human rights. This means that they must prevent human rights of others from being violated and address the negative human rights impacts they face.[113] It follows from the explanation that this obligation explicitly applies irrespective of the obligations of the state. The duties for the state on the one hand and companies on the other therefore exist independently and side by side. Therefore, companies cannot hide behind the state when it comes to human rights, at least not if their actions have a negative impact on human rights.

[110] Chapter III, clause 3 and notes No 34 and No 35.

[111] UNGP, Chapter I and Chapter II, respectively.

[112] UNGP, Chapter III.

[113] UNGP, Principle 11: "Business enterprises should respect human rights. This means that they should avoid infringing on the human rights of others and should address adverse human rights impacts with which they are involved."

4.60 Corporate responsibility relates to internationally recognised human rights including those from the UDHR, ICCPR and ICESCR. [114]

4.61 Importantly, companies should develop policies and procedures to meet their responsibilities. These include a policy statement, a due diligence mechanism and a mechanism that provides for compensation for damages resulting from human rights violations they cause or contribute to.[115]

4.2.3.4 Conclusion

4.62 As explained above, it is generally accepted internationally that companies must respect (honour) human rights. The OECD Guidelines and the UNGP do not oblige companies to (actively) protect human rights as might be expected of states, but the due diligence obligations that these guidelines impose on companies do extend beyond a mere negative obligation. After all, companies are required to develop policies and procedures by which they can fulfil their human rights responsibilities. In that context, they are expected, among other things, to compensate any harm resulting from human rights violations they cause or contribute to.

4.63 Companies that claim to adhere to the OECD guidelines and/or the UNGP can be called to account in civil law. But even if they do not espouse these principles, they can be held accountable in civil law for complying with the standards set out in those guidelines that are widely accepted internationally.[116]

4.2.4 DISPLACEMENT OF CARE BY ABBVIE

4.64 In this section, FTV looks specifically at the extent of the adverse effects that AbbVie has brought about on statutory insured basic care in the period 2004 to 2018.

4.65 FTV alleges that AbbVie breached its social duty of care by failing to charge a socially acceptable price for Humira in the period 2004 to 2018, in violation of the widely accepted international standards relating to corporate social responsibility as set out in the OECD guidelines and the UNGP, and the privileges that AbbVie enjoys as a company and with which it can participate in economic life.

[114] UNGP, Principle 12.
[115] UNGP, Principle 15.
[116] Rb. The Hague 26 May 2021, RDS, ECLI:NL:RBDHA:2021:5337.

4.66 Below, FTV first sets out what is to be understood by a socially acceptable price of a drug. FTV then substantiates that AbbVie did not use such a price in the period 2004 to 2018.

4.2.4.1 Socially acceptable price for medicines

4.67 In the Medical Affairs Minister's letter of 12 February 2021 on Medicines Policy, the minister articulates the government's policy. The letter states that the price of a medicine is socially acceptable if: (1) the medicine is cost-effective (the health outcomes are proportionate to the additional costs), (2) the price is reasonable and proportionate to the efforts and investments made to arrive at the medicine, and (3) the price provides sufficient room for innovation.[117]

4.68 On these principles, the minister provides a clear explanation, which reads (underlining lawyer):

> "These three elements must be balanced to get affordable innovation done, where the added value of the innovation for patients is worth the extra cost from the healthcare budget. This is a delicate balance. For example, a price that is cost-effective in itself may still not be acceptable if the volume combined with the high price leads to blockbusters with high profits that far exceed investment. There is then excessive pricing from the healthcare payer's perspective because only a fraction of the price paid is actually related to innovation and production. And even if the elements seem in balance with each other, there may still be a limit to what is affordable. After all, the expenditure has to be financed from a limited healthcare budget and may crowd out other forms of care. After all, for the budget of one expensive drug, we might be able to treat many more patients with another intervention that delivers more health benefits overall."

4.69 FTV argues that Humira, in the period 2004 to 2018, did not meet the abovementioned balance. Not even assuming that Humira was offered at a cost-effective price in itself during that period. Below, FTV provides an estimate of the extent of displacement of legally insured basic care - expressed in euros - in the period 2004 to 2018.

4.2.4.2 Estimated extent of displacement of legally insured basic care in the period 2004 to 2018

[117] Parliamentary Papers II 29 477, 696, p. 27.

4.70 Given the pricing of Humira in the period 2004 to 2018, FTV explains below how it arrived at an estimate of the extent of displacement of legally insured basic care in that period. FTV does this by first estimating the 'excess profit' achieved by AbbVie with Humira in the Netherlands that did not benefit legally insured basic care. FTV compares the excess profit with what legally insured basic care could have been offered before and how this excess profit has/can have affected the budget space of healthcare providers and thus the availability of legally insured basic care. FTV also explains how many healthy life years were (in theory) lost by not using the excess profit for healthcare treatments, and, finally, how many additional drugs AbbVie could have developed and marketed with the excess profit gained.

4.71 FTV stresses that it does not intend this estimate to concretely reflect the actual extent of damages suffered by victims. The estimate below and its justification only underline that it is realistic to assume that damages have been suffered, and that these damages, assuming a conservative calculation, have been substantial.

4.72 As mentioned, ZA (Consultant firm *Zorgvuldig Advies*) was commissioned by FTV to conduct an economic analysis of potential displacement of legally insured basic care due to the pricing and profit margins of the drug Humira (Production 7).

4.73 The period studied covered 2004 to 2020, therefore from the first year of Humira's introduction to the Dutch market. After 2018, the patent rights to Humira in the Netherlands expired and the drug's revenues declined sharply. Revenue was still over EUR 203 million in 2018, only EUR 49 million in 2019 and EUR 35 million in 2020. Because FTV argues that AbbVie acted unlawful during the period when Humira was protected by patent rights (2004 to 2018), the report mentions the extent of displacement during that period separately.

4.74 In Chapter 3 of the report, ZA outlined its research methodology.

a) Calculation and estimation of excess profit

4.75 First, ZA mapped the sales AbbVie estimated to have made with Humira in the Netherlands. The researchers relied on publicly available data. Any discounts granted by AbbVie when selling Humira were not deducted from the estimated turnover. Besides the fact that discounts are secret, ZA considered it too uncertain a factor to take into account in the calculations. Incidentally, it follows from the ACM Sector

Inquiry that net purchasing prices hardly changed until biosimilars entered the market.[118]

4.76 ZA then identified the (attributable) costs of Humira and deducted them from turnover. In doing so, it distinguished between so-called production and sales costs and research and development costs.

4.77 With regard to production and sales costs, ZA applies a range between what AbbVie itself claimed before the US Congress - namely, 11% of the sales AbbVie achieved with Humira - and the average cost used by the US Census Bureau for statistics for US drug manufacturers - namely, 40.7% of the relevant sales achieved.

4.78 Regarding R&D costs, ZA took the R&D costs reported by AbbVie, before the US Congress, in the period 2009 to 2018 and converted them into average annual costs, which it then allocated to the period under investigation. In doing so, ZA also attributed the entire acquisition sum for Knoll (US$6.9bn) to R&D costs, while Knoll itself was already generating sales of around US$2bn a year during that period.[119] Converted, R&D costs in that case amount to 10.7% of the relevant turnover achieved. ZA notes that the literature usually assumes a considerably lower average of R&D costs.

4.79 Next, ZA assumes that AbbVie could count on an "expected profit margin" of 25% of sales. This percentage is a robust estimate based on public sources it consulted. What remains is what ZA calls 'other profit' and is the portion of the surplus (sales minus costs) that provides insight into the degree of displacement.

4.80 Based on the estimated[120] turnover in the patent period 2004 to 2018 of EUR 2.3 billion, the above provides the following picture.

4.81 Depending on the percentage of costs used (40.7% and 11% of turnover respectively), ZA estimates the 'other profit' in the Netherlands, in the period 2004 to 2018, to be at

[118] Production 6, para 3.2, p. 19/37.

[119] In Aspen (10 February 2021, case AT.40394), the Commission considered in para. 157 that it is conceptually incorrect to treat the acquisition price as a relevant (production and sales) cost of the product: "[M]oreover, since the acquisition price should be interpreted as largely a transfer of expected future profits from GSK to Aspen, and not as the valuation of specific tangible or intangible assets acquired by Aspen, it would be also conceptually incorrect to treat the acquisition price as a relevant cost of production or cost of supplying the product, within the meaning of Limb 1 of the United Brands judgment."

[120] AbbVie has only disclosed figures on global sales of Humira and not Humira sales in the Netherlands (see also Production 7, p. 21).

least between (over) EUR 531 million (i.e. over 23% of Dutch turnover) and rounded EUR 1.2 billion (or 53% of Dutch turnover).

4.82 The graphs below further outline the 'breakdown' of revenue, costs and 'other profit' for the different scenarios (see Production 7, p. 27, figures).

Figure 1: Total costs, R&D expenditure, 'expected profits' and 'other profits' from 2004 to 2018

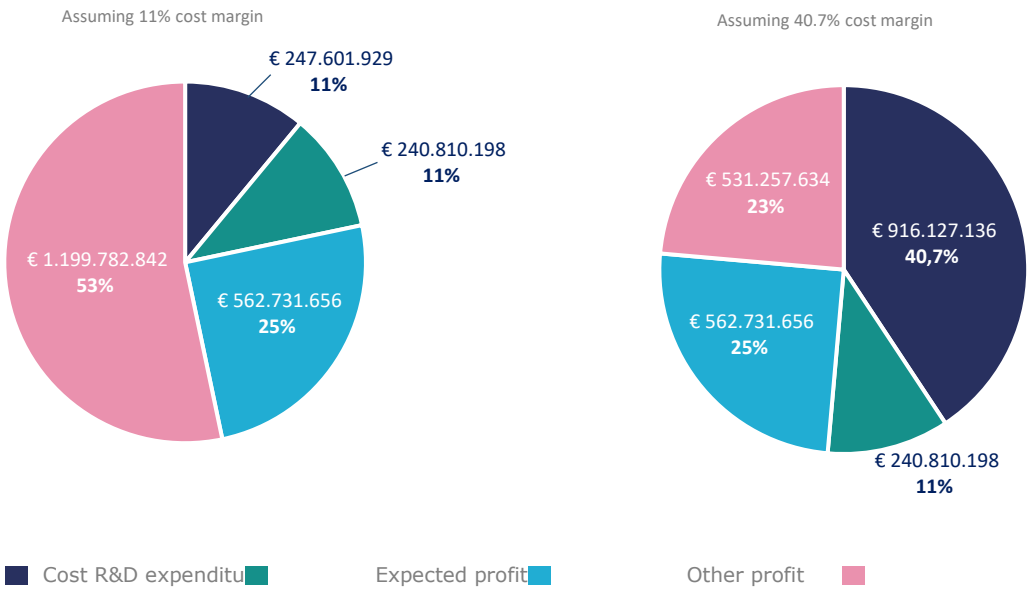
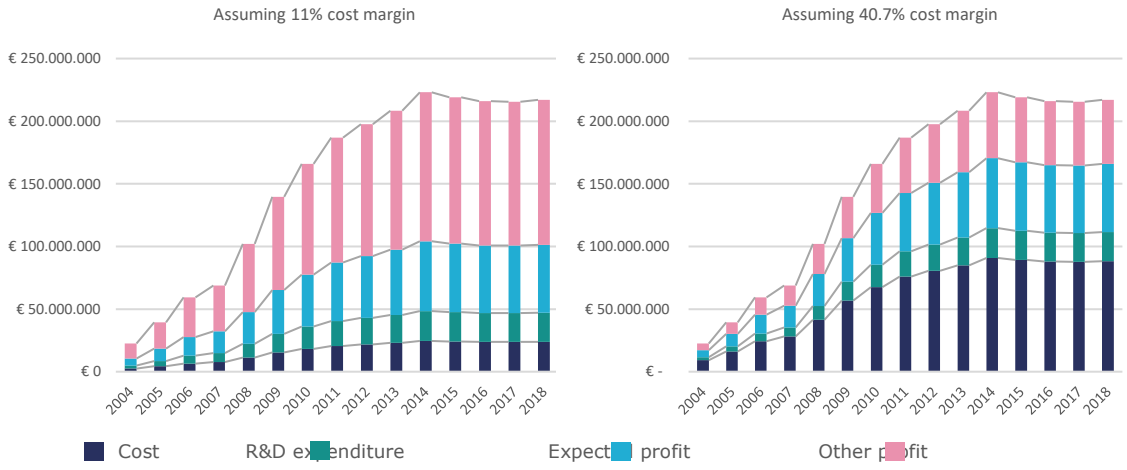


Figure 2: Total costs, R&D expenditure, 'expected profits' and 'other profits' from 2004 to 2018, by year



b) Legally insured basic care instead of excess profits

4.83 For comparison and further interpretation of the displacement effect of the calculated 'other profit', the minimum calculated 'other profit' was equal to the HagaZiekenhuis' turnover in 2018. At HagaZiekenhuis, 28,514 admissions, 54,840 emergency consultations and 46,544 surgical operations took place at that time. In the maximum calculated scenario, the 'other profit' is more than the turnover achieved by Amsterdam UMC, location AMC, in 2018. This academic hospital, with 7,083 employees, achieved a turnover of EUR 1.1 billion (see Production 7, p. 32). The remaining profit could therefore have been used for one year to provide all the care offered by a general or academic hospital (in the minimum and maximum scenarios, respectively).

4.84 The 'other profit' could also have significantly reduced the issue of unequal access to certain (expensive) drugs, so-called postcode medicine. To illustrate this point, FTV refers to a 2015 report in the trade magazine Zorgvisie (**Production 12**). In it, it is stated that due to lack of budget, hospitals often do not prescribe cancer drugs such as Avastin according to guidelines for the treatment of metastatic colorectal cancer. A more recent publication in the trade journal Medisch Contact (21 January 2021, **Production 13**) confirms the same issue for the treatment of metastatic colon cancer.

4.85 Nor can it be ruled out that hospitals would not have had to close departments or could have kept them operational for longer if they had experienced less budget pressure. If the 'remaining profits' had not leaked out of the healthcare system to AbbVie, health insurers would have been able to use the extra financial room to give targeted incentives to tackle these problems.[121]

c) Healthy life years lost and medicines missed

4.86 The 'other profit can also be translated into 'opportunity cost', or the value of what is lost when choosing between two or more options. It is partly on the basis of this economic principle that the maximum rate of new expensive drugs that can provide a year of life in good health (in jargon: QALY, Quality Adjusted Life Year) is determined. [122] Also in the Aspen case (abuse of a dominant economic position), the UK pointed out that the available healthcare budget is limited and the 'opportunity cost' was expressed in QALYs.[123]

[121] See also Production 7, pp. 32 to 34.

[122] The value of care is often measured in QALYs. The QALY is a generic measure of the (added) value of care (expressed in terms of lifespan and quality of life), which can be used broadly: in principle, it can be calculated for each care treatment how many healthy life years it adds.

[123] Commission 10 February 2021, Case AT.40394 - Aspen, pt. 194.

4.87 In the Netherlands, an amount of EUR 80,000 is used as the QALY standard. Above this financial limit, in principle, new expensive drugs that offer one life year in good health are not reimbursed and made available. In those cases, such a life year is lost as an 'opportunity'. Incidentally, this does not mean that a QALY always costs EUR 80,000; there are plenty of life-saving drugs that cost considerably less, such as antibiotics. So the QALY standard is explicitly a maximum standard.[124] In its study, ZA calculated with a marginal cost-effectiveness/QALY of EUR 73,600. In doing so, it relied on the report *Verdringseffecten binnen het Nederlandse zorgstelsel* (2018).[125]

4.88 Here, displacement is related to the economic concept of 'opportunity cost' and is defined as health lost on balance, expressed in QALYs, as a result of the inclusion of a new medical technology in the insured package. An econometric model was used to determine a marginal cost-effectiveness of EUR 73,600 as an average point estimate for all hospital care. This implies that the inclusion of new medical technologies in the insured package with a higher cost-effectiveness ratio than EUR 73,600 increases the likelihood of displacement of care. This will result in less efficient care in the Netherlands

4.89 The 'other profit' AbbVie made leaked out of the healthcare system; no care was provided for that amount. Now suppose that care had been provided for that amount, then - according to the QALY standard (used by ZA) - in the minimum scenario (rounded off) 7,200 healthy life years could be 'bought', and in the maximum scenario (rounded off) 16,300 healthy life years (Production 7, p. 34). By not spending the 'remaining profit' on care, these numbers of healthy life years are minimally lost.

4.90 Continuing this thought on opportunity costs, the question also arises to what extent AbbVie could have promoted societal health with Humira revenues, in terms of pharmaceutical innovations. Since AbbVie operates in a global market and develops innovative products for it, this may be based on Humira's global revenues.

4.91 Estimates on the cost of developing new drugs - including failures - vary widely. The Council for Public Health & Society, in its opinion *Developing new drugs - Better, faster, cheaper* (2017), states that these estimates range from EUR 900 million to EUR

[124] This reference value is relatively high, by the way. There is research that estimates the average price of one QALY in all Dutch care at less than EUR 20,000. And for cardiovascular hospital care, it is estimated at EUR 41,000. This means that reimbursing (new) care at a reference value of EUR 80,000 per QALY increases the risk of crowding out other care. See also section 3.2.2.

[125] E. Adang et al, *Verdringingseffecten binnen het Nederlandse zorgstelsel* (commissioned by ZIN), Nijmegen 2018, p. 11 and 40. (available at: https://www.zorginstituutnederland.nl/publicaties/publicatie/2018/04/17/verdringing-binnen-de-ziekenhuiszorg, among others)

2.6 billion.[126] Based on the highest estimate, the development costs of new medicines in 2020, with inflation factored in, would be around EUR 2.78 billion.[127]

4.92 Assuming total global Humira sales, from 2004 to 2018, of over EUR 108 billion, AbbVie achieved a global 'other profit' of rounded EUR 25.5 billion[128] under the '40.7% cost' scenario and a global 'other profit' of rounded EUR 57.7 billion under the '11% cost' scenario.[129] For these amounts, AbbVie could have developed and brought to market at least 9 and 20 new drugs - extra - respectively. It did not do this: AbbVie developed a total of only six new drugs in that period.[130]

4.2.4.3 Conclusion

4.93 To control collective healthcare spending, it is estimated and budgeted annually. These are determined in a democratically legitimised process; the financial resources available for health care are thus guaranteed as a public good (see section 3.2.6).

4.94 In short, the annual care provided, which is available to Dutch society, is the outcome of an allocation issue. What is reimbursed to one cannot be spent on the other. This means that if the demand for care exceeds the available care budget - which is the case - there is, by definition, (some degree of) displacement of care. Unfair prices of medicines promote such displacement.

4.95 FTV explained that the state can only rudimentarily try to influence the price of drugs and has no effective tool to force a drug manufacturer to charge a lower price for its patented drugs for which there are no or few substitutes (see section 3.2.6). The starting point is that a drug manufacturer itself determines the price at which it wants to market the drug. The price at which the manufacturer has obtained admission to the basic package - the manufacturer can control that price to a large extent himself -

[126] Public Health & Society Council, Opinion *Development of new medicines - Better, faster, cheaper*, 2017, p. 20.
[127] SiRM, L.E.K. Consulting & RAND Europe, in their study *The Financial ecosystem of pharmaceutical R&D: An evidence base to inform further dialogue*, 2022, assume an amount of $2.4 - $3.2 billion that a single approved drug costs the system on average, which includes costs for drugs that do not reach the market and capital costs. For the R&D performer, the average direct R&D cost of developing a single drug is $280 - $380 million (see p. 6 and para 2.3 of their report, available at: www.sirm.nl and www.lek.com). However, the development costs of EUR2.78 billion for a new drug used in this subpoena (and the ZA report) are still within the range of the latter study.
[128] Turnover - R&D (10.7% turnover) - production-sales costs (40.7% turnover) - expected profit (25% turnover): 108 - 11.5 - 44 - 27 = EUR 25.5 bln.
[129] Turnover - R&D (10.7% turnover) - production-sales costs (11% turnover) - expected profit (25% turnover): 108 - 11.5 - 11.8 - 27 = EUR 57.7 bln.
[130] According to the drug information database, AbbVie launched six innovative drugs (besides Humira) from 2003 to 2018, namely: Exviera, Maviret, Venclyxto, Viekirax, Chirocaine and Duodopa. However, the latter two drugs were acquired by AbbVie through acquisition and, moreover, had been developed before 2003.

gives him a strong negotiating position towards healthcare providers and/or health insurers. A manufacturer's negotiating position is further strengthened if he has been able to establish various exclusivity rights to his medicine, such as patent rights and data exclusivity rights.

4.96 In section 3.4.3, FTV explained that and how AbbVie, during the period when Humira was subject to patent rights, fully pursued its private interests. In the period 2004 to 2018, AbbVie is estimated to have achieved total net sales of EUR 2.3 billion with Humira in the Netherlands. During the same period, AbbVie is said to have invested an overstated EUR 241 million in R&D (10.7% of net sales), compared with sales achieved in the Netherlands.

4.97 At an expected profit rate of 25% of net sales, at a cost rate of 40.7% of net sales, the 'other profit' in that period amounted to at least (well over) EUR 531 million, and at a cost rate of 11% of net sales an amount of at least rounded EUR 1.2 billion. See above *Figure 1*, paragraph. 4.82.

4.98 With demand for care in the Dutch healthcare system outstripping the available healthcare budget and, by definition, causing (some degree of) displacement of care, AbbVie's 'other profits' leaked from the healthcare system equate to a degree of that displacement.

4.99 FTV had the degree of displacement of care by 'other profits', in the period 2004 to 2018, quantified in two scenarios. In one scenario, for instance, this could have involved one year of all the care offered by a general hospital, and in the other, one year of care offered by a teaching hospital.

4.100 Furthermore, if the 'other profits' had been spent on legally insured basic care, the practice of postcode medicine by hospitals, for example for colon cancer treatment, could have been largely avoided.

4.101 Also, in the healthcare system, for the entire patient population, that amount would have resulted in a minimum of over 7,000 healthy life years and a maximum of over 16,000 healthy life years.

4.102 Finally, AbbVie could have used the 'other profits' to develop at least between 9 and 20 *additional* new drugs; i.e. on top of the six drugs it developed in the 2004 to 2018 patent period. By withholding the opportunity to develop these additional drugs - and

otherwise withholding the 'remaining profits' from the healthcare system - AbbVie prevented or limited access to potentially available care.

4.103 The above concrete examples of forms of healthcare displacement in the Dutch healthcare system would not have occurred if AbbVie had charged a lower price for Humira.

4.2.5 SPECIAL POSITION OF ABBVIE IN SOCIETY AND THE ECONOMY

4.104 In the purely private sphere, individuals and private companies are in principle free to define and pursue exclusively their own goals. However, the freedom to pursue private interests in this way is not unlimited. Companies - including pharmaceutical companies - are regularly called to account in the media today for their 'social responsibility'. Especially when their actions have a negative impact on public interests. [131]

4.105 An example of such a negative consequence is the pollution of the environment by a company that, strictly speaking, does not violate applicable environmental regulations, but whose actions cause damage and/or mitigation costs to third parties and/or society as a whole. Economists refer to such a situation as 'externalities', or market supply and demand inefficiencies that give rise to unintended negative effects. These are then costs incurred or damages suffered by third parties as a result of an economic activity, for which those third parties are not compensated.[132]

4.106 It is now widely accepted internationally that private companies have independent obligations in complying with public standards. In that framework, the OECD guidelines and UNGP discussed above play a major role. The normative framework of the OECD guidelines and UNGP also fleshes out the unwritten standard of care of Section 6:162 of the Civil Code.

4.107 The issue of externalities is not limited to climate and/or environmental issues. In this case, the issue makes itself felt in relation to the functioning of the healthcare system. In FTV's view, the 'corporate responsibility' obligation applies in particular to drug manufacturers who, when exercising their actions, may have negative effects on the public interest.

[131] NRC 25 July 2019, Claassen and Sluijs, *Companies have great influence - that comes with duties*; FD 23 September 2019, Toebes and Sluijs, *Pharma companies must act on social duty of care*.

[132] Private action can also have *collective positive effects* (positive externalities). For example, companies invest in good infrastructure or skilled labour when they locate somewhere. This improves the location climate for other companies, which have not had to pay for those investments.

4.108 With the price of Humira during the period when the drug enjoyed patent protection in the Netherlands (2004 to 2018), AbbVie managed to serve its private interests - and those of its shareholders - to the best of its ability by charging a price that led to extreme excess profits. At the same time, that same price promoted the displacement of legally insured basic care and consequently hampered access to legally insured basic care. For example, healthcare treatments that were in need could not be offered because of Humira's pricing. With its pricing, AbbVie attracted a disproportionate share of the available care budget.

4.109 This pricing cannot be justified in any way: not by the costs incurred, not by the investments made, not by the risk taken, nor by R&D costs. In this regard, FTV notes that, compared to other drug makers, AbbVie has not done this. In the period 2003 to 2018, AbbVie launched only six new drugs.[133]

4.110 Nor does the fact that the drug Humira could potentially be described as cost-effective on an individual level detract from the collective adverse effects that its pricing has caused for years - i.e. the legally insured basic care it has displaced or impeded access to. In section 3.4.3, FTV explained how AbbVie took full advantage of its privileges, pursuing its own private interests and hardly delivering on the promise it makes to society in the context of (international) corporate social responsibility.

4.111 In summary, FTV concludes that AbbVie, as a biopharmaceutical company, occupies a special position in the social and economic sphere, and that it has used (unfair) pricing for Humira in the period 2004 to 2018 that has actually and foreseeably led to the displacement of legally insured basic care.

4.2.6 CONCLUSION : ABBVIE ACTS IN BREACH OF SOCIAL DUTY OF CARE

4.112 Section 4.2.2.4 concluded that the right to life, in the sense of protecting life and/or being able to enjoy a dignified life, has been recognised in case law as a human right in the context of health care. The right to health is also a recognised human right. In this case, it concerns the right to access (literally) healthcare as well as healthcare services at the highest attainable standard of health. In this context, four elements are essential: (i) availability, (ii) accessibility, (iii) acceptability and (iv) quality of healthcare.

[133] According to the drug information database, AbbVie launched six innovative drugs (besides Humira) from 2003 to 2018, namely: Exviera, Maviret, Venclyxto, Viekirax, Chirocaine and Duodopa. However, the latter two drugs were acquired by AbbVie through acquisition and, moreover, had been developed before 2003.

4.113 As described above, the pricing of Humira promoted the displacement of legally insured basic care and consequently unacceptably impeded access to legally insured basic care, except for the care for which Humira was used. This establishes the adverse effects on the above four elements and thus also establishes that AbbVie adversely affected human rights with that price.

4.114 AbbVie has a social duty of care to eliminate or mitigate these adverse effects. This duty of care is based on a social standard of care that can be defined in particular on the basis of the widely accepted international standards on corporate social responsibility as laid down in the OECD guidelines and the UNGP, and the privileges that AbbVie enjoys as a company and with which it can participate in economic life.

4.115 It can be inferred from the OECD Guidelines and the UNGP that it is generally accepted internationally that companies, such as AbbVie, must respect human rights, as enshrined in the ECHR. The responsibility to respect human rights means that companies must refrain from infringing on the human rights of others and prevent, mitigate and, where necessary, eliminate negative impacts on human rights in which they have a stake. This corporate responsibility is not optional. It applies everywhere and regardless of the local legal context and is not passive.[134]

4.116 The responsibility of companies to respect human rights applies to all companies regardless of size, sector, operational context, ownership and structure. However, the scale and complexity of the means by which companies fulfil that responsibility may vary according to these factors and the severity of the impact their activities may have on human rights.[135] The means by which a company fulfils its responsibility to respect human rights will be proportional to, among other factors, the size of the organisation. The seriousness of the impact on human rights will be assessed based on its scale, scope and degree of reversibility. What means a company uses to respect human rights may also depend on whether and to what extent it operates within a group or autonomously. [136]

4.117 In view of what FTV has put forward above, the conclusion is that AbbVie has not sufficiently complied with these widely accepted international standards. AbbVie, by pursuing its private interests, caused and magnified negative human rights impacts and did not, or at least inadequately, eliminate those impacts.

[134] Rb. Den Haag 26 May 2021, RDS, ECLI:NL:RBDHA:2021:5337, paras 4.4.14 and 4.4.15.

[135] Rb. Den Haag 26 May 2021, RDS, ECLI:NL:RBDHA:2021:5337, para 4.4.16 and UNGP, Principle 14.

[136] Rb. Den Haag 26 May 2021, RDS, ECLI:NL:RBDHA:2021:5337, para 4.4.16 and UNGP, Principle 14 Commentary. Cf. also OECD Guidelines, Chapter IV (Human Rights) and its commentary.

4.118 The negative effects on human rights manifested themselves in the displacement of a large amount of available legally insured basic care in the period 2004 to 2018; legally insured basic care to which access, due to the pricing of Humira, was denied. By acting in this way, AbbVie breached the unwritten standard of care referred to in Section 6:162(2) of the Dutch Civil Code.

4.3 Breach of competition law : abuse of dominant economic position

4.3.1 INTRODUCTION

4.119 In this paragraph, FTV reasons that AbbVie, despite having valid patents on Humira in the period 2004 to 2018, abused its economic dominance by pricing Humira during that period.

4.120 Patents, such as those that were established on Humira, are protected by intellectual property law (**IP law**), in particular patent law.

4.121 On the one hand, patent law aims to reward inventive labour by providing exclusivity on being allowed to disclose and market the invention in question. On the other hand, patent law aims precisely to make the invention public - albeit in time - for the benefit of the general public. Consequently, a patented invention cannot be kept as a trade secret.[137] Rewarding inventive labour will encourage innovation.[138] Promotion of innovation is often cited in practice as an important element of patent law. In light of this case, an important notion is that patent law is neutral with respect to the pricing that the inventor charges for his invention.

4.122 Competition law aims to protect the competitive process, that is, the process of mutual rivalry under which firms compete independently for the favour of consumers. In this way, economic efficiency is sought to benefit consumers.

4.123 Article 24 Mw and (its equivalent in Union law) Article 102 TFEU prohibit companies from abusing a position of (economic) dominance if they have such a position on the Dutch and EU market respectively. One form of abuse within the meaning of Article 24 Mw and Article 102 TFEU is the imposition of unfair prices.

[137] B.M. Telders, *Nederlands Octrooirecht - Handboek voor de Praktijk*, Martinus Nijhoff, 1946, pp. 2 and 3.

[138] Telders expresses himself in more nuanced terms: "The rewarding of the inventor's work can, moreover, exert a socially useful, stimulating effect on the initiative and perspicacity of the individual, so that with the reward, in addition to justice towards the individual, a certain socially useful effect is also practised.

4.124 Given, on the one hand, the neutral position that patent law has with regard to pricing and, on the other, the prohibition in competition law of unfair pricing in cases of economic dominance, the two areas of law can 'collide' with each other. For example, when (as in this case) a drug manufacturer applies pricing for a patented drug that is unfair within the meaning of Article 24 Mw and Article 102 TFEU and therefore prohibited. From the point of view of patent law, this seems permissible and enforcing a lower price or having to compulsorily release the patent - leaving aside the imposition of a compulsory licence - would constitute a patent infringement. Nevertheless, in such a case, the finding of abuse of a dominant economic position will stand and cannot be set aside by invoking patent law.

4.125 The Court of Justice of the European Union (hereinafter: **Court**) already ruled in the late 1970s: "[...] although the Treaty does not affect rights acquired under the law of a Member State in the field of industrial and commercial property, the exercise of those rights may nevertheless be restricted by prohibitions under the Treaty in certain circumstances."[139] This includes the prohibitory provision of Article 102 TFEU.[140] In short, patent law does not give the holder carte blanche for unfair or excessive pricing of its product for which there is concrete demand.

4.126 The above means that, in the light of competition law, where there are allegedly unfair prices for patented medicines, there must be an assessment of, on the one hand, the need to reward dynamic efficacy and innovation and, on the other hand, to protect consumers and society from the harm that such prices cause them. [141,142]

4.127 Below, FTV first explains that AbbVie holds an economic dominant position with Humira (section 4.3.2) and then substantiates that AbbVie abused this (section 4.3.3).

4.3.2 ECONOMIC DOMINANCE

[139] ECJ 23 May 1978, ECLI:EU:C:1978:108 (Hoffmann-La Roche), pt. 6.

[140] The Court considered in Hoffmann-La Roche that an IP right may not be used as a means of abusing a dominant position (ECLI:EU:C:1978:108 (Hoffmann-La Roche), para 16).

[141] See also Report from the Commission to the Council and the European Parliament, *Enforcement of Competition Law in the Pharmaceutical Sector (2009-2017)*, COM(2019) 17 final, p. 31.

[142] In this context, the ACM's fine decision in the case on CDCA-Leadiant is also worth mentioning (Decision of 1 July 2021, case ACM/20/041239). CDCA-Leadiant is a life-saving drug for patients with cerebrotendinous xanthomatosis (CTX), a rare, inherited metabolic disease. In late 2014, drug manufacturer Leadiant obtained so-called orphan drug status and, in April 2017, marketing authorisation for the drug CDCA-Leadiant. This gave Leadiant 10 years of market exclusivity in the EU for CDCA-based drugs to treat CTX. After gaining market exclusivity, Leadiant started billing and collecting a much higher price of EUR 140 (including distribution fee). This new price was more than 15 times higher than the price of the drug before Leadiant started its project to obtain orphan drug status in 2014, and 500 times higher than the price of CDCA in 2008 in the Netherlands.

4.3.2.1 Introduction

4.128 According to established Union case-law and Article 1(i) of the Mw, a 'position of economic strength' means the position of one or more undertakings which enables them to prevent the maintenance of effective competition on the relevant market by affording them the possibility of behaving to an appreciable extent independently of their competitors, their suppliers, their customers or end-users.[143] However, an undertaking need not be able to eliminate every possibility of competition; the partial elimination of actual or potential competition is sufficient for a finding of dominance.[144]

4.129 The existence of a dominant position generally results from a combination of several factors, each of which may not necessarily be decisive.[145] Usually, high market shares are an indication of dominance, with the caveat that the meaning of market shares may vary from market to market.[146] Other important factors to consider when assessing dominance are the (im)possibilities of entry by competitors and the bargaining power of customers (countervailing buyer power). [147]

4.130 In summary, holding a dominant position presupposes that the undertaking can determine or significantly influence the conditions under which competition will develop, without being adversely affected (by competition).[148] The ability to behave independently, for example with regard to pricing and volume, vis-à-vis (potential) competitors and customers is therefore a decisive characteristic that an undertaking has a dominant position.[149]

4.131 The following first discusses delineation of the relevant product and geographic market for Humira (Sections 4.3.2.2 and 4.3.2.3, respectively). Next, the main conclusions of the ACM from its Sector Inquiry into TNF-alpha inhibitors in relation to Humira are considered (section 4.3.2.4). Following this, FTV substantiates in section 4.3.2.5 that AbbVie has an economic dominance with Humira.

[143] The Court also uses this definition and adopted it very early on, see ECJ 14 February 1978, ECLI:EU:C:1978:22 (United Brands), pt. 65, ECJ 13 February 1979, ECLI:EU:C:1979:36 (Hoffmann-La Roche), pt. 38. And more recently ECJ 6 December 2012, ECLI:EU:C:2012:770 (AstraZeneca), pt. 175 and Commission 10 February 2021, Case AT.40394 - Aspen, pt. 62 .

[144] ECJ 14 February 1978, ECLI:EU:C:1978:22 (United Brands), pt. 113.

[145] ECJ 14 February 1978, ECLI:EU:C:1978:22 (United Brands), pt. 66.

[146] ECJ 6 December 2012, ECLI:EU:C:2012:770 (AstraZeneca), pt. 176.

[147] Commission 10 February 2021, Case AT.40394 - Aspen, pt. 65.

[148] ECJ 13 February 1978, ECLI:EU:C:1979:36 (Hoffmann-La Roche), pt. 39.

[149] See, first, ECJ 14 February 1978, ECLI:EU:C:1978:22 (United Brands), pt. 65.

4.3.2.2 Relevant product market

4.132 In competition law, the relevant product market is defined as: the market comprising all products and/or services which are regarded as interchangeable or substitutable by the consumer, by reason of their characteristics, prices and intended use.[150]

4.133 According to the Court's settled case-law, it is not sufficient in this context to assess the interchangeability or substitutability of products and/or services on the basis of their objective characteristics, but the conditions of competition and the structure of supply and demand on the market must also be taken into account.[151]

4.134 In the provision of healthcare, the relevant product market is determined by the medical interchangeability of treatments. In the present context, however, the relevant product market is determined by the medical interchangeability between medicinal products for the indications for which Humira is suitable, as no alternative treatment exists for the indications in question.

4.135 However, the extent to which different medicines are considered medically interchangeable is not straightforward. It is determined in the force field of a government that determines which indications medicines are registered for, medical-scientific associations and other bodies that make recommendations regarding the interchangeability of medicines, hospitals and purchasing groups that develop policies based on their own surveys and literature studies, and finally the preferences of individual prescribers and patients.[152]

4.136 While medical interchangeability is a necessary condition, it is not an exclusive condition for two or more medicines to belong to the same product market. To belong to the same product market, medicines must also be able to exert and actually do exert significant competitive pressure on each other. Indeed, purchasers of medicines do not necessarily switch to a cheaper alternative, even if the cheaper alternative is interchangeable in a medical sense.[153]

4.137 In cancer drug cases, the Commission found that differences in efficacy, risks/side effects and the price of the drug are factors limiting therapeutic and/or economic

[150] Commission notice on the definition of the relevant market for the purposes of Community competition law (OJ 1997, C 372/5), pt. 7.
[151] ECJ 23 January 2018, ECLI:EU:C:2018:25 (Hoffmann-La Roche and Others), pt. 51 and the case-law cited therein.
[152] ACM Sector Inquiry, p. 13/37 (Production 6).
[153] See also Commission 10 February 2021, Case AT.40394 - Aspen, pt. 26 and 27.

substitutability.[154] There is no reason to suppose that the same elements are not also, in general, important for defining relevant markets for other (non-cancer) drugs.

4.138 With regard to the delineation of the product market of Humira (Adalimumab), the following now applies.

4.139 Adalimumab ranks with etanercept (brand name: Enbrel), infliximab (brand name: Remicade), certolizumab pergol (brand name: Cimzia) and golimumab (brand name: Simponi) among the five active substances within the drug group TNF-alpha inhibitors.

4.140 All five active substances are registered for the indications rheumatoid arthritis and arthritis psoriatica. In addition, adalimumab has the only registration for three other indications, infliximab is the only TNF-alpha inhibitor for two indications and etanercept for one indication.

4.141 The guidelines of medical specialists prescribing TNF-alpha inhibitors state that patients once on a particular active substance should be transferred to another agent only in case of failure of that therapy.[155] Medical reasons to do transfer a patient are (i) limited efficacy or (ii) relevant side effects. This means that the choice between different active agents is usually made once, namely at the time a patient is new, or at least has not previously been prescribed a TNF-alpha inhibitor.[156] It is a good principle among doctors to switch therapy only if there is a medical reason for doing so. As a result, interchangeability between biological originators - i.e. the original (patented) biological drugs - for the same indication is low. In practice, price does not appear to be a factor in choosing a particular originator at the first point of administration. Why this is so is discussed below, in section 4.3.2.5.

4.142 In the (potential) interchangeability between biologics, the method of administration also plays a major role. Drugs administered by infusion (intravenous), such as infliximab, are less sought after by patients than those that they can administer themselves with an injection pen (subcutaneous), as in the case of adalimumab and etanercept. For subcutaneous branded drugs, these have their own lancing pen, which may be perceived differently by patients.

[154] Commission 10 February 2021, Case AT.40394 - Aspen, pt. 29 and merger decisions cited therein: COMP/M.8523 - BD/Bard (18.10.2017), COMP/M.7559 - Pfizer/Hospira (04.08.2015), COMP/M.5999 - Sanofi Aventis/Genzyme (12.01.2011) and COMP/M.5865 - Teva/Ratiopharm (03.08.2010).
[155] https://richtlijnendatabase.nl/richtlijn/reumato_de_artritis_ra/biological_dmards_bij_reumatoide_artritis.html.
[156] ACM Sector Inquiry, p. 14/37 (Production 6).

4.143 So while there is hardly any medical interchangeability between biological originators (between active substances) once a patient uses them, there is interchangeability between originators and biosimilars. These are biologics that, after the patent on an originator expires, are marketed as alternatives. However, a biosimilar is never an exact copy of one, due to its complexity and use of biological sources. (Originators may also vary slightly from one production round to another for this reason). A biosimilar is therefore defined as a medicine with no clinically meaningful differences from the reference product.

4.144 The above leads to the conclusion that the product market of Humira at the time of patent protection must be very narrowly defined. It is possible that Humira even constituted its own product market.

4.3.2.3 Relevant geographical market

4.145 In competition law, the relevant geographic market is defined as: the area in which the undertakings concerned are involved in the supply and demand of goods or services, in which the conditions of competition are sufficiently homogeneous and which can be distinguished from neighbouring areas because the conditions of competition are appreciably different in those areas.[157]

4.146 The competitive conditions of supply and demand for pharmaceuticals differ between Member States, particularly as a result of different insurance/refund rules and different prescribing practices by doctors. The Commission has therefore defined the geographical market as 'national' in several decisions on pharmaceuticals.[158] For the same reasons and the fact that there are no indications of (significant) competitive pressure on Humira from abroad, the geographic market for Humira in this case should be defined as national (Dutch) territory.

4.3.2.4 Conclusions from ACM Sector Inquiry

4.147 In 2018-2019, the ACM conducted a sector enquiry into competition in TNF-alpha inhibitors. It published the results in September 2019 in the Report, *Sector enquiry TNF-alpha inhibitors - Competition before and after biosimilars entry* (Production 6).

[157] Commission notice on the definition of the relevant market for the purposes of Community competition law (OJ 1997, C 372/5), pt. 8.

[158] E.g. Commission 15 June 2005, Case COMP/A/37/507/F3 - AstraZeneca, pt. 503 and Commission 10 February 2021, Case AT.40394 - Aspen, pt. 59-61.

4.148 The ACM Sector Inquiry firstly shows that within the drug group of TNF-alpha inhibitors, the active substances adalimumab and etanercept (from manufacturer Pfizer) have the largest overlap with each other. Together, both drugs (biological originators) account for more than 90% of prescribed TNF-alpha inhibitors for rheumatological and dermatological conditions (rheumatoid arthritis and arthritis psoriatica, respectively) and each accounts for an almost equal share of the patient population. An advantage of adalimumab over etanercept is that the former does not need to be administered weekly, but only once every fortnight. That ease of administration can mark a dividing line in the relevant market is confirmed by the fact that infliximab was significantly cheaper than adalimumab and etanercept;[159] alone, therefore, the price for the same active ingredient is not decisive in exerting competitive pressure.

4.149 The ACM draws three relevant conclusions from the sector enquiry. [160]

I. In the pre-patent period, price competition between different active ingredients was limited

4.150 The ACM notes that net purchase prices paid by hospitals for TNF-alpha inhibitors barely fluctuated prior to the expiry of patents on the active ingredient, and on average, these net purchase prices were marginally below the pharmacy purchase price. An important part of the explanation for this limited price competition, according to the ACM, is the medical practice that existing patients are not switched to another active substance without medical considerations. Given the mostly chronic use of TNF-alpha inhibitors, this practice severely limits the scope for competition.

II. Competition from biosimilars causes substantially lower net purchase prices of TNF-alpha inhibitors

4.151 After the expiry of the active ingredient patents of three originators and the market introduction of biosimilars, discounts for hospitals reached more than 70% of the list prices of drugs with the same active ingredient. However, the speed and extent of price reductions varied by TNF-alpha inhibitor. For infliximab, the first of which (in 2015) patent protection ended, the price drop was initially gradual and eventually reached 60%. An even sharper and immediate price drop occurred after the biosimilar launch for adalimumab, whose patent protection ended last (in 2018).

[159] Production 6, p. 21/37 (Figure 3.3), p. 11/37 (Figure 3.5) and p. 25/37 (Figure 3.9).
[160] Production 6, p. 4/37.

III. Market share of biosimilars lags in subcutaneous administration

4.152 Despite the price pressure exerted by biosimilars, the market share of biosimilars lags in some cases. For two of the three TNF-alpha inhibitors for which biosimilars are on the market, the originator has managed to remain by far the largest provider for the time being. According to the ACM, there are several explanations for the limited entry of biosimilars.

4.153 First, switching patients to another drug involves costly effort for the hospital. This is especially true for agents that are self-administered by the patient using a lancing pen. Patients need to be educated and accustomed to a different lancing pen, and for some patients the switch may be too stressful. Consequently, hospitals do not achieve complete switchover with these agents; per hospital, a residual population of 5-20% of patients is usually left with the originator. Moreover, switching costs offer the originator a structural advantage: indeed, with equal net prices between originator and biosimilar, but with additional switching costs, hospitals are more likely to continue to choose the originator.

4.154 Another possible explanation for the limited entry of biosimilars is the conditional rebates used by originators. Such a discount system incentivises hospitals to continue using the originator's drug for a large proportion of patients. In fact, if a hospital does want to switch to a biosimilar, it is going to pay a much higher price for the group of patients who will not or cannot switch. This is because when switching, the discount on the list price expires in its entirety and the original drug will still be needed for the residual population. This too may make switching to a biosimilar financially unattractive for the hospital even if the biosimilar manufacturer offers a lower net purchase price than the originator. Incidentally, the ACM has put a stop to this methodology, or at least it managed to persuade AbbVie and Pfizer to stop using such conditional discounts after biosimilar introduction.[161]

4.3.2.5 Assessment of AbbVie's dominant position in the relevant market for Humira

4.155 To assess whether AbbVie has a (economic) dominant position in the relevant market with Humira, it is important that AbbVie was able to determine or significantly influence the conditions under which competition would develop, without being

[161] Resp. ACM news release of 24 September 2020, https://www.acm.nl/nl/publicaties/acm-sluit-onderzoek-naar-geneesmiddelenfabrikant-abbvie-nu-meer-ruimte-voor-concurrentie and ACM news release of 11 February 2022, https://www.acm.nl/nl/publicaties/geneesmiddelenfabrikant-pfizer-stopt-met-sturende-prijsstructuur-voor-enbrel-na-gesprekken-met-acm. ACM (commitment) decision, case ACM/20/041954 (unpublished).

adversely affected (by competition) (see above Introduction, section 4.3.2.1). Therefore, the obvious test question is: could AbbVie adopt and maintain the high pricing of Humira - which it did -[162] , because it was not forced by competition to moderate it? With this in mind, FTV notes the following.

4.156 During the period when Humira enjoyed patent protection, no (significant) competition with other biological originators existed, despite (potential) medical interchangeability in the field of some indications between adalimumab and other originators.

4.157 The lack of competition was primarily due to the fact that patients were not switched to another originator if there was no medical need to do so. As a result, patients once using an originator were kept 'captive' (trapped or 'locked in'); they use the drug in question, as a result of their chronic illness, indefinitely. Partly as a result, manufacturers experienced no incentive to compete with each other for the favour of new patients. After all, the number of new patients who can (theoretically) choose one of the biological originators every year is obviously smaller than the substantial group that can be kept captive for an indefinite period of time due to chronic disease.

4.158 Nor were manufacturers incentivised to lower their prices by hospitals' purchasing policies. Indeed, under the NZa policy rules and tariffs, any discounts provided by the manufacturer to a hospital were offset against the health insurer's reimbursement. Moreover, health insurers do not negotiate separate reimbursements with hospitals for the same treatment within a given patient group. In the case of treatment with Humira, this means that the same reimbursement is contracted for both the hospital's existing patients and that hospital's expected intake of new patients.

4.159 The above means that a manufacturer of a biologic originator, in this case AbbVie with Humira, has no incentive to lower the price of its product with the aim of attracting new patients to it and keeping them captive. Moreover, a price cut for new patients would trigger demand for the same price cut for the already existing captive group. Therefore, applying price reduction was/is not an effective strategy for profit maximisation by the manufacturer in the long run.

4.160 This allowed AbbVie and Pfizer who were theoretically each other's closest competitor to continue charging around the same prices for their products Humira and Enbrel respectively. Both manufacturers behaved similarly, but also - assuming there was no

[162] In the period 2004 to 2018, sales per patient per year were stable between over EUR10K and over EUR12K (source: GIP data). With regard to maintaining the price level, it should be noted that the ACM also found in its sector enquiry into TNF-alpha inhibitors that net purchasing prices barely fluctuated prior to the expiry of patents on the active ingredient.

cartelisation - independently of each other where they were not disciplined by competitors. In this context, it is also worth noting that the ACM concluded that hospitals cannot adopt a strict originator preference policy because some patients appear to respond differently to available originators. In practice, hospitals should therefore purchase (as much as possible) all available originators.[163]

4.161 In addition to it being established that AbbVie had nothing to tolerate from competitors during the period 2004 to 2018, it is also established that it achieved very high profit margins during that period (see section 4.2.6). This fact - the maintenance of very high profit margins over a long period by a company - is in itself a strong indication of economic dominance, as it reflects the power to behave to a significant extent independently of competitors and customers.[164]

4.162 In summary, FTV concludes that AbbVie had an economically dominant position in the Dutch market with Humira during the 2004 to 2018 patent period. It was only after the patent protection on Humira expired and competition from biosimilars emerged that AbbVie was no longer able to behave independently of competitors and customers, diminished its dominant position and drastically reduced the price of Humira.

4.3. 3MISUSE

4.3.3. 1Introduction

4.163 As mentioned, Article 24 Mw and Article 102 TFEU prohibit companies from abusing their (economic) dominant position on the Dutch and EU market respectively.

4.164 One form of abuse within the meaning of Article 24 Mw, which is expressly mentioned in point (a) of the second paragraph of Article 102 TFEU,[165] , is the imposition of unfair prices. A well-known example is charging 'disproportionately high' or 'excessive' prices.

4.165 Advocate General N. Wahl, in his opinion of 6 April 2017 in AKKA/LAA (ECLI:EU:C:2017:286), provided a short and clear overview of the case-law on unfair pricing under Article 102 TFEU, which is still relevant today. It is therefore useful to

[163] According to the ACM, this too constitutes a constraint to organising keen competition for new patients, see Production 6, p. 27/37.

[164] See also Commission 10 February 2021, Case AT.40394 - Aspen, pt. 71.

[165] Article 102, second paragraph, point a TFEU says: "Such abuse may consist in particular in: a. the direct or indirect imposition of unfair purchase or selling prices or other unfair contractual terms;"

discuss this overview as an 'introduction' and assessment framework. Below, AbbVie's actions are assessed in that light (sections 4.3.3.2 and 4.3.3.3) and concluded with a conclusion (section 4.3.3.4).

4.166 The relevant passages from Advocate General Wahl's opinion on assessing unfair prices under Article 102 TFEU read as follows:

> **16**. In United Brands[2] and in several subsequent judgements[3] the Court held that charging a price that was excessive because it was not reasonably related to the economic value of the product supplied was contrary to the rule now set out in Article 102 TFEU. Consequently, only "disproportionately high" or "exorbitant" prices could constitute a violation of that provision.[4] The Court developed a two-step analysis in this regard.
>
> [2] Judgment of 14 February 1978, United Brands Continental v Commission, 27/76, EU:C:1978:22 (hereinafter United Brands judgment).
>
> [3] See e.g. judgment of 17 July 1997, GT-Link, C242/95-, EU:C:1997:376, pt. 39.
>
> [4] See, e.g., judgment of 5 October 1994, Centre d'insémination de la Crespelle, C323/93-, EU:C:1994:368, paras 19 and 21.
>
> **17**. The first step in the analysis is to determine whether there is an excessive margin - i.e. a significant difference - between, on the one hand, the price actually charged by the dominant undertaking in the relevant market and, on the other hand, the price that - hypothetically - this undertaking would have charged if there was effective competition in the market (hereinafter: "standard price").[5]
>
> [5] See in this regard United Brands judgment, pt. 249.
>
> **18**. The Court recognised that various methods can be used to determine whether a price is excessive.[6] For example, if possible and appropriate, a comparison can be made between the selling price and the cost of production.[7] This method seems to be based on the idea that there is a threshold price that guarantees an adequate margin[8] in relation to costs, and that prices demanded by a dominant firm in excess of this threshold are excessive.[9] The analysis thus focuses on the margins (or profitability) of the dominant undertaking in selling the goods or services in question.
>
> [6] Judgment United Brands, pt. 253.
>
> [7] See, in particular, United Brands judgment, pt. 251.
>
> [8] See in this regard judgment of 11 April 1989, Saeed Flugreisen and Silver Line Reisebüro, 66/86, EU:C:1989:140, pt. 43.
>
> [9] See, e.g., Motta, M., and de Streel, A., "Excessive Pricing in Competition Law: Never say Never?", The Pros and Cons of High Prices, Konkurrensverket (Swedish Competition Authority), Kalmar, 2007, p. 33.

19. In other cases, the Court has made a comparison between, on the one hand, the prices charged for the product in question by the dominant undertaking and, on the other, the prices charged in the same market by non-dominant undertakings (comparison between competitors)[10] or by the same dominant undertaking at different times (comparison over time)[11] , or the prices charged in other geographic markets by the same dominant undertaking[12] or by other undertakings (geographic comparison).[13] The underlying idea is that a price comparison can be meaningful if the selected products or geographic markets are sufficiently homogeneous.[14] Similarly, the patterns according to which a firm sets its prices over time can provide useful clues.

[10] See, inter alia, judgments of 29 February 1968, Parke, Davis and Co., 24/67, EU:C:1968:11, and 5 October 1988, CIRCA and Maxicar, 53/87, EU:C:1988:472.

[11] See judgments of 13 November 1975, General Motors Continental v Commission, 26/75, EU:C:1975:150, and 11 November 1986, British Leyland v Commission, 226/84, EU:C:1986:421.

[12] Ibid.

[13] See judgments of 8 June 1971, Deutsche Grammophon Gesellschaft, 78/70, EU:C:1971:59, and 4 May 1988, Bodson, 30/87, EU:C:1988:225.

[14] In this regard, see Organisation for Economic Co-operation and Development, Roundtable on Competition Policy, "Excessive Prices", 2012 [DAF/COMP(2011)18] (hereinafter OECD report), p. 70.

20. Once it has been established by one or more of these methods that there is a significant difference between the price actually demanded by the dominant undertaking and the standard price, it should be determined to what extent that price actually demanded is unfair, either by itself or compared to the prices of competing products.[15]

[15] Judgment United Brands, pp. 249 to 253; see also decision of 25 March 2009, Scippacercola and Terezakis v Commission, C159/08 -P, unpublished, EU:C:2009:188, pt. 47.

21. That second step in the analysis is to examine whether the price differential is purely the result of an abuse of market power by the dominant firm or has other, legitimate causes.

22. Only if there is no valid justification for the difference between the standard price and the price that the dominant undertaking actually charges its customers can the latter price be considered "unfair" within the meaning of point (a) of the second paragraph of Article 102 TFEU.

4.167 It follows from the case-law on unfair pricing investigations under Article 102 TFEU (and therefore also Article 24 Mw) that the Court uses a two-step analysis.

4.168 First, it is examined whether the price in question is excessive. Several methods can be used to do this; for example, by comparing the costs plus a reasonable margin with the actual sales price, or by comparing the sales price in a benchmark with non-dominant competitors.

4.169 The second step then examines whether any excessively high price, or rather the excessive price differential established, is the result of an abuse of dominance by the company concerned or has other legitimate causes. If the latter is not the case and therefore there is no valid justification for that price differential - the burden of proof rests with AbbVie[166] - the price in question is deemed unfair within the meaning of Article 102 TEU.

4.170 The above is confirmed by the Commission in the Aspen case,[167] stressing that for the chosen method used to determine the excessive price differential, it comes down to the fact that that method itself 'must be considered valid'.[168]

4.171 Below, FTV assesses the price of Humira using the two-step analysis outlined above.

4.3.3.2 Excessive price (first step in the analysis)

4.172 For an analysis into the degree of excessiveness of Humira's price, FTV notes upfront that determining the economic value of the medicine to customers (the demand side of the market) is not in itself sufficient. All the more not in a situation, as is the case in this case, where users are dependent on the product and thus, due to the absence of competition, they must in fact pay any price demanded of them.[169]

4.173 On the (chosen) methodology on which FTV relies to assess whether the price of Humira is excessive, FTV notes that it is not properly possible to compare the sales price of Humira in a benchmark with non-dominant drug manufacturers. Firstly, because interchangeability between TNF-α biologicals is very limited and these drugs may form their own product market - making the dominance of each one a given - as long as there are no competing biosimilars on the market (see section 4.3.2.2 above). Secondly, drug care reimbursement systems differ from country to country, making a comparison of Humira pricing in other countries not very fruitful. In short, Humira does not compare well in the 'benchmark option' as intended in the case law.

[166] See, e.g., ECJ 12 May 2022, ECLI:EU:C:2022:379 (ENEL and Others), paras 84 and 103.
[167] Commission 10 February 2021, Case AT.40394 - Aspen, pt. 80 to 86.
[168] Commission 10 February 2021, Case AT.40394 - Aspen, pt. 86, referring to ECJ 14 September 2017, ECLI:EU:C:2017:689 (AKK/LAA), pt. 38.
[169] See also, to this effect, Advocate General F.G. Jacobs 26 May 1989, ECLI:EU:C:1989:215 (Tournier), pt. 65.

4.174 Nevertheless, ZA was able to identify an excessive profit share on Humira due to the pricing applied. As a result, the price charged by AbbVie on Humira can also be considered excessive.

4.175 ZA calculated the excessive profit share by breaking down the turnover achieved after R&D costs and production and sales costs, or surplus, into profits achieved by drug manufacturers in the industry in the upper range (ZA calls this 'expected profit') and *other* profits.

4.176 The 'expected profit' can be considered an 'acceptable profit' in the sector concerned, in legal terms it could be considered a 'reasonable profit'.

4.177 The 'other profit' established by ZA in a range shows a significant difference from the reasonable profit; the range in question concerns 23% to 53% of Humira sales achieved in the Netherlands. This establishes the excessiveness of Humira's price in the first step of the analysis.

4.178 The question then arises to what extent this excessive profit share is the result of AbbVie's abuse of dominance, which, according to the case law, is addressed in the second step of the analysis.

4.3.3.3 Unfair price (second step in the analysis)

4.179 FTV substantiated in section 4.3.2 that AbbVie was (economically) dominant with Humira during the patent period 2004 to 2018.

4.180 In this second step of the 'abuse' analysis, the question now arises whether the excessive profit share identified above is the result of AbbVie abusing that dominant position. FTV considers that this is undoubtedly the case and submits the following in this regard.

4.181 First, FTV recalls that AbbVie had nothing to endure from competition during the patent period and there was no incentive to charge a lower price for Humira to its customers. As a result, AbbVie could and did make excessive profits on Humira during that period, as established above.

4.182 In section 4.2.6, FTV used mathematical methods and illustrative examples to establish that Humira sales in the Netherlands led to significant displacement of care in

the legally insured basic care system. This displacement would not have occurred if AbbVie had been satisfied with the 'expected profit' or 'reasonable profit' percentage of 25% of sales. The part of Humira's pricing that gave AbbVie the 'other profit' should therefore be considered unfair within the meaning of Article 24 Mw and/or Article 102 TFEU.

4.183 Secondly, FTV points to what it put forward in section 4.2.6 about AbbVie's displacement of care, in particular the *counterfactual relating to* potential but undone investments in developing new drugs. AbbVie developed and marketed only six new drugs in the period 2004 to 2018, whereas - given the 'other profits' achieved - it could have developed nine to at least 20 new drugs.

4.184 Therefore, a legitimate reason for the excessive profit share achieved is not to develop and produce new drugs. While this is (or would be) perhaps the main business objective of an innovative biopharmaceutical company like AbbVie. Nor do other (public) facts show that AbbVie can justify its excessive profits on Humira. Moreover, AbbVie bears the burden of proof of a valid justification for the excessive profits achieved on Humira.[170] This is all the more true in light of all the facts and substantiated views presented by FTV regarding the excessive profit part.

4.3.3. 4Conclusion

4.185 In section 4.3.2.5, FTV concluded that AbbVie enjoyed a position of economic dominance in the Dutch market with Humira during the 2004 to 2018 patent period.

4.186 The price AbbVie charged customers for Humira during that period was excessive and such that AbbVie made an excessive profit share on Humira.

4.187 AbbVie has only been able to maintain that excessive pricing of Humira, or achieve the excessive profit share on Humira only, by abusing its dominant position.

4.4 Liability AbbVie

4.4.1 INTRODUCTION

4.188 It has been explained above that AbbVie acted in breach of its duty of care (section 4.2) and that AbbVie abused its dominant position in violation of Articles 24 Mw and 102 TFEU (section 4.3). Both wrongful acts result in liability for AbbVie.

[170] See, e.g., ECJ 12 May 2022, ECLI:EU:C:2022:379 (ENEL and Others), paras 84 and 103.

4.4.2 LIABILITY FOR BREACH OF SOCIAL DECENCY

4.189 As explained above, AbbVie acted in breach of its duty of care. This conduct should also be attributed to AbbVie on the basis of culpability.

4.190 The breached standard - the duty of care arising from unwritten law (in the fulfilment of which account must be taken of the right to life and the right to health) - also serves to protect the interests of the Closely Defined Group that FTV is defending in these proceedings. As described above, AbbVie placed its own private interests (and shareholder interest) above the public interest of affordable care. AbbVie must have known that there has been a displacement of care and that this displacement has been unnecessary by charging a price that has resulted in extreme excess profits that have not been used for the development of new drugs but for distributions to shareholders.[171]

4.191 The ZA report makes it clear that without AbbVie's actions - and thus with a lower price for Humira (without extreme excess profits) - no or far fewer healthy life years would have been lost.

4.4.3 LIABILITY FOR BREACH OF COMPETITION LAW

4.192 By abusing its dominant position, AbbVie also acted in breach of the legal obligation laid down in Articles 24 Mw and 102 TFEU. This breach constitutes an unlawful act consisting of a breach of a statutory duty as well as an act contrary to social decency (Section 6:162(2) of the Civil Code).

4.193 The prohibition of abuse of a dominant position laid down in Article 102 TFEU is aimed at undertakings. According to the Court's settled case-law, it covers "*any entity engaged in an economic activity, regardless of its legal form and the way in which it is financed, and consequently designates an economic unit, even if, from a legal point of view, it is composed of various natural or* legal *persons.*" [172]

4.194 This competition law concept of undertaking is important not only in the context of public enforcement of competition law. In Skanska, the Court made it clear that the concept of 'undertaking' within the meaning of Article 101 TFEU - but the same is true

[171] In one of the hearings on the *Drug Pricing Investigation, AbbVie - Humira and Imbruvica*, Katie Porter calculated that it was US$50 billion over the period 2013 to 2018, see: https://www.youtube.com/watch?v=7axjk-9poKc.
[172] ECJ 10 September 2009, ECLI:EU:C:2009:536 (Akzo Nobel), ECJ 27 April 2017, ECLI:EU:C:2017:314 (Akzo Nobel).

of Article 102 TFEU - is an autonomous concept of Union law and cannot have a different meaning in the context of the Commission's imposition of fines than in the context of claims for damages for breach of Union competition rules.[173]

4.195 This was further confirmed and clarified by the Court in Sumal. In that judgment, the Court considered, inter alia, that where it is established that the parent company and its subsidiary form part of the same economic unit and therefore constitute a single undertaking within the meaning of Article 101 TFEU, the very existence of that economic unit that committed the infringement is decisive for the liability of one or the other member company for the undertaking's anti-competitive conduct.[174] This makes it clear that Union law - based on the
competition law concept of undertaking - determines which legal entities are
are jointly and severally liable to compensate the damage caused by a competition infringement
caused by a competition infringement.

4.196 The defendant AbbVie entities all belong to the same undertaking (within the meaning of the competition law concept).

4.197 **AbbVie Inc** is the parent company of the AbbVie group and in that
as such, it is responsible for setting (global) policy with respect to the
with respect to the products and
services, including the drug Humira and its pricing.

4.198 **AbbVie B.V**. is engaged in the business of buying, selling, importing, exporting, manufacturing, distributing, and using pharmaceutical, hospital, nutritional, chemical, diagnostic medicine and related products. It is thus indirectly a subsidiary of AbbVie Inc active in the field in which the competition infringement took place.

4.199 **AbbVie Deutschland GmbH Co. KG** is also an (indirect) subsidiary of AbbVie Inc and is the brand owner of Humira in Europe.

4.200 The foregoing makes it clear that the defendant AbbVie companies are all part
are part of the same company in the context of the sale of the drug Humira and, as such, are already jointly and severally liable under Union law for the infringement of competition law.

[173] ECJ 14 March 2019, ECLI:EU:C:2019:204 (Skanska).
[174] ECJ 6 October 2021, ECLI:EU:C:2021:800 (Sumal), pt. 43.

4.201 By abusing its dominant position, AbbVie acted in breach of the legal obligation laid down in Articles 24 Mw and 102 TFEU. This breach also constitutes an unlawful act consisting of a breach of a statutory duty as well as an act contrary to social decency (Section 6:162(2) of the Civil Code).

4.202 As explained above, the imputability of liability for the competition infringement to the defendant AbbVie companies already follows from Union law itself. But even apart from this attribution under the Union law concept of undertaking, the unlawful conduct can be attributed to AbbVie Inc., AbbVie B.V. and AbbVie Deutschland GmbH Co. KG.

4.203 The described infringements of competition law are primarily attributable to AbbVie Inc. as the company at the head of the AbbVie group and is responsible for setting the (global) policy regarding the products and services developed by its subsidiaries, including the production and sale of Humira.

4.204 In addition, the described infringements of competition law can be attributed to AbbVie B.V. and AbbVie Deutschland GmbH Co. KG as if these companies are or were involved in the infringing behaviour, which can be imputed to these companies on the basis of culpability or on the basis of common practice.

4.205 The unlawful conduct has also resulted in harm to those entitled to legally insured basic care, consisting of unnecessary displacement of care and related lost years of life in good health, as explained above and implementation described in the ZA report.

5 Applicability of WAMCA and admissibility

5. 1Introduction

5.1 FTV is bringing this class action based on Article 3:305a of the Civil Code. This article was amended by the entry into force of the *Wet Afwikkeling Massaschade in Collective Actie* ("**WAMCA"**) on 1 January 2020.[175] FTV's primary position is that the claimed declaratory judgment must be assessed on the basis of Article 3:305a BW as amended by the WAMCA. FTV will explain this in the next section.

5.2 The writ of summons in a class action must meet a number of requirements according to Section 1018c(1)(a) to (f) Rv. Chapter 3 of this summons has already dealt in detail with the events relevant to collective claims (Section 1018c(1)(a) Rv). The other requirements are discussed below.

5.3 In this chapter, FTV will successively address the applicability of the WAMCA to the present claims (para 5.2), the persons whose interests the collective claim is aimed at protecting (para 5.3), the admissibility of FTV (para 5.4), the efficiency and effectiveness of these collective proceedings (para 5.5), the application for designation as Exclusive Interest Defender (para 5.6), and the entry in the Central Register of Class Actions (para 5.7).

5.2 Applicability of WAMCA

5.4 The WAMCA entered into force on 1 January 2020. With regard to transitional law, Article 119a Transitional Act New Civil Code stipulates the following:

> **1**. Notwithstanding Section 68a and Section 74(2) to (4), for an action aimed at protecting similar interests as referred to in Sections 305a to 305d of Book 3 and instituted before [date of entry into force of the Act], the conditions in force before that date shall continue to apply.
>
> **2**. Notwithstanding section 68a, for an action aimed at protecting similar interests as referred to in sections 305a to 305d of Book 3 and instituted on or after [date of entry into force of law], the conditions that applied before that date continue to apply insofar as the action relates to an event or events that took place before 15 November 2016.

[175] Act of 20 March 2019 amending the Civil Code and the Code of Civil Procedure to allow the settlement of mass damages in a collective action.

5.5 The original legislative proposal of the WAMCA did not contain transitional law, so the immediate effect of the new regulation would be the starting point. This has been subject to criticism. Immediate effect would (could) mean that interest representatives in collective actions already pending would suddenly have to comply with stricter legal requirements than they had to take into account when starting the proceedings. It was not considered reasonable to change the rules of the game for advocates pending a class action.

5.6 In the (first) Memorandum of Amendment, at the request of VNO-NCW/MKB-Nederland and the Consumers' Association, a transitional rule was included to the effect that a collective action instituted before the date of entry into force of the WAMCA had to be settled on the basis of the existing rule in Article 3:305a of the Civil Code.[176] This would prevent that representatives in a class action pending proceedings would suddenly have to meet stricter admissibility requirements , or that the court would suddenly start appointing an exclusive interest representative, when several class actions (possibly before different courts) were pending on a similar factual question or legal issue.

5.7 The transitional law was subsequently tightened by amendment, adding the phrase "*relating to an event or events that occurred on or after 15 November 2016*".[177] This tightening is explained in the amendment as follows:

> "(...) Therefore, this amendment regulates that an action under the new law is only possible if the loss-causing event occurred on or after 15 November 2016. That is the date that the bill was sent to Parliament and thus, in theory, the parties can know that the new law is coming. If someone wants to bring a mass tort action for an event that occurred before 15 November 2016, they can do so based on the law as it was then. For proceedings for an event that took place on or after that date, the law as it will apply after the present bill comes into force will apply. In the theoretical case of a series of events occurring both before and after 15 November 2016, the law as in force at the time the last event to which the claim relates will apply.
>
> The advantages of this form of transitional law, compared to the transitional law as proposed in the bill, is that the principle of legal certainty is better guaranteed. Moreover, it reduces the possibility of double proceedings under

[176] Parliamentary Papers II 2017-2018, 34 608, no. 7, p. 3.
[177] Parliamentary Papers II 2018-2019, 34 608, no. 13, p. 2.

different legal regimes. Finally, this form of transitional law is more in line with the legislation of our neighbouring countries, such as England and Belgium."

5.8 The present case involves a class action based on a series of events that occurred both before and after 15 November 2016. Indeed, AbbVie's wrongful conduct consists of excessive pricing of Humira during the period 2004 to 15 October 2018. This is a continuous unlawful conduct that started in 2004 and ended in October 2018. The parliamentary history shows that, according to the legislator, the law applicable in such a case is the law in force at the time the last event to which the claim relates took place. This means that the WAMCA applies to AbbVie's actions throughout the entire period in which it acted unlawfully, including the part before 15 November 2016.

5.9 To the extent your court would rule that AbbVie's conduct before 15 November 2016 should not be assessed under the WAMCA, the claims insofar as they relate to AbbVie's conduct prior to that date should be brought under the old Article 3:305a of the Dutch Civil Code (as applicable before 1 January 2020). This makes no difference to the assessment of the claim as only a declaratory judgment is sought, which was also already possible under Article 3:305a (old) of the Dutch Civil Code. The same applies if the court were to consider that Article 3:305a (old) of the Civil Code applies to the entire period instead of the WAMCA.

5.3 The persons whose interests the collective action seeks to protect

5.10 The group of persons represented by FTV in this collective action (the "**Closely Defined Group**") may be defined as follows:

all persons who (may) be entitled to legally insured basic care in the Netherlands . The majority of the persons whose interests the legal actions are aimed at protecting will therefore have their habitual residence in the Netherlands.

5.4 Admissibility of FTV

5.4.1 SIMILAR INTERESTS, STATUTES AND SAFEGUARDING INTERESTS

5.11 The power of interest groups to bring legal actions under Article 3:305a DCC is limited to the protection of similar interests. It follows from established case law of the Supreme Court that the requirement of similarity is met "*if the interests whose protection the legal action seeks to protect lend themselves to bundling, so that efficient and effective legal protection can be promoted for the benefit of the interested parties.*" Claims are suitable for bundling if they can be adjudicated in a single proceeding, "*without the need to consider the particular circumstances on the side of the individual interested parties*".[178]

5.12 The idealistic interests advocated by FTV are similar. The representation of interests in these proceedings further falls within the statutory purpose of the Foundation. According to Article 2 of its articles of association (hereinafter: the **Articles of Association**) (**Production 14**), FTV's objects are:

> "to serve the public interest by striving to ensure that medicines and other medical technologies are available on the market in a sustainable and a socially acceptable manner, in which context the foundation values fair pricing and distribution that complies with written and unwritten national, European and international legal standards."

[178] See HR 26 February 2010, ECLI:NL:HR:2010:BK5756 (Stichting Baas in Eigen Huis/Plazacasa), para 4.2.

5.13 FTV seeks to achieve its purpose by, among other things:

> "The provision of advice, information and education, the conduct of legal proceedings as well as the performance of all further acts, which are directly or indirectly related to the foregoing or may be conducive thereto, all in the broadest sense."

5.14 In accordance with Article 2.4 of the Articles of Association, FTV has no profit motive. FTV is a non-profit foundation that operates on the basis of funds, (project) grants and donations.

5.15 FTV has also been effectively pursuing the aforementioned statutory interest for a long time since its inception in 2018. Some examples include:

- Submitting an enforcement request to the ACM regarding the drug CDCA from the pharmaceutical Leadiant. The ACM subsequently, on 19 July 2021, fined Leadiant over EUR 19.5 million for abuse of economic dominance by charging excessive prices for the drug CDCA. FtV made its enforcement request public, and sought cooperation with organisations in other countries. Leadiant has since been condemned by national competition authorities in Italy, Spain and Israel;
- Publication describing drug hijacking of the drug CDCA by Leadiant and the threat of drug hijacking of the drug mexiletine by Lupin in the Dutch Journal of Medicine.
- After the threat of drug hijacking became public, the health minister, on the advice of the Health Care Institute, refused the admission of 100x priced mexiletine (Namuscla, Lupin) to the basic package because cheaper magistral preparation and importation of a cheaper generic drug was possible;
- During the Covid-19 pandemic, FtV assessed 26 pharma companies, which developed Covid-19 vaccines or drugs, on the basis of their compliance with 19 human rights principles. The Fair Pharma Scorecard provides insight into how the discussed pharma companies performed in terms of human rights, transparency, international cooperation, and equality, non-discrimination and justice.[179] Based on this study, FtV developed and published three guidelines:
    - A 'Fair Pharma guideline' that pharmaceutical companies can follow to operate responsibly in line with human rights principles to ensure their medicines are available, accessible and affordable.[180]

[179] https://fairpharmascorecard.org/.

[180] https://fairpharmascorecard.org/guidelines/.

- A guideline for NGOs on the use of legal procedures to promote access to medicines.[181]
- A policy brief 'Time to legislate' recommending legislative measures that parliaments and governments can take to better realise the human right to health and the human right to access medicines.[182]

5.4.2 FTV IS SUFFICIENTLY REPRESENTATIVE (ARTICLE 3:305A PARAGRAPH 2 OPENING WORDS OF THE CIVIL CODE)

5.16 Finally, Article 3:305a paragraph 1 of the Civil Code stipulates that the interests of those for whom FTV stands up must be sufficiently safeguarded. Article 3:305a paragraph 2 of the Civil Code further specifies and strengthens these requirements. According to this provision, the interests are sufficiently safeguarded when the foundation, as an interest organisation, is sufficiently representative, given the constituency and the size of the claims and the foundation meets a the requirements in sub a to e.

5.17 Article 3:305a paragraph 6 BW stipulates that the court declares a legal entity as referred to in paragraph 1 admissible, without the requirements of paragraph 2, subsections a to e, and paragraph 5 having to be met, when the legal action is instituted with an idealistic purpose and a very limited financial interest or when the nature of the claim of the legal entity as referred to in paragraph 1 or of the persons whose interests the legal action seeks to protect gives cause to do so. When this paragraph is applied, the action may not seek monetary damages.

5.18 FTV is such a legal entity as its claim is for an idealistic purpose and does not seek monetary damages. FTV therefore does not have to comply with the requirements set out in Article 3:305a(2)(a) to (e) of the Civil Code. Only for the sake of completeness will these requirements therefore be discussed below.

5.19 Whether FTV is sufficiently representative can be deduced from various data. For instance, FTV's expertise and experience, the other work FTV has done and the number of statements of support can be considered.[183] What is important here is that the requirements for representativeness should not be set unnecessarily high for an ideal action. After all, the additional safeguards introduced by the WAMCA are not

[181] https://farmaterverantwoording.nl/richtlijnen/.
[182] https://farmaterverantwoording.nl/2023/02/06/nieuwe-beleidsnota-tijd-voor-wetgeving-toegang-tot-geneesmiddelen-realiseren-via-de-verplichting-van-staten-om-het-mensenrecht-op-gezondheid-te-beschermen/.
[183] Parliamentary Papers II 2003/04, 29414, 3, p. 15.

intended to impede idealistic actions, but only to prevent any excesses in claiming collective damages.

5.20 FTV enjoys considerable support both from individuals and organisations, including insurers and (international) advocacy organisations. For an up-to-date overview, please refer to FTV's website (see below).

5.21 FTV has an advisory board under the Articles of Association. The task of the advisory board is to provide solicited and unsolicited advice to the board on specific topics and sub-areas as mutually determined by the management and the advisory board from time to time. Currently, the advisory board consists of 14 members.[184]

5.22 FTV has a publicly accessible internet page (www.farmaterverantwoording.nl) on which the information referred to in Article 3:305a(2)(d) of the Dutch Civil Code can and will be found, in particular: (1) FTV's articles of association, (2) FTV's management structure, (3) FTV's most recently adopted annual report, (4) FTV's objectives and operating procedures, (5) an overview of the status of current proceedings and (6) an overview of the manner in which persons whose interests the legal action seeks to protect may affiliate with the legal entity and the manner in which they may terminate such affiliation.

5.23 FTV has the experience and expertise necessary to bring this class action. It has this expertise primarily in-house, as its board members and advisory board members have the required expertise and know-how, as detailed in this summons. FTV is additionally assisted by the law firms Coupry and Hausfeld Advocaten.

5.24 Article 3:305a(3)(a) of the Civil Code stipulates that directors of FTV may not have a direct or indirect profit motive, which is realised through FTV. FTV has no profit motive (Article 2.4 of the Articles of Association). Its directors also have no profit motive.

5.25 Pursuant to Article 3:305a(3)(b) of the Civil Code, the collective claim must have a sufficiently close connection with the Dutch legal sphere. FTV must make a sufficiently plausible case that:

- the majority of the persons whose interests the legal actions seek to protect have their habitual residence in the Netherlands; or
- the person against whom the legal action is directed is domiciled in the Netherlands and additional circumstances indicate sufficient connection with the Dutch legal sphere; or

[184] For an overview of the advisory board, see: https://farmaterverantwoording.nl/wie-we-zijn/.

- the event or events to which the legal claim relates took place in the Netherlands.

5.26 As explained above, FTV is acting in these proceedings on behalf of all persons claiming legally insured basic care in the Netherlands. Accordingly, the majority of the persons whose interests the legal actions seek to protect will have their habitual residence in the Netherlands.

5.27 The legal claim thus relates to events that took place in the Netherlands. It therefore follows from the above that the collective claims in the present proceedings have a sufficiently close connection with the Dutch legal sphere.

5.28 FTV held AbbVie liable by letter dated 21 December 2021. In doing so, FTV invited AbbVie to enter into consultations with FTV on reaching an amicable settlement. This has not resulted in an amicable settlement. FTV thus met the requirement of Article 3:305a(3)(c) of the Civil Code with the foregoing.

5.4.2. CONCLUSION REGARDING THE (STATUTORY) ADMISSIBILITY REQUIREMENTS

5.29 The above shows that FTV amply meets the statutory admissibility requirements set out in Article 3:305a of the Civil Code. It therefore requests your court to declare it admissible in its collective claims.

5.5 Efficiency and effectiveness of this collective procedure

5.30 Pursuant to Section 1018c(5) Rv, the court shall only proceed to the substantive handling of a collective claim, when the claimant has made it sufficiently plausible that pursuing this collective claim is more efficient and effective than bringing an individual claim, because:

a. the factual questions and the legal issues to be answered are sufficiently common
b. the number of persons whose interests the claim seeks to protect is is sufficient; and
c. if the claim is for damages: that they individually or jointly have a sufficient financial interest.

5.31 FTV's class action against Defendants on the above points - where point c. is not relevant as the claim does not seek damages - is obviously more efficient and effective than bringing individual proceedings. The nature of a nonprofit action means that it should ideally be conducted collectively and not individually. FTV has already explained

in Section 5.4.1 of this summons that the factual and legal questions to be answered are sufficiently common and therefore lend themselves to bundling.

5.6 Request for designation of Exclusive Representative

5.6.1 INTRODUCTORY REMARKS

5.32 FTV believes it is the most suitable party to be appointed as Exclusive Representative.

5.33 In appointing the exclusive representative, all the circumstances of the case should be taken into account, including at least: [185]

a. the size of the group of persons on whose behalf the claimant is acting;
b. the size of the financial interest represented by this group;
c. other work performed by the claimant on behalf of the persons for whom he represents in or out of court;
d. previous work done by the claimant or collective claims brought.

5.34 FTV believes that based on the aforementioned perspectives, it is suitable to be appointed as exclusive representative.

5.35 A relevant circumstance concerns other activities performed by the claimant on behalf of the persons for whom it acts in or out of court. According to the legislator, those other activities may include, for example, acting as a voice for injured parties or other activities on the basis of which precisely this representative comes into view to act for the entire group of persons.[186]

5.36 Some activities undertaken by FTV have been discussed above (paragraph. 5.15). Other activities that can be highlighted include the following (for an up-to-date and complete overview, please refer to FTV's website):

- 13 December 2022, SwissInfo. Big Pharma's big push into Africa's cancer market;
- 28 June 2022, Wed: Most pharmacists get insufficient for fair distribution of covid funds;
- 3 June 2022, Pharmaceutical Weekly. Another hefty fine for manufacturer CDCA;
- May 6, 2022. Parool: 'The era of drug hijackers and grabby pharmacists is over';
- 21 February 2022, Radar: 'Medicine hijackers' and buyers make existing drugs unnecessarily expensive;

[185] Article 1018e paragraph 1 subsections a to b Rv.
[186] Parliamentary Papers II 2016-2017, 34 608, no. 3, p. 43.

- 9 February 2022, De Groene Amsterdammer: 'You have to take back control';
- 2 February 2022, Radio 1: Hope for Africa through patent-free mRNA vaccine?
- 5 January 2022, Pharmaceutical Weekly: Foundation holds AbbVie liable for Humira price;
- October 2021 ARTE TV documentary. Medicine - les profits de la pénurie;
- 11 June 2021, RTL4 Edition [Radio interview]: Once and for all: surplus of 60 million vaccines goes to?
- 6 May 2021, Radio 1, Een Vandaag [Radio interview]: Releasing patents corona vaccines: unmentionable for some, not going far enough for others;
- 26 March 2021, Der Spiegel: interview with Wilbert Bannenberg, Das Geheimnis von Halix;
- 25 March 2021, Trouw: Anne ter Reele. Reconstruction: how Leiden pharmaceutical company Halix ended up in a European vaccine conflict;
- 15 March 2021, BBC Radio Ulster programme TalkBack (12:17-12:22) [Radio interview]: Interview with Wilbert Bannenberg on AstraZeneca;
- 30 January 2021, Humo: What went wrong between the EU and AstraZeneca;
- 29 January 2021, Volkskrant: Brussels versus AstraZeneca: how a poking contest turned into vaccine war;
- 27 January 2021, BNR Radio [Radio interview]: Interview with Wilbert Bannenberg on AstraZeneca;
- 21 January 2021, NRC: Developing countries also devoid of vaccine expertise;
- 14 January 2021, NRC: Healthcare institute: orphan drug Namuscla need not be reimbursed.

5.37 Another circumstance mentioned in the first paragraph of Section 1018e Rv concerns previous work or collective claims brought by the claimant. According to the legislator, this previous work may indicate whether the necessary expertise and experience for conducting a collective claim and acting therein as an exclusive representative is available.[187] In this regard, FTV points to the aforementioned enforcement application filed by FTV with the ACM, which resulted in the imposition of a fine and also led to identical actions in other countries (see paragraph 5.15).

5.38 Weighing the above factors, it can be concluded that FTV is the most appropriate party to be appointed as exclusive representative by your court.

5.7 Entry in the Central Register of Collective Claims

[187] Parliamentary Papers II 2016-2017, 34 608, no. 3, p. 43

5.39 FTV will not only file the summons at the registry, but simultaneously have it annotated in the Central Register of Collective Actions.

6 Jurisdiction and applicability of Dutch law

6.1 The Amsterdam court has jurisdiction over the dispute before it.

6.2 For the defendants domiciled outside the Netherlands, your court's international jurisdiction should be determined by reference to the common rules of jurisdiction with respect to AbbVie Inc. and by reference to the (recast) EEX Regulation (hereinafter **EEX-Vo**) with respect to AbbVie Deutschland Co KG .[188] FTV will set out below that your court has jurisdiction to hear its claims.

6.3 The applicable law should be based on the Rome II Regulation[189] Under Article 4(1) and/or Article 6(3)(a) Rome II Regulation, Dutch law applies.

6.1 Jurisdiction of the District Court of Amsterdam

6.4 There can be international jurisdiction on several grounds. Pursuant to the main rule, the court of the (member) state where the defendant is domiciled has jurisdiction (article 2 Rv article 4 section 1 EEX-Vo), but in addition, other courts may also have jurisdiction on the basis of special rules of jurisdiction (article 6 Rv and article 5 section 1 EEX-Vo).

6.5 AbbVie B.V. has its registered office in Amstelveen. The Dutch courts therefore have jurisdiction pursuant to Article 4 of the (recast) EEX Regulation ("EEX-Vo"). There can be international jurisdiction with respect to the foreign AbbVie companies on several grounds pursuant to special jurisdiction rules (Article 6 Rv and Article 5(1) EEX-Vo).

6.1.1 JURISDICTION BASED ON CLOSE CONNECTION

6.6 As explained above, Defendants form one and the same company making them jointly and severally liable for the infringement of competition law. Pursuant to Article 8(1) Recast Brussels I Regulation (with respect to AbbVie Deutschland Co KG) and Article 7 Legal Action (with respect to AbbVie Inc.), your court thereby also has international jurisdiction to hear the claims against the other Defendants.

[188] Regulation (EU) No 1215/2012 of the European Parliament and of the Council of 12 December 2012 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters.
[189] Regulation (EC) No 864/2007 of the European Parliament and of the Council of 11 July 2007 on the law applicable to non-contractual obligations.

6.7 There is such a close connection between the claims against these Defendants and those against AbbVie B.V. that the proper administration of justice calls for and simultaneous hearing and adjudication in order to avoid incompatible decisions in separate adjudication of the cases

6.1.2 JURISDICTION BASED ON THE HARMFUL EVENT

6.8 Under Article 6(2) Rv and Article 7(2) EEX-VO, an action may also be brought before the court of the place "*where the harmful event occurred or may occur*". According to established case-law of the CJEU, this phrase refers both to the place where the damage occurred (the *Erfolgsort*) and to the place of the event having a causal connection with the damage (the *Handlungsort*), so that the defendant can be sued in the courts of one or the other place, according to the plaintiff's choice.[190]

6.9 With regard to damages arising from infringements of Article 102 TFEU, the Court ruled that the event causing the damages is the implementation of the abuse. These are the actions taken by the dominant undertaking to put the abuse into practice.[191]

6.10 As discussed, AbbVie has acted unlawfully by charging excessive prices for Humira in breach of what is socially acceptable under unwritten law and has abused its dominant economic position.

6.11 This unlawful conduct that has resulted in unnecessary displacement of care has taken place in the Netherlands. The present collective action brought on behalf of persons claiming basic care legally insured in the Netherlands. Against this background, it must be assumed that Abbvie's damaging acts took place in the Netherlands.

6.12 The place where the damage occurred (the Erfolgsort) is also in the Netherlands. As regards the place where the damage was suffered as a result of the competition infringements the CJEU has formulated the following rule: "where the market affected by the anti-competitive conduct is located in the Member State in whose territory the alleged harm is alleged to have occurred, the place where the harm occurred must be deemed to be in that Member State."

[190] ECJ 30 November 1976, ECLI:EU:C:1976:166 (Kalimijnen). See also ECJ 16 May 2013, ECLI:EU:C:2013:305 (Melzer).
[191] ECJ 5 July 2018, C-27/17, ECLI:EU:C:2018:533 (flyLAL II), pt. 52.

6.13 In other words, the place where the damage was suffered is equal to the place of the market affected by the competitive conduct and on which the injured party claims to have suffered that damage.

6.14 The place of entry of the harm consisting of the displacement of care and lost QALYs of persons claiming statutory insured basic care is therefore in the Netherlands. This Erfolgsort was also foreseeable for AbbVie now that it is also marketing Humira in the Netherlands.

6.15 Finally, FTV notes that part of the Closely Defined Group is domiciled in Amsterdam and - (partly) on the basis of the Brussels I bis-Vo - the Amsterdam court therefore also has (relative) jurisdiction.

6.2 Applicable law

6.16 Under Article 4(1) Rome II Regulation, the law applicable to an unlawful act is the law of the country where the damage occurs, regardless of in which country the event giving rise to the damage occurred and regardless of in which countries the indirect consequences of that event occur.

6.17 As described above, both the Handlungs- and Erfolgsort are located in the Netherlands so that Dutch law applies to the unlawful act.

6.18 Article 6(1) Rome II Regulation states that the non-contractual obligation arising out of a restriction of competition shall be governed by the law of the country whose market is affected or likely to be affected.

6.19 As explained above, FTV's claims are based on AbbVie's abuse of its dominant position. As the abuse of dominance consists of excessive pricing in the Dutch market, the restriction of competition has affected the Dutch market. Consequently, FTV's claims are governed by Dutch law.

7 Known defences

7.1 FTV is not familiar with AbbVie's substantive defences.

8 Evidence

8.1 In support of its statements, FTV refers to Productions 1 to 14 referred to in this summons, which will be submitted at the time the summons is filed. In particular, FTV refers to the report prepared by Zorgvuldig Advies (Production 7).

8.2 Without otherwise incurring any burden of proof, FTV additionally offers to further prove its contentions by all means in law, including by hearing witnesses or experts who were involved in, or can otherwise testify about, AbbVie's wrongful conduct.

9 Claim for relief

FTV asks the court to, as far as possible enforceable:

– To the extent that the WAMCA applies to the present claims, designate FTV as exclusive representative within the meaning of Section 1018e(1) Rv.

– Declare that AbbVie Inc. and/or AbbVie B.V. and/or AbbVie Deutschland GmbH Co KG acted unlawfully towards the Closely Defined Group by violating Article 2 ECHR and/or Article 6 ICCPR and/or Article 6 ICCPR and/or Article 2 Charter and/or Article 12 IVESCR and/or Article 11 ESH and/or Article 24 ICCPR and/or Article 35 Charter, or at least by acting contrary to social decency within the meaning of Article 6:162 of the Dutch Civil Code.

– Declare that AbbVie Inc. and/or AbbVie B.V. and/or AbbVie Deutschland GmbH Co KG have acted unlawfully vis-à-vis the Closely Defined Group by abusing their dominant economic position (Article 24 Mw and/or 102 TFEU).

– Order AbbVie Inc. and/or AbbVie B.V. and/or AbbVie Deutschland GmbH Co KG jointly and severally to pay FTV the costs of these proceedings, including the follow-up costs, within seven days of the date of the judgment, with the stipulation that if the costs of the proceedings are not paid within the aforementioned period, statutory interest will be payable thereon from the eighth day .

List of productions

Production 1	Court of Audit 2020 - Report Horse remedy or emergency bandage?
Production 2	VIG code, *Integrity, transparency, social responsibility and quality*
Production 3	The AbbVie Code of Business Conduct
Production 4	AbbVie our commitment to human rights
Production 5	U.S. House of Representatives, Committee on Oversight and Reform, Staff Report, Drug Pricing Investigation, AbbVie - Humira and Imbruvica, May 2021
Production 6	ACM Sector enquiry TNF-alpha inhibitors
Production 7	Care Advice, Report Dispelling care through high profits, an economic analysis of sales and profits achieved with Humira®
Production 8	UN Human Rights Committee, General comment No. 36: Article 6 right to life
Production 9	Office of the High Commissioner for Human Rights, CESCR General comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12)
Production 10	The OECD Guidelines for Multinational Enterprises, Dutch translation, 2011 version
Production 11	United Nations Guiding Principles Business on Business an Human Rights (UNGP)
Production 12	Healthcare Vision 16 June 2015 - Half colon cancer patients does not get expensive drugs
Production 13	Medical Contact 21 January 2021 - Hospitals frugal with expensive colon cancer treatment
Production 14	FTV Articles of Association