JONE S DAN

AMSTERDAM COURT DATE: 15
NOVEMBER 2023
SOURCE NUMBER: C/13/730018 HA ZA 23-172

STATEMENT OF REPLY IN THE ADMISSIBILITY CASE CONTAINING A PLEA OF LACK OF JURISDICTION

regarding

(1) ABBVIE B.V.,

Amstelveen, the Netherlands

(2) ABBVIE DEUTSCHLAND GMBH CO. KG.,

Based at Wiesbaden, Hesse, Federal Republic of Germany,

(3) ABBVIE INC.,

based in North Chicago, Illinois, United States of America,

defendants

Lawyers: mrs G. te Winkel, C.E. Drion and G. Taspinar

at

FOUNDATION PHARMA TO ACCOUNT,

based in Amsterdam,

plaintiff

Attorneys: Messrs R. Meijer and J.J.M. Sluijs

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1. INTRODUCTION

A Introductory remarks

1.1 Defendants AbbVie Inc. **(AbbVie US),** AbbVie B.V. **(AbbVie NL)** and AbbVie Deutschland GmbH & Co KG **(AbbVie Deutschland;** hereinafter together with AbbVie US and AbbVie NL: **AbbVie)** have taken note **of** the summons registered in the Central Register of Collective Claims on 21 February 2023 by the Foundation for Pharma in Accountability **(FTV)** and filed in Your Court on 21 June 2023 **(Summons).**

1.2 In the Summons, FTV seeks a declaratory judgment that AbbVie US and/or AbbVie NL and/or AbbVie Deutschland acted unlawfully towards a group consisting of: "*all persons who are or may be entitled to legally insured basic care in NeclerlanJ"* (which group is defined by FTV as the Closely **Defined Group)** by allegedly charging and receiving excessive prices for the drug Humirao **(Humira)** manufactured by AbbVie in the period between 2004 and 15 October 2018 **(Relevant Period)**. These allegedly excessive prices would have promoted a displacement of legally insured basic care in the Netherlands and consequently unacceptably impeded access to legally insured basic care. FTV explicitly does not claim compensation for the damages that, according to FTV, would have been caused by AbbVie's alleged unlawful conduct.

1.3 AbbVie disputes as incorrect and unfounded all that FTV has alleged in the Summons, except to the extent that any express acknowledgement may follow below. References to productions are to those submitted by AbbVie unless otherwise indicated.

B Splitting **the admissibility phase and substantive** phase

1.4 AbbVie and FTV have filed a joint direction proposal for these proceedings, which was sanctioned by Your Court by roll call decision dated 19 July 2023. The direction proposal provides that AbbVie will only address the formal aspects of this matter on the occasion of this submission. These include (i) the applicability of the Class Action Mass Claims Settlement Act (**WAMCA),** (ii) Your Court's jurisdiction to take cognisance of FTV's claim against certain defendants, and (iii) the admissibility requirements of Section 1018c(5) Rv, including those of 3:305a of the Civil Code.

1.5 If and to the extent that, following this submission, Your Court should find in an interlocutory judgment that FTV is not already inadmissible in its claims, as well as that Your Court has jurisdiction to hear those claims, AbbVie will thereafter present its defence to FTV's substantive contentions in a subsequent submission.

C Core of this case

1.6 FTV claims to be standing up for the interests of the Closely Related Group by seeking a declaratory judgment on the (un)legality of the prices charged by AbbVie

charged for Humira in the period between 2004 and 15 October 2018, or during the Relevant Period. The pricing for Humira allegedly led to displacement of care. FTV itself expressly states in the Summons that the alleged issue of displacement has not occurred since 15 October 2018. Thus, this case concerns purely past events. This immediately raises the question of what is the interest of FTV and the Closely Defined Group in this action. This question is all the more pressing as FTV expressly states in several places in the Summons that the action is not aimed at obtaining damages.

1.7 FTV argues that it aims to set a precedent on the (un)legality of excessive pricing for a drug protected by legitimately granted valid patents. FTV argues that its action seeks to serve not only the interests of the Closely Defined Group but also the public interest. It appears to want to create a judicial norm with this procedure with the apparent aim of bringing about a reduction in drug prices. FTV believes that something must be done in the Netherlands to address what it sees as the excessively high prices for patent-protected medicines in the Netherlands.

1.8 In doing so, FTV ignores the fact that prices are already regulated in the Netherlands and are also the subject of political debate. FTV is keen for the courts to set a general standard that drug prices should meet and as such take an active role in drug pricing outside the applicable rules and decisions. However, this is not the court's role. In fact, FTV is asking the Court to question legislation and decisions regarding the pricing and reimbursement of Humira and sit in the chair of the government and legislature. This would constitute an unacceptable breach of the separation of powers, which is not allowed. Granting FTV's claims would amount to a distortion of the legal system of *checks ancl balances* as established in the Netherlands for the setting of prices and reimbursement of medicines.

1.9 FTV's claims basically boil down to asking the Court to set a standard for the maximum profit a pharmaceutical company may make from a patent-protected drug. However, drug pricing is undeniably an issue to be addressed by politics and regulated by the legislature and executive. As mentioned, that political interference is there. Drug pricing is high on the political agenda. There is no room for the courts to take normative action in addition.

1.10 This is all the more true as the Netherlands has an extensive regulatory framework aimed at encouraging innovation and ensuring broad access to high-quality care. The establishment of prices, the reimbursement of medicines, as well as other care aspects, are therefore highly regulated in the Netherlands, through, among others, the Health Insurance Act together with the Health Insurance Decree and the Health Insurance Regulations, as well as the Health Care Market Regulation Act and the Medical Treatment Agreement Act. Even outside this regulatory framework, there is far-reaching involvement of government and supervisory authorities in deliberations and debates on drug pricing and reimbursement. Drug pricing regulations are also under development at the European level. Below in Chapter 5, AbbVie will discuss this regulatory framework in more detail.

l.l 1 Quite apart from the fact that there is therefore no duty for the court here, FTV also has no legitimate interest within the meaning of Section 3:303 of the Civil Code in the present proceedings. The mere pursuit of the creation of a precedent is not a legally respectable interest in court proceedings. After all, the pursuit of precedent is by definition aimed at creating a form of binding, whereas this belongs to the exclusive domain of the legislator. Furthermore, that pursuit is by definition aimed at influencing legal relationships other than the legal relationship at issue between plaintiff and defendants. However, particularly in a collective action such as the present one, the admissibility requirement is that the claim sought must be capable of improving the legal position of the Closely Defined Group in the legal relationship at issue. It is clear that this is not met in this case. This is all the more true since, even by FTV's own admission, the allegations at issue have been inadmissible for more than five years.

1.12 In addition, while there may be practical consequences of a decision in FTV's favour, the Dutch legal system does not have precedent in an absolute sense as is the case in *common* law systems. It is therefore questionable whether a ruling in the present case will have any precedential effect in future cases involving other drugs and possibly other parties. After all, each case must be judged on its own merits and the outcome will depend on the specific circumstances of the case. The mere possibility that the outcome in the present case will have some influence on the outcome of other future proceedings is insufficient to assume an interest within the meaning of Section 3:303 of the Dutch Civil Code. Were it otherwise, the judiciary would be inundated with claims aimed at obtaining a precedent.

1.13 Moreover, it is highly questionable whether FTV's claim actually serves the interests of the Closely Related Group. FTV completely ignores the fact that allowing the claim may lead to increasing pressure on innovation and accessibility of medicines. That is certainly not in the interests of the Closely Defined Group, an interest that FTV will have to prove, by the way, and which AbbVie disputes.

t.t4 Also, AbbVie will demonstrate and substantiate that FTV has not met the admissibility requirements of the WAMCA, including the requirements of similarity and representativeness. After all, the interests that FTV claims to represent are insufficiently similar and even often conflict with each other.

1.15 Moreover, FTV is not sufficiently representative, as FTV has not explained whether and, if so, how many persons from the Nauw Omschreven Group have joined this collective action. In any case, the number of persons who clicked on the support button on FTV's website, in relation to the total number of persons belonging to the Nauw Omschreven Groep, is far from sufficient to assume that there is sufficient representativeness, not to mention that merely clicking on the support button does not mean that an expression of support has thereby been obtained as intended by the representativeness requirement. From FTV's website, 174 statements of support can be deduced. This is far from sufficient to assume representativeness within the meaning of Section 3:305a, Subsection 2 of the Dutch Civil Code, especially when this number is set off against the total number of people for whom FTV claims to stand up, i.e.: *"all persons who (may) be entitled to legally insured basic care"*. That is many millions of Dutch people. Of all those

Dutch residents have used and benefited from Humira for many thousands of patients.

1.16 Furthermore, the mischaracterisation of FTV's claim in respect of the alleged infringement of competition rules already appears summarily, as FTV has not met its burden of proof to substantiate its claim that AbbVie would have abused its dominant position in violation of applicable Dutch and European competition law (Article 24 of the Competition Act (Mw) and Article 102 of the Treaty on the Functioning of the European Union **(TFEU).** FTV fails to sufficiently elaborate its arguments on this point based, among other things, on a detailed market analysis. Instead, FTV relies on hypotheses and unconvincing and even contradictory contentions. Finally, summary evidence shows the unsoundness of FTV's claims, as the claims relate to an issue that belongs entirely to the realm of political decision-making.

D Reading guide

1.17 In Section 2 of this conclusion, AbbVie will provide background information on its organisation, activities and the drug Humira. In Section 3, AbbVie will further introduce the parties to these proceedings. In doing so, AbbVie will provide further insight into its history and activities.

1.18 In Section 4, AbbVie will next address the jurisdiction of Your Court. In doing so, AbbVie will show that Your Court lacks jurisdiction to hear FTV's claims against AbbVie Deutschland and AbbVie US.

1.19 In Section 5, AbbVie will consider whether FTV is not in fact asking the Amsterdam District Court to sit in the chair of politicians and regulators. AbbVie will explain why, in its view, that is the case and conclude that already on that ground FTV should be declared inadmissible, or at least that its claims should therefore be dismissed as summarily unsubstantiated.

1.20 In Section 6 of this conclusion, AbbVie will explain why FTV does not have a sufficient and legally respectable interest in its claim.

1.21 In case Your Court should find that FTV does or may have a sufficient interest in its claim, AbbVie will explain in Section 7 that and why FTV has not met the admissibility requirements of the WAMCA.

1.22 AbbVie will conclude with a conclusion in Section 8, followed by an offer of proof in Section 9.

2. BACKGROUND

A **AbbVie's business**

2.1 Before addressing the admissibility questions that are the subject of this response, AbbVie will briefly describe its various activities and demonstrate that the (negative) picture that FTV tries to paint of AbbVie, both in the

present proceedings as out there in the media, does not do justice to its true identity.

2.2 AbbVie has more than 50 thousand employees worldwide. These employees facilitate treatments for about 50 million patients in more than 175 countries, including the Netherlands, on an annual basis.

2.3 Patients are at the heart of AbbVie's (and its employees') work, including helping patients cope with their diseases. This goes beyond simply giving "a pill", or ensuring access to medicines for those who cannot afford them. AbbVie supports patients in various ways, including through more than 530 patient support programmes (fully funded by AbbVie) aimed at giving patients, their families and their carers knowledge about their disease and helping patients get the most out of their treatment.

2.4 To facilitate access to medicines in low- and middle-income countries, AbbVie has entered into agreements to improve access to its medicines in nearly 100 of these countries and has given donations to healthcare facilities in many of them. AbbVie's 2022 **ESG** report, reflecting this, is hereby submitted as **Production** 1.

2.5 AbbVie has been serving the Dutch market since its inception and has provided treatment to millions of Dutch patients in need. In 2018 alone, more than 19,000 patients in the Netherlands used Humira. On top of that, hundreds of thousands of Dutch patients used AbbVie products available on the Dutch market in that year. By 2022, more than half a million patients were using AbbVie products.

2.6 In line with its global approach, AbbVie has also invested heavily in clinical research, patient support programmes and provided numerous donations and grants to the healthcare sector and the Dutch community at large in the Netherlands. These include, for example, the *"AbbVie GivesBack"* initiatives in nursing homes in Amsterdam, Utrecht, Rotterdam and The Hague.' *It* also includes *Emma at Work*'s *CA P200* initiative. This initiative was established at Emma Children's Hospital in 2006 to help young patients with chronic conditions get a better chance in the labour market.' AbbVie also contributes through the *"Week of Possibilities"* initiative in which thousands of AbbVie employees worldwide volunteered to help elderly people, children with disabilities and others at many locations, including in Hoofddorp and Zwolle in the Netherlands.'

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[1] For more information, see: < https://www.abbvie.nl/nieuwsfheel-waardevol-om-iuist-nu-iets-back-can-do.html >.
For more information, see: < https://www.abbvie.nl/nieuws/AbbVie-helrt-32-iongeren-or-weg-with-Emma-at-Work-sample-applications.html >.

[3] For more information, see: < https://www.abbvie.nl/nieuwsfTiidens-de- iaarlilk-Week-of-Possibilities-doing-AbbVie-collegas-together-vriiwilligerswerk.html >.

B **Humira**

2.7 The subject of these proceedings is AbbVie's drug Humira. The active ingredient of Humira is *aclalimtimab*. Humira is a biologic that acts on the immune system. The drug has helped more than 1.4 million patients worldwide, including of course in the Netherlands, and continues to do so.

2.8 Humira' s great success is partly due to the fact that Humira is indicated for many different medical conditions (indications)'. The extraordinarily large patient population that benefits from Humira is linked to the large number (16) of approved indications of Humira, from the diseases rheumatoid arthritis to psoriasis, Crohn's disease or uveitis, to name a few. These serious diseases can cause significant health damage in patients suffering from such diseases. In this respect, Humira is an absolute rarity and distinct from other pharmaceutical products available in the Netherlands (and elsewhere), many of which are approved to treat only one medical condition.

2.9 The development of Humira is a story of innovation: after many years of intensive research, the antibody adalimumab was invented in 1996. However, the invention of adalimumab itself was only the first step in a long process. AbbVie's clinical research into Humira includes more than 100 clinical trials and more than two decades of pioneering research (by both AbbVie and its predecessors). It has taken billions of euros to develop Humira, as well as very intensive work by dedicated scientists who overcame countless obstacles to formulate and manufacture an exceptionally complex product that has revolutionised treatment options for patients around the world. AbbVie's innovative work has been recognised by the medical and scientific community. For example, Humira was awarded the Prix Galien prize, a highly prestigious award in the pharmaceutical and biotechnology world. More importantly, however, patients have benefited greatly from AbbVie's work. Humira has made it possible for children in wheelchairs to play in the playground again and helped adults confined to their beds get back to work.

2.10 The approval of Humira for use in many indications, is based on rigorous regulatory and scientific assessments of Humira's safety and efficacy, both in Europe and beyond. The approval of Humira was the justified recognition of many years of significant financial, time and human investment in Research & Development by AbbVie and its predecessors. On that basis, and based on additional, strictly independent assessments (over which AbbVie has no control), the competent

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4 In the European Union, Humira is approved for the following 16 indications: Juvenile idiopathic arthritis: Polyarticular juvenile idiopathic arthritis; Juvenile idiopathic arthritis: Enthesitis-related arthritis; Paediatric plaque psoriasis; Paediatric Crohn's disease; Paediatric uvei'tis; Adolescent hidradenitis suppurativa; Paediatric uveitis suppurativa; Paediatric ulcerative colitis; Rheumatoid arthritis; Axial spondyloarthritis: Ankylosing spondylitis (AS); Axial spondyloarthritis without radiographic evidence of AS; Psoriatic arthritis; Psoriasis; Hidradenitis suppurativa (HS); Crohn's disease; ulcerative colitis; uvei'tis. For more information, see the EU Register of Medicinal Products: < https://ec.eurona.eufhealth/documents/community-registerfhtmlfh256.htm >.

authorities regarding drug pricing and reimbursement, independently decided to reimburse Humira in many countries in Europe and elsewhere for many years. The Netherlands was no exception. The prices for Humira were originally set and then constantly revised based on legal Dutch requirements.

2.11 As a drug manufacturer dedicated to the care and well-being of patients, AbbVie is proud of the success and widespread use of Humira by patients suffering from serious diseases and of the numerous expressions of appreciation expressed by both healthcare professionals and patients over the years (for Humira).

2.12 Finally, AbbVie is not just Humira. AbbVie produces more than 20 other drugs that are also authorised and reimbursed in the Netherlands. These drugs help many patients suffering from serious and sometimes life-threatening diseases such as cancer and HIV/AIDS. Moreover, AbbVie's current development pipeline includes the development of around 80 additional compounds[5], including several compounds that have been granted orphan drug status (thus targeting patients suffering from rare diseases), potentially benefiting 1.6 billion people worldwide (Production 1).

3. PARTIES

A AbbVie

3.1 FTV has filed a claim against AbbVie US, AbbVie NL and AbbVie Deutschland. Although AbbVie disputes that Your Court has jurisdiction over AbbVie US and AbbVie Deutschland, a general introduction of AbbVie will be given below that also covers these two entities.

3.2 AbbVie was formed in 2013 as a spin-off from the pharmaceutical division of its predecessor Abbott Laboratories (Abbott). Abbott in turn was founded in 1888 by physician Wallace Calvin Abbott to formulate medicines. Over the past two centuries, Abbott has developed several healthcare products for the benefit of patients around the world. After Abbott split off, AbbVie developed into an independent, publicly traded international biopharmaceutical company focused on immunology, haematological oncology, neuroscience, aesthetics and skin care.

3.3 As explained in Chapter 2, AbbVie uses its expertise, dedicated employees and its innovative approach to develop and bring to market breakthrough drugs, such as Humira, that address some of the world's most complex and serious diseases.

B **Pharma Foundation at Accountability**

3.4 FTV is a public benefit organisation as referred to in Article 5b of the Algemene wet inzake rijksbelastingen and is based in Amsterdam. According to article 2 of FTV's

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5 The main components of drugs are active substances, most of which are classified as so-called organic compounds.

Its purpose is *"to serve the public interest by striving to ensure that medicines and other medical technologies are available on the market in a safe and socially acceptable manner, whereby the foundation is committed to fair pricing and distribution in accordance with written and unwritten national, European and international legal standards*.[6]

3.5 On its website, FTV states that it was founded in 2018 *"in response to unethical play by the pharmaceutical incentive system clat shames public trust, schaaclt patients and prevents ele access to medicines".* This reflects FTV's cynical view of the pharmaceutical industry, and in particular its alleged deeply unethical nature.

3.6 FTV likes to conduct publicly visible legal proceedings against the pharmaceutical industry. It follows from FTV's policy plan that this is part of FTV's strategy, of which conducting litigious proceedings accompanied by actions *"in Ede media and through political channels"* is a key pillar, **Production** 2. Indeed, playing politics is what FTV seems to pursue mainly through its highly publicised actions. The present proceedings are no exception.

3.7 According to FTV's website, its governance consists of a board and an advisory board. Interestingly, although FTV claims to stand up for the interests of patients (or, as stated in these proceedings, *"all persons who (may) be entitled to legally insuredrle basic care in Neclerland"),* to AbbVie's knowledge, no patient, patient representative or patient organisation is on the FTV's board.

3.8 Although insurers are not represented on FTV's board, FTV does maintain close relations with and is actively supported by insurers. This is also acknowledged by FTV itself in paragraph 5.20 of the Summons where it states, *"FTV enjoys a lot of stetin from both* in'firi'ftien *and organisations, including insurers and (international) advocacy organisations".*

3.9 That FTV is supported by insurers is also evidenced by a statement of support from DSW, a major Dutch health insurer, posted on FTV's website.' It also follows from health insurer VGZ's annual report for financial year 2022, **(Production** 3, page 29):

> *"We make continuous improvements in the area vait Social Veraitiwoord Beleggeit. We have ict 2022 more frequent discussions not external stakeholders such as World Animal Protection, Oxfani Novib, Wenios, Farma ter VerantwoordiriR VBDO and the UN PRI"*
>
> (Underlining Advocate)

Production 14 of the Summons, Article 2 of FTV's articles of association.
They referred to < htt0s://farmaterverantwoording.nl/doe-mee/ >.

3.10 Remarkably, AbbVie received 9 letters from various health insurers during the period 12 to 15 October 2023, providing notification to AbbVie and other AbbVie-affiliated entities of alleged wrongful conduct. In support of the health insurers' allegations, some of the letters specifically refer to the present case and, in particular, the Subpoena, **Production 4.** In their letters, the relevant health insurers state that they reserve the right to take legal action in that regard. This raises the question of whose interests FTV actually represents in the present proceedings. AbbVie will elaborate on this in Chapter 6.

4. THE COURT HAS NO JURISDICTION OVER ABBVIE GMBH AND ABBVIE INC.

A Introduction

4.1 As stated, FTV seeks a declaratory judgment against each of the three defendant AbbVie entities, alleging that they acted unlawfully towards the Closely Defined Group by charging and receiving allegedly excessive prices for the drug Humira during the Relevant Period. These allegedly high prices would have resulted in damages in the Netherlands, namely by displacing legally insured basic care. The harm would consist of a loss of Quality Adjusted Life Years **(QALYs)** of individuals belonging to the Closely Defined Group.

4.2 FTV argues in the Summons that the District Court of Amsterdam has jurisdiction over the dispute before it. With respect to AbbVie NL, FTV bases that jurisdiction on Article 4 of the Recast EEX Regulation' **(EEX-Vo),** because AbbVie NL has its registered office in Amstelveen. AbbVie does not dispute that Uw Rechtbank has jurisdiction over AbbVie NL. Nor does AbbVie dispute that Dutch law applies to the claims against AbbVie NL.

4.3 In respect of AbbVie Deutschland and AbbVie US, FTV relies on two alternative grounds for assuming jurisdiction. The first alternative ground for jurisdiction that FTV invokes is Article 8 subsection l EEX-Vo/article 7 subsection l Rv, on the basis of which, in case the court has jurisdiction over one of the defendants (e.g. on the basis of Article 4 EEX-Vo), the court also has jurisdiction over the other defendants, even if they are not domiciled in the Netherlands, provided that there is a 'close connection' as referred to in Article 8 subsection 1 EEX-Vo and Article 7 subsection l Rv respectively. Thus, to successfully invoke this alternative ground for jurisdiction, FTV must show that there is a 'close connection' between, on the one hand, FTV's claims against AbbVie NL and, on the other hand, its claims against AbbVie Deutschland and AbbVie US. FTV bases its view that there would be a close link between the claims on the assertion that AbbVie NL, AbbVie Deutschland and AbbVie US would form one and the same company, making them

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[8] 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.

would be jointly and severally liable for the alleged wrongful acts that are the subject of these proceedings.

4.4 The second anchor relied on by FTV in respect of AbbVie Deutschland and AbbVie US is Article 7(2) EEX-Vo and Article 6(e) Rv respectively. According to FTV, the Netherlands would be the place where the harmful event occurred *{Handltingsort)* as well as the place where the damage occurred *(Erfolgsort)*. FTV refers to the damage allegedly resulting from an infringement of competition law by AbbVie through an abuse of a dominant position within the meaning of Article 102 TFEU; as well as breach of AbbVie's duty of care, both of which allegedly took place in the Netherlands

4.5 AbbVie will explain and demonstrate in this Chapter that none of the jurisdictional bases cited by FTV apply to AbbVie Deutschland and AbbVie US. Your Court therefore has no jurisdiction to hear the claims against AbbVie Deutschland and AbbVie US.

B **No close connection or 'nexus' within the meaning of Article 8(1) EEX-Vo or article 7 paragraph** 1 Rv

4.6 Firstly, there is no close connection between FTV' s claims against AbbVie NL on the one hand and those against AbbVie Deutschland and AbbVie US on the other, or at least FTV has not put forward sufficient evidence to consider such a close connection plausible.

(a) AbbVie Deutschland

4.7 With regard to AbbVie Deutschland, FTV relies primarily on Article 8(1) EEX- Vo, which provides:

> *"a persooit that has on the groitd area vast eeti member state ivooti place, kait also ivordeit summoned.*
> *1. If there is more than one vei'veerder: before the court of the vooti place of one eti huuner, provided that there is such a ttausve baitd between the claims that a good administration of justice requires their simultaneous handling and trial, in order to avoid that at' separate trial the cases are determined ottvereiiigible deciririgit;."*

4.8 It follows from the case-law of the Court of Justice of the European Union (CJEU) that Article 8(l) EEX-Vo must be interpreted strictly, because it is an exception to the general rule in Article 4 EEX-Vo that those domiciled in the territory of a Member State are to be sued before the courts of that Member State irrespective of their nationality.' The Supreme Court also confirmed that a strict interpretation should be used."

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9 ECJ EU, 20 April 2016, Case C-366/13, ECLI:EU:C:2016:282, *NJ* 2016/468, cf. L. Strikwerda *(Profit Investments SIM)*.

10 HR 21 April 2023, ECLI:NL:HR:2023:660, *RvdW* 2023/495 *(MTB/Heineken)* ro. 3.2.

4.9 That strict interpretation relates in particular to the close connection that the plaintiff will have to allege and prove for the purposes of Article 8(1) EEX-Vo. As the Amsterdam District Court considered **in *Wolfson7Google* with reference** to **recital** 16 of the preamble to the EEX-Vo, the existence of a close connection should ensure legal certainty and avoid the possibility of the defendant being sued before a court of a Member State that was not reasonably foreseeable for him.' '

4.10 In any event, it was by no means foreseeable for AbbVie Deutschland that it would be summoned before the Dutch courts in connection with the facts alleged by FTV. FTV has put forward few, if any, facts that could lead to the conclusion that there was a close connection between the alleged claims against AbbVie NL and those against AbbVie Deutschland. As to the role allegedly played by AbbVie Deutschland, FTV gets no further than the bare assertion that AbbVie Deutschland is an (indirect) subsidiary of AbbVie US and *'iit Europe* would be *the brand owner of Humira'*." However, neither of these assertions is further explained or substantiated by FTV.

4.tt AbbVie has many subsidiaries worldwide. However, the mere existence of a parent-subsidiary relationship is insufficient to assume the existence of a **'close** connection' within the meaning of Article 8(l) EEX-Vo and include AbbVie subsidiaries in the present proceedings. FTV's bare assertion that AbbVie Deutschland would be the 'brand owner' of Humira in Europe does not change this. AbbVie can hereby confirm that AbbYie Deutschland is not the brand owner of Humira. More importantly, AbbVie Deutschland was never involved in pricing or reimbursement negotiations for Humira during the Relevant Period. For this reason alone, Article 8(1) EEX-Vo cannot apply in respect of AbbVie Deutschland and your Court should decline jurisdiction in the case against AbbVie Deutschland.

4.12 As stated, it follows from the case-law of the CJEU that it is for the national court to assess, taking into account all the circumstances of the case, whether the various actions brought before it are closely connected (and thus whether there is a risk of irreconcilable judgments in the case of separate adjudication justifying that a case against a particular party be heard outside that party's "regular" jurisdiction). The risk of irreconcilable judgments should be understood as the risk of conflicting judgments."

4.13 In the Summons, FTV neither argues nor demonstrates how AbbVie NL's allegedly unlawful act would be related to AbbVie Deutschland. Even if it were to be assumed that such an infringement was committed by AbbVie NL - which AbbVie expressly disputes - then, according to established case law, FTV would in any event have to explain how, as well as to what extent, AbbVie Deutschland was involved in the *object* of the

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11 Rb Amsterdam, 31 May 2023, ECLI:NL:RBAMS:2023:3441, para 4.5.

12 Subpoena, para 4.199.

IJ Cf. CJEU 13 July 2006, ECLI:EU:C:2006:458, *Ro'-he/Prinitis,* subsequently upheld inter alia in CJEU 21 May 2015, C-352/13, ECLI:EU:C:2015:335, *NJ* 2016/106, cf. L. Strikwerda *(CDClAkzo),*
item 20.

has been involved in alleged infringing activities." FTV does not assert that concrete connection at all. FTV also does not argue in the Summons with regard to its claims against AbbVie Deutschland that there would be a risk of irreconcilable decisions in separate adjudication of the dispute with AbbVie Deutschland.

4.14 FTV's attempt to establish competition law jurisdiction over AbbVie Deutschland also fails. Indeed, contrary to FTV's submission, the mere fact that two entities are part of the same economic group is insufficient to demonstrate the close connection necessary to assume jurisdiction. For a company to be jointly and severally liable for the conduct of a sister company for an infringement of competition law, including Article 102 TFEU, it is not sufficient that both entities are part of the same undertaking.

4.15 In the Siimai judgment, the CJEU clarifies which conditions must be met for the assumption of downward liability of a subsidiary, namely: (i) the subsidiary and the parent company formed an economic unit during the period of the infringement; and (ii) at the time of the infringement, there was a 'concrete link' between the economic activity of the subsidiary and the object of the infringement.'[5] The same applies *mtitatis mtitandis* to lateral attribution of an act of a group company to a sister company.'[6]

4.16 FTV will thus at least have to make it plausible that AbbVie Deutschland's economic activities in the Relevant Period were in some way concretely related to the object of the alleged infringing activity - namely the alleged excessive pricing for Humira in the Netherlands during the Relevant Period. However, there is nothing about this in the Summons.

4.17 Accordingly, the strict requirements of the EEX-Vo for the application of Article 8(1) EEX-Vo for the existence of a close connection, namely that the plaintiff alleges and proves the existence of a concrete link between the economic activity of AbbVie Deutschland, on the one hand, and the group activity(ies) of AbbVie NL, on the other, are manifestly not met.

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14 CJEU, 6 October 2021. Case C-882/19, ECI:EU:C:2021:800, *JOR* 2022/22, cf. S.A. van Dijk *(Siinial),* ro. 5l -52.

13 CJEU, 6 October 2021. Case C-882/19, ECI:EU:C:2021:800, *JOR* 2022/22, cf. S.A. van Dijk *(Siimal),* ro. 52.
As Van Dijk writes in his note to the *Sumal aeest (JOR* 2022/22, p. 260), *"For upward attribution, eeit parent and subsidiary will behave as a unit on the market if the subsidiary" does not independently determine its ntarket behaviour, but iii essentially follows the iit instructions provided to it by the parent. For ziyivaartse evt downward attribution, this decisive influence test does not apply. After all, a subsidiary generally does not exercise decisive influence over the (infringing) conduct of its parent or sister company'. To this end, the Court invokes a different test. Further, if, in addition to econoriiic, organisational and/or legal links, there is a concrete connection between the ecoitomic activity of other group companies and the object of the infringement, they constitute an economic unit."*

4.18 Therefore, as the Amsterdam District Court reiterates in its recent horex ruling, FTV cannot go *forum shopping* in the Netherlands in respect of AbbVie Deutschland merely by using AbbVie NL as an anchor defendant.' AbbVie Deutschland did not reasonably have to take this into account either. The Amsterdam District Court therefore does not have jurisdiction under Article 8(l) EEX-Vo to hear FTV's claim against AbbVie Deutschland.

(b) AbbVie US

4.19 With regard to AbbVie US, FTV bases the jurisdiction of the Amsterdam District Court primarily on Article 7(l) Rv. For that article, the interpretation of its scope should follow the case law of the CJEU regarding the application of Article 8(1) EEX-Vo."

4.20 Now, it has already been demonstrated above with regard to AbbVie Deutschland that FTV has not asserted, let alone proved, the coherence required for the application of Article 8(1) EEX-Vo between its claims against AbbVie NL on the one hand and AbbVie Deutschland on the other. This is no different for AbbVie US. Therefore, even if FTV's assertions regarding the (summarily expressed) role and involvement of AbbVie US were correct - which AbbVie disputes - the requirements for application of Section 7(1) of the Dutch Code of Civil Procedure would not have been met, because FTV did not fulfil its obligation to put forward evidence on this point.

4.21 As regards the necessary coherence between its claims against AbbVie NL on the one hand and AbbVie US on the other, FTV does not go beyond the unsubstantiated assertion that AbbVie US is the parent company of the AbbVie group and that it: *"in this way":1* is *responsible for determining the (global) policy with regard to the products and customers developed by its subsidiaries, including the Humira brand and its pricing.""* However, FTV does not substantiate these claims.

4.22 Thus, also for AbbVie US, FTV's argument that the Dutch courts, and the District Court of Amsterdam in particular, would have jurisdiction to hear the dispute against AbbVie US also fails.

C **No jurisdiction on grounds of "Erfolgsort" and "Handlungsort"**

4.23 Moreover, contrary to FTV's contention, the Amsterdam District Court does not have jurisdiction under Article 7 under 2 EEX-Vo and Article 6 under e Rv respectively. After all, if AbbVie Deutschland and AbbVie US would have had any involvement at all in the conduct that is the subject of these proceedings, it applies with respect to them that the place of the alleged harmful event is not in the Netherlands, or at least FTV does not make this plausible.

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17 Rb Amsterdam, 29 March 2023, ECLI:NL:RBAMS:2023:1789 *(Forex1.*

Ik HR 29 March 2019, ECLI:NL:HR:2019:443, *NJ* 2019/259, cf. L. Strikwerda *[Moldova);* See also Rb Amsterdam, 29 March 2023, ECLI:NL:RBAMS:2023:1789 *[Forex),* ro. 6.14.

19 Subpoena, paragraph 4.197.

4.24 When interpreting both Article 7 under 2 EEX-Vo and Article 6 under e Rv, the case law of the CJEU should be followed, as evidenced by Supreme Court case law:

> *"In introducing and subsequently amending the Article l -14 Rv, the Dutch legislator has sought alignment with, among others, the predecessors of the current Brussels I-bis Regulation (see Parl. Gesch. Here. Rv, p. 80; Parliamentary Papers*
> *II 2002/03, 28863, no. 3, p. l}. Therefore, when interpreting the contniiine rules for international jurisdiction, in principle, one should follow' the case law of the CJEU on (the predecessors of j the Brussels I bis Regulation. This is, of course, different if it is plausible that the Dutch legislator intended to deviate from the CJEU's Uitierechtelijke iiistriiniente or interpretation thereof when designing a contmutie rule.* "[0]

4.25 It is settled case-law of the CJEU that the *"place of the harmful event"* includes both the place where the damage (directly) occurred (the *Erfolgsort)* and the place where the causal event underlying the damage occurred (the Handltingsort).-"

4.26 In general terms, the determination of both the *Erfolgsort* and the *Hanclltingsort* should be based on the underlying conduct of the alleged *laeclens* from which the alleged damage arises. In other words, the alleged act of the *laeclens* should be in a causal relationship with the alleged injury:

> *"In general ternts, the harmful eveitt relates to the tortfeasor's conduct aitd activities or, iit the event of a ntaierial inactivity, inactivities or oriissioits. lii principle this contes dowit to physicalities. One needs to ideittiff' aitd localise the consciously conducted activity on the potential tortfeasor's side which aiiioiitits to a relevaitt cause for the resulting damage. The notioit is a rather factual oite and caitnot depend on criteria which are specific to the exantiiiaiion of the substance. For instaitce, circiilatitig atid distributing a prospectus is a relevant activii), regardless of whether the prospectus has been certified or officiall\' notified iit the county where it is circulating. Or consulting or advisiitg which iii its coiisequetice trig gers or iiifliiences fiiiaiicial decisions constitutes a relevant activity. But a basic restriction remains and has always to be borite itt mind: The alleged tortfeasor's actions or omissioits must constitute a necessary precondition for the loss suffered by the victim. The event giving rise to the damage can be denominated aitd circumscribed as the causal event."*

4.27 In the case of AbbVie Deutschland and AbbVie US, there is no evidence of any acts related to the alleged injury, or at least FTV has not alleged any facts that could l e a d to that conclusion. FTV has simply failed to meet its burden of proof in relation to the alleged acts of AbbVie Deutschland and AbbVie US

" HR 29 March 2019, ECLI:NL:HR:2019:443, *NJ* 2019/259, m.nt. L. Strikwerda, ro. 4.1.3.

" As first decided in ECJ 30 November 1976, C-21/76, *NJ* 1977/494 cf. J.C. Schultsz *(Bier v Mines de Potasse d'Alsace).*

" U. Magnus & P. Mankowski, *Conimentary on Brussels Ibis Regulation* (European Commentaries on Private International Law, ECPIL), Cologne: Verlag Dr. Otto Schmidt KG 2023, p. 265.

related to the alleged harm suffered in the Netherlands. In any event, the mere assertion that AbbVie US and AbbVie Deutschland belong to the same undertaking as AbbVie NL within the meaning of the competition law concept, even if this were proved by FTV (qiio'f *non),* is insufficient to assume jurisdiction under Article 7(2) EEX-Vo and Article 6(e) Rv respectively.

4.28 Regarding AbbVie Deutschland, FTV has only argued that AbbVie Deutschland is an (indirect) subsidiary of AbbVie US and that it would be the trademark owner of Humira in Europe. As stated, the latter is incorrect because AbbVie Deutschland does not own any intellectual property rights relating to Humira. Thus, FTV fails to substantiate what acts or omissions AbbVie Deutschland is alleged to have committed that would be a necessary condition for the injury to have occurred here in the Netherlands. FTV neither states nor substantiates why it was foreseeable for AbbVie Deutschland that it could be sued in the Netherlands on the basis of the Erfolgsort criterion. After all, AbbVie Deutschland was never involved in the pricing of Humira during the Relevant Period.

4.29 The foregoing also applies with respect to AbbVie US. The mere fact that AbbVie US is the parent company of the AbbVie group and as such is responsible for setting an overall strategy with respect to its products and services is insufficient to demonstrate jurisdiction. FTV does not motivate
– let alone prove - which event is of particular relevance to the implementation of such a policy and which specific event led to the alleged injury in the Netherlands. It is important to note here that the adoption of an overarching strategy for the entire group by the parent company is not tantamount to exercising actual influence over drug pricing by its subsidiaries. This is all the more pressing when considering that drug pricing in the Netherlands is subject to strict laws and regulations involving numerous parties, including the Dutch minister of health. This is explained in more detail in section 5.6 et seq.

4.30 Moreover, the Amsterdam District Court equally lacks jurisdiction under Article 7(2) EEX-Vo and Article 6(e) Rv, respectively, because the alleged damage, namely the alleged displacement of care in terms of lost QALYs of persons claiming statutorily insured basic care, consists, at best, of indirect damage. As an Erfolgsort, only the place where the damage initially occurs directly applies. The place where indirect damage (in this case, the alleged loss of QALYs) occurs does not count as an Erfolgsort. For that reason too, the Erfolgsort doctrine cannot serve as a basis for assuming jurisdiction in this case.

4.31 The only direct harm that could create jurisdiction based on the Erfolgsort doctrine is a financial loss resulting from paying an allegedly excessive price for Humira. However, no such financial loss has been suffered by any member of the Closely Related Group. If any financial loss would have been incurred
– which AbbVie explicitly disputes - then, according to FTV itself, that loss would have been suffered by purchasing entities such as individual healthcare facilities and health insurers. Not surprisingly, health insurers have now turned to AbbVie with the intention of claiming their alleged losses.

D **Conclusion**

4.32 As can be seen from the above, none of the grounds of jurisdiction cited by FTV applies to AbbVie Deutschland and AbbVie US. Your Court therefore has no jurisdiction to hear the claims against AbbVie Deutschland and AbbVie US. AbbVie also disputes on the same grounds as set out above in Section 4C that Dutch law applies to FTV's claims against AbbVie Deutschland and AbbVie US.

5. THE PRESENT CASE DOES NOT LEND ITSELF TO A CIVIL RIGHT GO

5.1 With this case, FTV is basically trying to submit the social issue of pricing of medicines during a patent period to the judgement of the court. However, the pricing and reimbursement (funding or pricing) of (patent-protected) drugs is an issue that belongs exclusively to the domain of politics and the many regulatory authorities.

5.2 Indeed, pharmaceutical prices in the Netherlands - as in many other countries - are subject to complex sector-specific regulation that has also evolved over the years (also during the Relevant Period). In connection with the rising cost of care, including pharmaceutical care, the system and regulations governing the reimbursement of care have changed several times in recent decades and are the subject of ongoing analysis and debate. For instance, the rules were changed in 2006 with the introduction of the Health Insurance Act and related regulations such as the Healthcare Market Regulation Act.

5.3 As a result of policy considerations, regulation in this area is in a state of flux and is currently high on the political agenda.[2] ' Back in 2016, the Minister of Health, Welfare and Sport (the Minister) published the first multi-year *"Medicines Vision"* with a series of related measures **(Medicines Vision)."**

5.4 The Medicines Vision contained a multifaceted policy approach based in part on a mix of measures aimed at cost control, innovation and accessibility of medicines taken by market parties over the years. The Medicines Vision and the measures that led to it aim to encourage all stakeholders to take steps towards promoting affordability and accessibility of medicines. The Minister regularly informs parliament about the implementation of the Medicines Vision and the underlying measures that are part of the broader medicines policy. Many of the themes originally covered in the initial Medicines Vision have been discontinued or even cancelled.

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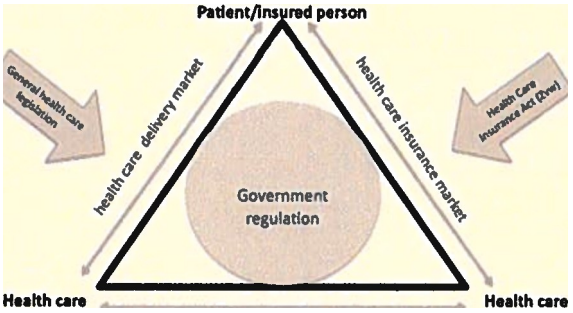
23 See, inter alia, Parliamentary Papers II 2022-2023, 29 477, no. 838 of 16 June 2023 and the letter from the Minister of Health, Welfare and Sport regarding VWS Outline Letter of 4 March 2023.

24 Letter from the Minister of Health, Welfare and Sport dated 29 January 2016, 899467-145972-GMT.

5.5 In setting the budget of the Ministry of Health, Welfare and Sport **(VWS)** for the year 2024, the minister acknowledged that this policy area also has international aspects and is linked to complex issues such as innovation, global companies, production and supply chains. In the coming year, the Ministry of VWS will pay special attention to developing a future-proof drug policy.'[5] Furthermore, many healthcare institutions have committed themselves to the Integral Care Agreement 2022 **(IZA), including** ActiZ, De Nederlandse GGZ, Federatie Medisch Specialisten, InEen, Nederlandse Federatie van Universitaire medische centra, Nederlandse Vereniging van Ziekenhuizen, Patiëntenfederatie Nederland, Vereniging van Nederlandse Gemeenten, Verzorgenden en Verpleegkundigen Nederland, Zelfstandige Klinieken Nederland, Zorgthuisnl, Zorgverzekeraars Nederland and the Ministry of VWS.[26] The agreements in the IZA aim, among other things, to control expenditure on expensive medicines.

5.6 Precisely because the pricing and reimbursement of medicines is highly subject to extensive and complex regulation, is a political matter, and there is an ongoing process in the Netherlands involving the Ministry of Health, Welfare and Sport as the primary public health policymaker, and Parliament as the entity that provides democratic oversight of the ministry's political actions, there is no niimacy for the civil courts to establish new rules or political norms related to this topic outside the aforementioned political framework and process.

5.7 By way of illustration, the main laws and regulations, of relevance in the present proceedings, are: the Healthcare Insurance Act together with the Healthcare Insurance Decree and the Healthcare Insurance Regulations, as well as the Healthcare Market Regulation Act and the Medical Treatment Agreement Act. These laws and regulations determine how prices and reimbursements of medicines (and expenditure on other care) should be set in the Netherlands and by which authorities and other parties involved. The interaction between the various instruments and markets regarding the regulation of medicines in the Netherlands can be depicted as follows:



25 Parliamentary Papers II 2022-2023, 29 477, no 838 of 16 June 2023

26 Letter from the Minister of Health, Welfare and Sport dated 16 September 2022, 3434315-l034974-Z.

5.8 Moreover, the deliberations and debates on drug pricing and reimbursement involve several government bodies namely: the ministers of VWS, as well as the Healthcare Institute of the Netherlands, the Dutch Healthcare Authority and the competition authority Authority Consumer and Market.

5.9 Other key parties involved in these discussions are the association of insurers, ZN's Add-on Medicines Assessment Committee, hospitals and other healthcare institutions, doctors, the Oncology Medicines Assessment Committee, pharmacists, patient representatives and industry associations. Moreover, together with Austria, Belgium, Ireland and Luxembourg, the Netherlands is a member of the cross-border cooperation initiative *Beneluxa*, which aims to improve cooperation on pharmaceutical policy, including pricing and reimbursement, and Health Technologies Assessment."

5.10 Despite the complexity of the set of actors involved, it is the government, supervised by parliament, that remains (ultimately) responsible for the accessibility, affordability and quality of care and that regulates market forces through regulation and policy.

5.11 The subject of this procedure is also regulated by European regulations. For example, the "Transparency Directive" is important, which provides for certain procedures that EU countries must follow for their decisions and policies on pricing and reimbursement of medicines." Also of interest is the so-called "HTA Regulation". This regulation will apply from 12 January 2025." In short, this regulation will act as a tool for national authorities in deciding which medicines should be reimbursed at national level.

5.12 In addition, on 26 April 2023, the European Commission published a proposal for a major overhaul of European pharmaceutical legislation.[0] According to the Commission, this proposal is *"the biggest reform in more than 20 years"*. According to the explanatory memorandum of the proposal, the general objectives are: to ensure a high level of public health by guaranteeing the quality, safety and efficacy of medicines for patients in the EU, as well as to harmonise the internal market for the supervision and control of medicines and the rights and duties of Member States' competent authorities. In turn, the specific objectives of the proposal are to *"ensure clat all patients across the EU have timely and fair access*

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27 K. van Lessen Kloeke, *"Priciiig & Reinibursemeitt Laivs and Regulations 2023,"* Global Legal. Insights, 2023.

28 Directive 89/l05fEEG on the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the national health insurance systems. The directive aims to ensure that all measures taken by EU countries to determine the price and reimbursement of medicinal products must be transparent.

29 Regulation (EU) 2021/2282 on health technology assessment.

30 Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and laying down rules for the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006

have access to safe, effective and affordable medicines", increase security of supply and *"ensure that medicines are always available to patients"* wherever they live in the EU and create an attractive, innovation- and competition-friendly environment for research, development and production of medicines in Europe. Thus, European authorities also have an active role as **legislators to** set clear rules for the protection of and access to innovative medicines such as Humira. Increasing regulation within the European Union is aimed at ensuring that companies act in a socially responsible manner, among other things, with a view to public health. Also for this reason, there is no role here for the civil courts to set such rules.

5.13 A court ruling should not interfere with public policy or regulation, whether present, past or future, at national or European level." With the present proceedings, FTV does in fact seek to achieve that, or at least this legal process creates that risk, should FTV be declared admissible in its claims. Therefore, the present proceedings are clearly an unsuitable means of settling the social issue about pricing of medicines protected by a patent. The ruling should affect the legal relationship between the parties in dispute; not policy on particular political issues. FTV's claim is also contrary to the requirements of due process for that reason.

6. NO INTEREST WITHIN THE MEANING OF SECTION 3:303 BW

A **Introduction**

6.1 Section 3:303 of the Civil Code requires, on pain of inadmissibility, that the plaintiff has a sufficient interest in his claim. Without a sufficient interest, the plaintiff is not entitled to a legal claim. According to the parliamentary history, this rule of law means that there must be a sufficient interest to justify proceedings." The requirement of Section 3:303 of the Civil Code also includes a balancing of the interests of the parties involved, as well as the requirements of due process and the interests of justice in general."

6.2 In cases where the plaintiff seeks a declaratory judgment, the starting point is that there must be a concrete interest. To this end, it is important that the party seeking the declaration benefits from the declaration and that the declaration has binding effect on the other party. If that interest is disputed or the court wishes to clarify that interest of its own motion, the burden of proof and the burden of proof in that regard rests, in principle, on the party bringing the action."

6.3 In the Summons, FTV seeks only a declaratory judgment that AbbVie acted unlawfully during the Relevant Period. It expressly does not seek damages. Also, according to FTV, the action does not seek damages.

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31 See HR 24 March 2023, ECLI:NL:HR:443 *Deliveroo 1* roy. 3.2.6.
32 Parl. Gesch. BW Book 3 1981, p. 915 (T.M.); C.J.J.M. Stolker, T&C BW, Article 3:303 BW, ann. 1; H.J. Snijders and A. Wendels, Civil Appeal (BPP no. 2) 2009/79
33 MoA II, Parl. History of Book 3 of the Civil Code, pp. 915 -916.
34 Cf HR 12 April 2019, ECLI:NL:HR:2019:590, para 4.1.2. *(Dexia)*

FTV explicitly states in its Summons that it has brought these proceedings for a different purpose, namely to set a precedent on the alleged (un)legality of excessive pricing for a drug protected by a patent'.[5]

6.4 FTV does not substantiate why the Closely Defined Group would benefit from the claimed declaratory judgment. In other words: FTV does not motivate how granting its claims would benefit health insurance policyholders in the Netherlands. Nor does it demonstrate how the declaratory relief it seeks would actually reduce displacement of care. FTV therefore does not substantiate its interest in bringing its legal action against AbbVie, or at least insufficiently.

6.5 The lack of a sufficient and legally respectable interest is all the more compelling given that the precedent that FTV seeks to obtain through these proceedings relates to allegedly unlawful conduct - namely charging the allegedly excessive prices for Humira during the Relevant Period - that took place exclusively in the past. That allegedly unlawful conduct has not been at issue for quite some time, as the allegedly excessive prices challenged by FTV have not applied since the expiry of the patent in 2018. It follows from this alone that there cannot even be any improvement in the situation of the Closely Related Group by initiating the present action. After all, your Court is not being asked to rectify a situation (e.g. in the form of an injunction or prohibition, or any form of compensation).

6.6 FTV explicitly states in paragraph 1.6 of the Summons:

> *"The issue thus has two dimensions: eiterZiyds the general interest that there is no unnecessary verdriiigiitg vait care not resulting in the loss of life years ict good health and aitder the problem of overpaying for medicines. While these problems are natiiv santetihanpeit coriit FTV iit this procedure printair on for the only interest concerning the otiitodipe verdrineiiie of gore ett friet on for the aforementioned vernioReiisrechteli]interest. It is iit principle aati the care providers en/o(hospitals to look after* the *latter interest."*
>
> (Underlining lawyer)

6.7 FTV thus claims that there would be two dimensions, namely (i) the (alleged) unnecessary displacement of care and (ii) the (alleged) overpayment for medicines. FTV claims that it serves the public interest of preventing unnecessary displacement of care, while health insurers and/or hospitals should serve the interest of not overpaying for drugs. However, this is inconsistent with FTV's main claim in the present proceedings. Indeed, FTV is not seeking a declaratory judgment on displacement of care, but precisely on what it believes should be the responsibility of insurers and hospitals to pursue, namely the (alleged) overpricing of the drug

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35 Paragraph 1.7 of the Summons.

Humira. There is thus an inextricable link between the two "dimensions" claimed by FTV which leads to the conclusion that FTV actually serves the interests of insurers and hospitals.

6.8 To some extent, this is also confirmed by FTV's own assertion in paragraph 5.20 of the Summons:

> *"FTV enjoys a lot of stetat both from individual persons and orgaitisations, including insurers and (iitternatiotial j belaitgenorgaitisations."*
>
> (Understrcping lawyer)

6.9 As already noted in section 3.10, several Dutch health insurers sent letters to AbbVie in which they unequivocally reserved the right to compensation for the damages they would have suffered as a result of AbbVie's alleged unlawful behaviour in connection with its pricing and/or discounting policy with respect to Humira.

6.10 AbbVie will further explain in the following why the mere obtaining of precedent is not a sufficient and legally respectable interest for FTV to be accommodated in its claim

B **Wanting to** obtain **precedent is not a sufficient interest**

(a) FTV asks court to set new standard

6. I I The interest that FTV claims to have in bringing AbbVie to court in this case is thus to create an 'example case', which implies an intention to be able to rely on that example in other - future - cases between other parties, whether in relation to other products or not, about allegedly excessive pricing for drugs protected by patents. This interest, as stated above, is not a sufficient interest within the meaning of Section 3:303 of the Civil Code.

6.12 If the creation of a precedent were accepted as the mere objective of legal proceedings, the court would in fact take on the role of a regulator, as it would be asked to formulate a standard in that precedent (which would then have to be violated). This is all the more pressing as the precedent would concern an area of law - in this case, the pricing, reimbursement and patent protection of medicines - that is highly regulated by horizontal and sector-specific rules, as explained above in Chapter 5. In effect, the civil court would be taking on a competence that rests with public bodies that are precisely those specifically authorised to regulate, among other things, the pricing of medicines. However, that is not what the civil court is for. Were it otherwise, the Dutch legal system would be inundated with requests for precedent.

6.13 Also, FTV does not motivate at all how granting its claim will serve the interest of the Closely Related Group. If FTV's objective is to secure sharp reductions in drug prices through these proceedings, it should be noted that such an objective would by no means be the guaranteed outcome of these proceedings should the claim be upheld. And in case this

would be the outcome, FTV would have to demonstrate this and also show that it would also be beneficial to the entire Closely Associated Group in both the short and long term.

6.14 Although AbbVie will not raise its substantive defences until the substantive hearing of the case, if and to the extent that it comes to a substantive hearing, AbbVie wishes to note at this stage that the declaratory relief sought by FTV would upset the careful balance that the pricing and reimbursement regime in the Netherlands seeks to create (as described in Chapter 5). FTV does not take into account the possible negative practical consequences of upsetting such a balance, including, for example, that innovation and/or the availability of medicines in the Netherlands - an issue that already exists in the Netherlands - would be put under pressure. The objective alleged by FTV will therefore not be achieved by the present action, which already establishes that there is no interest justifying the present proceedings. For the purpose alleged by FTVs, this action is simply not effective.

(b) Seeking precedent no interest shown by case law

6.15 Back in 1993, the Supreme Court ruled that there is no sufficient interest in bringing an appeal (cassation in that case) if the sole purpose is to prevent a ruling from acting as a precedent in other cases.[36] The *Alp/Staat* case involved the application for a residence permit by a refugee (plaintiff) that had been rejected by the lower courts, but which he had meanwhile obtained legally in another way. The claimant nevertheless appealed in cassation against the court's rejection judgment. The claimant's aim was to overturn the lower court's earlier decision so that it could no longer be invoked in future cases against other refugees. However, the Supreme Court ruled that this was not a sufficient interest within the meaning of Section 3:303 of the Civil Code:

> *"The forekorneit that the court's decision in his case, according to Alp otijtiiste, will be further used by the State to supportimiitg vaii his stattdpiint ict aitdere zakeit, is* not a *sufficient belatig iii cassation."*

6.16 The same applies *a fortiori* to the interest in obtaining a precedent that can then be used in other cases - as FTV expressly states in its Summons that it intends to do.

6.17 Also with regard to the right to join in civil proceedings, the Supreme Court has explicitly ruled on whether obtaining precedent may count as a sufficient interest to be allowed to join in a case. The Supreme Court's most recent ruling on this issue is HR 21 May 2021, ECLI:NL:HR:2021:750 *(Stichting Loterij Incasso/Staatsloterij B.V.).* In that case, Stichting Loterij Incasso had explained its interest in detail. The Supreme Court summarised that alleged interest, as claimed by the claimant, in paragraph 2.3:

> *"In the appeal in cassation lodged by the State Lottery against that judgment, Stichting Loterij Incasso sought leave to intervene on the side of the fixed*

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36 Supreme Court 16 April 1993, NJ 1994/444 *(Alp7Staat).*

Defendant J. It explained its interest in food as follows. Stichfittg Loterij Incasso was founded for the specific, statutory purpose of defending the interests of its members in establishing and *collecting claims against the State Lottery and obtaining compensation. The interests of [defendant J and Stichting Loterij Incasso run completely parallel. The outcome of the cassation proceedings in the case of [defendant J is of evident importance for the legal position of Stichting L o t e r i j" Incasso. In this cassation proceeding,* issues *will be raised such as causality between the unlawful communications by the State Lottery and the damage suffered by the participants, the manner in which that damage is assessed and the benefit stocktaking, which will also come up for discussion in lawsuits that Stichting Loterij' Incasso will have to bring in the future if* no *such settlement is reached. In addition, the cassation proceedings in the case of [defendant J for Stichting Loterij Incasso are of factual importance for the progress of the determination of damages. Annulment of the judgment under appeal will irrevocably lead to a major delay in achieving the objective of Stichting Loterij' litcasso.*

6.18 The Supreme Court responds in paragraphs 2.4 and 2.5:

"2.4 Any person who has an interest in a lawsuit *pending between several parties may claim to be joined therein (Article 217 of the Dutch Code of Civil Procedure). To have such an interest, it is sufficient that the party claiming to be joined may suffer adverse consequences of the outcome of the proceedings which is unfavourable to the party to whose side he joins. In this context, 'adverse consequences' means the factual or legal consequences which the granting or dismissal of the action brought in those proceedings or the final decision taken in those proceedings may have for the party seeking t h e joinder. (See, inter alia, HR 15 noventber* 2019, *ECLI.-NL.-HR.-2019.' 1787 (NJ 2019/451,' ed.}, para. 2.3. j" Thus, in the niopeli]ke precedeittsverkiitg vait that ruling, itiet is not already a sufficient belaiip geleeeit, also tiiet iiidieti there is talk of very similar claims o([eity coniplexes ttisseit partly the same parties. (HR 12 June 2015, ECLI:NL:HR:2015:1602 (NJ 20157295; ed.}, para 3.2.)*

2.5 The interest claimed by Stichting Loterij Incasso in these cassation proceedings iii in connection with the issues which will be r a i s e d in those proceedings, relates exclusively to the precedential value of the judgment to be given. That interest is not one that Article 217 Rv is intended to protect. This also applies to the interest claimed by Stichting Loterij Incasso that a nullification of the contested judgment will lead to erosion of the achievement of its objective. The claim must therefore be dismissed.".

" See also the cases cited by the A-G in *SfiChting Lottery" Incasso v State Lottery B.V.* in her opinion at r.o. 2.13.

(Underlining lawyer)

6.19 Whereas FTV is definitely shrouded in mists as to exactly what its interest in precedent consists of," the Lottery Collection Foundation cited concrete interests in support of its claim for joinder." Nevertheless, the Supreme Court is perfectly clear in its conclusion: potential precedent is not a sufficient interest, even if there are very similar claims or factual complexes between partly the same parties. It appears to AbbVie that the negative consequences for a party that is joined in proceedings by a third party as a mere exemplary defendant are generally even greater than the negative consequences for the original parties in a case where a third party seeks joinder merely to set a precedent.

6.20 With this in mind, it is obvious that the interest in obtaining a precedent in the present case should, at the very least, not be subjected to a lower interest requirement than the interest in joinder within the meaning of Section 217 of the Dutch Code of Civil Procedure. What the Supreme Court ruled in Stichting Loterij Incasso v. Staatsloterij B.V. therefore applies *a fortiori* to an interest in commencing proceedings with the pure purpose of creating a precedent. This is all the more compelling as the intended precedent relates to allegedly unlawful conduct that took place in the past, and which, according to FTV's own words, has not existed for a long time now. The prices that FTV claims were unlawful have not been in force in the Netherlands for years.

(c) Not every interest is an interest within the meaning of Section 3:303 of the Civil Code

6.21 Moreover, not every interest that does exist is automatically considered an interest as referred to in Section 3:303 of the Civil Code. An interest may be of such a nature that the civil judicial process is not designed to serve that interest and is therefore not equipped to dispose of the case in question. For example, previous case law has repeatedly ruled that a purely emotional or purely principled interest is insufficient to constitute a legal or legally relevant interest within the meaning of Section 3:303 of the Civil Code. A claim in civil proceedings must be able to affect the legal position of the parties to pass the test of Section 3:303 of the DCC. Thus, at the very least, rights of the claimant must be at stake. This is not the case if mere precedent is sought in a case in which only past facts play a role, as in this case.

6.22 To illustrate that a claim must be able to affect the rights of the parties in order to have a sufficient interest to bring it in proceedings, AbbVie, for example, refers to case law from which it follows that a purely principled interest does not constitute a sufficient interest within the meaning of Art. 3:303 of the Civil Code. For example, in its judgment of 16 April 1993, NJ 1994/445, the Supreme Court held that:

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18 In fact, there is little more than what she states in paragraph 1.7 of the Summons, see supra.

19 It is up to the joinder claimant, as it is up to the claimant in the present case, to state the grounds on which its interest consists (see the A-G's opinion in *Stichting Loterij' Incasso v Staatsloterij B.V.,* at para 2.14).

40 HR 9 October 1998, ECLI:NL:PHR: 1998:ZC2735, *NJ* 1998/853 *(Van Aalten7VlJ).*

> *"obtaining a principled judgment by a higher court is not a sufficient interest of plaintiffs in" their appeal in cassation. In view of the undertaking giitg vait de Staat not to collect the costs awarded by the court and to bear the remaining costs, the plaintiffs cannot derive any interest from the costs of the proceedings either."*

6.23 In its decision of 8 December 2005, the Amsterdam Court of Appeal also decided inadmissibility, on the grounds that the outcome of the appeal lodged with that court would not affect the legal relationship between the parties. In that case, the appellant Remaz wished to continue the appeal even though, as part of a settlement between the parties, Remaz had in the meantime complied in full with the judgment of the subdistrict court, including payment of the legal costs on the part of the intimidated party. Regardless of the outcome of the appeal, Remaz would also not recover the legal costs from its other party if it won the appeal. The case was important only because of the principled nature of the case for Remaz. However, the principled interest asserted by Remaz was not held by the Court to be a sufficient interest."

> *"In the light of the above (.... j shown above - which amounts to saying that the outcome of the appeal - under enip importance -al least for the legal relationship between the parties - the Court of Appeal finds that there is an insufficient interest in the appeal brought by Rema. The fundamental interest claimed by Renia cannot iii this zediit p be regarded as a sufficient interest, especially since a judgment in interlocutory proceedings is not entitled to a hearing.*
>
> *The court will therefore declare Reiita- inadmissible in its appeal.*
>
> (Underlining lawyer)

6.24 A purely principled interest is thus an example of an interest that is not a matter of law respectable interest within the meaning of Section 3:303 of the Civil Code.

6.25 The Supreme Court ruled in the JeJrey judgment that a purely emotional interest cannot be regarded as a sufficient interest within the meaning of Section 3:303 of the Civil Code either. In that case, Jeffrey's parents had claimed a declaratory judgment that the hospital was liable for the death of their child, which declaration was necessary for the parents' grieving process. The Supreme Court ruled that this emotional interest, however weighty, did not qualify as a sufficient interest within the meaning of Section 3:303 of the Civil Code."

6.26 In the Jeffrey judgment, the sticking point was the parents' position that a declaratory judgment was necessary for their coping process and not for determining the

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41 HR 16 April 1993, *NJ* 1994/445 *(Karaca and Toptas v state)*

42 Amsterdam Court of Appeal 8 December 2005, ECLI:NL:GHAMS:2005:AV3085.

43 HR 9 October 1998, ECLI:NL:PHR: 1998:ZC2735, *NJ* 1998/853 *(Van Aalten7VU).*

legal relationship between the parties and the exercise of their subjective rights. Granting the claimed declaratory judgment to support the parents' emotional coping process would not affect the parents' legal relationship with the hospital. Granting the claimed declaratory judgment for the parents' coping process would not result in a legally different position of the parents. However, a litigation interest does require that the claimed may have an impact on the legal position of the plaintiff.

6.27 And precisely the latter is also lacking in the present case. Granting FTV's claimed declaratory judgment will not result in a legally different position of the Closely Associated Group vis-à-vis AbbVie.

6.28 Section 3:303 of the Civil Code thus has restrictions on the type of interest that can be invoked to justify legal proceedings." What is required is that an interest in legal proceedings (a) relates to the legal relationship between the parties to the proceedings and (b) that the outcome of the case must be capable of improving the legal position of the plaintiff vis-à-vis the defendant. This essentially makes the procedural interest immediately also a legal or legally relevant interest. Where there is no procedural interest, a legal interest or interest relevant to the law is also missing. Moreover, the nature of the interest may entail that the civil court proceedings are not designed to dispose of the case in question.

6.29 The interest alleged by FTV - namely obtaining precedent - is no more relevant in a legal sense (for the purposes of establishing a legitimate litigation interest) than a purely emotional interest and/or a purely principled interest. The outcome of the present proceedings - given that they are aimed solely at obtaining precedent[5] - will also be without any relevance to the legal relationship between the Closely Related Group and AbbVie, partly because the prices for Humira applicable during the Relevant Period have not been in force for more than five years.

(d) Obtaining precedent has no effect on the legal relationship Between the Closely Related Group and AbbVie

6.30 Thus, for a sufficient interest in the action, a declaratory judgment must lead to an improvement of the plaintiff's legal position in the legal relationship with the defendant.^ FTV wishes to use the claimed declaratory judgment to obtain a precedent on the pricing of Humira with a view to pricing - future or otherwise - for other drugs and from other pharmaceutical companies. That declaratory judgment would therefore not affect the legal relationship between the Closely Related Group and AbbVie. FTV apparently wants to ensure that in the future it will be able to take action against other parties (or AbbVie as far as AbbVie's products other than Humira are concerned), which in its view have a

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44 For more examples, see A. Hartkamp & C. Sieburgh, AsserfHartkamp & Sieburgh Law of Obligations 6-IV, Deventer: Wolters Kluwer 2015, no 155; F. Bakels, A. Hammerstein & E. Wesseling-Van Gent, Asser Procesrecht 4 Hoger Beroep, Deventer: Wolters Kluwer 2012, no 182.

45 As FTV itself states in paragraph 1.7 of the Summons.
According to A-G Koopmans for HR 15 October 1993, *NJ* 1994/8, it can be deduced from the case law that the declaration of right must 'benefit' the plaintiff vis-à-vis the defendant; the circumstance that the court determines what the legal situation is should be able to bind the defendant.

charge an excessive price for a drug protected by a patent, may sue, relying on the judgment in the present case. Such an outcome, as said, will be without any relevance to the legal relationship between the Closely Related Group and AbbVie.

6.31 According to established case law, any interest in a declaratory judgment for legal relationships other than those between the parties will not pass the test of Section 3:303 of the Civil Code." For example, in a judgment of 24 February 2015, the 's-Hertogenbosch Court of Appeal ruled that there was no sufficient interest within the meaning of Section 3:303 of the Civil Code because the declaratory judgment sought by ABN AMRO in that case was no longer relevant to the legal relationship between ABN AMRO and the respondent."

> *"3.5. The court of appeal observes that ABN AMRO only claims a declaratory judgment in these proceedings. The court of appeal should assess ex officio whether ABN AMRO has (still) an interest in the claimed declaratory judgment on appeal within the meaning of article 3:303 of the Dutch Civil Code. First of all, if a declaratory judgment is claimed, the claimant must demonstrate its interest in the claim. Special circumstances must be established or proven which make it desirable that the claimant's liability be secured by a declaratory judgment.(...)*
>
> *3.7. ABN AMRO argues that it' has an interest in a ruling in the oitderhaviee* - t/ii *the* above-mentioned *passage from the statement of appeal, the court of appeal deduces that the declaratory judgment claimed by ABN AMRO in appeal is no longer relevant to the legal relationship between ABN AMRO and [intimateJ. The labour agreement between the parties has meanwhile irrevocably ended and ABN AMRO will, iii if the declaratory judgment is granted, according to its own words, not attach any consequences to it vis-à-vis [intimate] J by claiming any wages or other amounts from it.*
>
> *A declaratory judgment may serve to establish a legal relationship in a binding manner or to specify its identity to the other party or parties involved in this legal relationship (cf. HR 22 January 1993, ECLI:NL:HR.-1993.' ZC0833). In these proceedings, only the legal dispute between ABN AMRO and the claimant is at issue. The claimed declaratory judgment is not of more importance for that, or at least the bank has not sufficiently explained it. Possibly ABN AMRO would like a read-out of the Collective Labour Agreement applicable to the employment contract between it and [an individual] with regard to disputes with other employees (whether or not applicable), but that is not an interest that concerns the legal relationship between it and the fee'i'ntinued and that is therefore insufficient to justify the claimed declaratory judgment."*

Cf: Court of Appeal of The Hague 9 April 2019, ECLI:NL:GHDHA:2019: 1076; Court of Appeal of The Hague 10 July 2018,
ECLI:NL:GHDHA:2018:167 l, rulings 3.1 and 3.2.

48 Hof 's-Hertogenbosch 24 February 2015, ECLI:NL:GHSHE:2015:600.

(Underlining Lawyer)

6.32 Thus, the declaratory judgment must relate only to the specific legal relationship between the parties. This amounts to saying that the declaratory judgment must relate to the legal relationship between AbbVie and the Closely Related Group and AbbVie's allegedly unlawful conduct that is the subject of the present proceedings insofar as it relates exclusively to the pricing of Humira during the Relevant Period. Thus, FTV cannot seek a declaratory judgment that may affect the rights or obligations of other parties not involved in the present dispute and that would have no practical effect on the legal position of the Closely Related Group. On that ground too, the claim must be declared inadmissible.

(e) No precedent will be attached to a ruling in the present proceedings arrive

6.33 Moreover, any judgment in the present case will not have any precedential effect. Under Dutch law, the general principle is that each case is judged on its own merits - and thus on its own specific facts and circumstances. Precedent effect is at odds with this principle, as it is limited to pure legal judgments based solely on legal principles and not containing findings of fact. Thus, the precedent mechanism does not apply to disputes in which 'open standards' are applied to the underlying facts of the case such as the interpretation of a particular duty of care based on those facts."

6.34 In the present case, a ruling on the question of the legality or otherwise of allegedly excessive pricing for Humira will not result in a pure judgment of law. The judgment will therefore not be able to set a precedent. After all, assessing the question whether excessive pricing of a medicine protected by patents exists is a factual matter that requires an analysis of the specific circumstances. A ruling on the pricing of Humira, therefore, cannot in any case be applied one-to-one to the pricing of other drugs. The price for Humira against which FTV's action is directed has not, even by FTV's own admission, been charged for Humira since 2018, so the declaratory judgment sought also cannot set a precedent for future actions against the price for Humira itself.

6.35 Therefore, the Dutch legal system (unlike *common law* systems) does not have an absolute precedential effect of court decisions, in the sense that previous court decisions in the Netherlands cannot serve as binding legal authority for future cases. In a *civil law* system such as the Dutch legal system, the generally applicable rules are, in principle, laid down in codified law and that forms the primary basis of judicial decisions. Since judicial decisions are highly factual of

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[49] B. van der Wiel, *Derderiwerking van rechterlijke verdicts,* NJB 2011/671: *"Now that precedent effect is objectively limited to pure legal judgments, this mechanism does not offer solace insofar as the issues in dispute go beyond the realm of pure legal judgments, such as, in particular, in the application of vague norms. To that extent, the significance of precedent in facilitating the settlement of similar disputes is limited."*

nature and the rules on which they are based are enshrined in codified law rather than in jurisprudence, such decisions in principle have no legally binding effect on future court decisions.

6.36 Even Supreme Court judgments, while highly authoritative, do not have absolute precedent in a strictly legal sense. After all, firstly, lower courts are still free to depart from judgments if they believe that a Supreme Court ruling has become obsolete. Second, the specific facts and circumstances of the case at hand may require a different approach. Apart from *res* itidicara, judicial rulings of course do serve as *apursuasive authoriiy* (persuasive authority), meaning that judges can use the ruling as a source of legal reasoning in future cases. However, a ruling in the current court case will not set a precedent in the strict legal sense, as it will be specific to the unique circumstances of this case and, as a result, will not be binding on future legal proceedings.

6.37 The precedent that FTV seeks to obtain will therefore also be of no use in the relationship between the Nauw Group and other parties (and/or in respect of different products). A declaratory judgment specifically relating to the pricing of Humira will, as stated above, not be applicable one-to-one in any future cases concerning the pricing of any (other) medicine. In such future cases, applications for a declaratory judgment that the pricing of a particular medicine is unlawful will not be admissible on the simple ground that such a declaratory judgment was obtained in a previous case on the basis of the specific circumstances involved in that particular case. Claims such as the present one that merely seek to create an example should therefore be declared inadmissible for lack of interest. This applies to any ordinary proceedings and it applies *a fortiori,* or at least equally, to a collective action.

6.38 As there can be no precedential effect and no other legal consequences are intended by the action, granting FTV's claims would thus not improve the legal position of the persons belonging to the Closely Defined Group vis-à-vis AbbVie. In short, FTV's claims will therefore make no demonstrable positive difference to the Closely Defined Group.'[0] Thereby, FTV has a lack of litigation interest. Thus, FTV also lacks a sufficient interest in its legal claim on this ground and should be declared inadmissible.

C **Balance of interests, breach of due process** and interest **justice in general**

(a) Introduction

6.39 As mentioned above, the requirement of Section 3:303 of the Civil Code also involves weighing the interests of the parties involved, as well as the requirements of proper

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50 See in this connection, for example, the judgment of Rb. 's-Gravenhage of 10 December 2001, ECLI:NL:RBSGR:2001:AL9081. This ruling shows that, from a substantive point of view, the parties do not appear to have a legal dispute and that the eviction claim is only aimed at helping her former partner obtain an urgency declaration for housing.

litigation and the interests of justice in general. AbbVie will set out in the following that the present action by FTV is also contrary to the requirements of due process and the interests of justice in general, and that a balancing of interests should also result in AbbVie's favour.

(b) No defensible split between illegality and liability (contrary to due process requirements)

6.40 The declaratory judgment sought by FTV is actually a bare declaration, as FTV explicitly stated in the Summons that it does not seek compensation for damages. In fact, FTV is trying to separate one of the elements of tort, namely unlawfulness, from the other elements of tort (namely: imputability, damages, causal link and relativity), and is only seeking a declaration in respect of that particular element. However, such separation is not possible in litigation.

6.41 The requirements of due process mean that a division of claims concerning the recognition of a right and those for an order for performance is only admissible if special circumstances justify such a division. According to the Supreme Court, this follows from the fact that the plaintiff must have an interest in his claim. Thus, the Supreme Court considered in the Dominee judgment in question":

> *"0. that an action, the sole purpose of which is to have the existence of a legal relationship determined by res judicata, is admissible only if the plaintiff has an interest in the fact that such a statement, binding on the opposing party, is immediately made by the court,- that the court must take note of such an interest, as an indispensable requirement for the existence of the right to legal protection by judicial process, even ex officio; when assessing whether such an interest is material, it should be taken into account that the interests of due process and the interests of justice should not be infringed, that the plaintiff may not arbitrarily divide his legal claim into separate claims relating to the recognition of entitlement and an order to pay, and that this division is only admissible when special circumstances justify it in order to preserve the plaintiff's rights."*

FTV has neither alleged nor argued any special circumstances that justify a division of claims in this case.

6.42 The rationale behind the splitting ban as formulated in the Dominee judgment is to avoid, as much as possible, a proliferation of separate proceedings that protect the same legal interest or right - or at least derive their legal basis from it. FTV goes even further by waiving not only the request to order performance (or prohibit an act), but also by separating tortiousness from the other elements of tort, including liability and

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[51] Supreme Court 30 March 1951, *NJ* 1952/29 *Reverend).*

compensation. The prohibition on splitting is fully applicable in the present case. All the more so since, should FTV's claim for a declaratory judgment be upheld, the risk of an uncontrollable proliferation of proceedings lurks.

6.43 The unnecessary proliferation of cases that the Dominee judgment thus seeks to prevent is not affected by the Supreme Court's subsequent AfGZf judgment[52] . In that judgment, the Supreme Court did partially reverse the prohibition on splitting from the *Dominee* judgment, but only insofar as it concerns the claim for a declaratory judgment regarding liability for damages in cases where the possibility of damages is plausible. The A/GZY judgment refers to the situation where the plaintiff would seek a declaratory judgment that the defendant *is liable for damages.* However, FTV specifically argues precisely that the action is not for damages (and therefore not for a finding of liability). Thus, for cases like the present one, where it is impossible to see what a person's interest is in a bare statement of law, the doctrine from the Dominee judgment is still valid. Groeneveld-Tijssens writes in this regard5':

> *"From the AIG7X judgment, I do not 'vordeit infer that the Supreme Court has completely departed from the prohibition in the Dominee judgment of unnecessarily splitting claims. (...) In my opinion, the Supreme Court, in the oitderhis judgment, has only partially complied with the Doriiirlee judgment, in the sense that it has created an exception to the rule that the plaintiff may not arbitrarily divide his claims - to the extent that the claim relates to liability for damages, the plaintiff may do so, provided that the possibility that the plaintiff has suffered or is suffering damage is plausible."*

6.44 In his opinion on the A/GZY judgment, Advocate General Spier argued that there are good grounds to uphold the splitting ban. For instance, he pointed out that a "bald statement of law" would allow the plaintiff to circumvent the need to make his damage plausible, as is required in a claim for damages to be further recorded by the state. Furthermore, the claimant would deprive the court of the power to assess the damages itself under Section 612 Rv.

6.45 Finally, Spier highlighted the main ground for the doctrine of the Domfnee judgment namely that: "it *is necessary to prevent flat participants in the legal process from being harassed with claims in which' plaintiff* [has] *no reasonable interest*". He concluded that it cannot be said that the doctrine from the ***Domfnee judgment is*** a meaningless formalism. Nevertheless, Spier concluded that in the situation of *AIG7X,* the rule of law from the *Dominee judgment* would lead to excessive formalism and therefore should not be applied. In doing so, the decisive factor in that case was that the defendant had already: *'resigned itself to the fact that a sequel gproceclure might be necessary*'.[5] ' That is evidently different in the present case.

5? Supreme Court 27 March 2015, ECLI:NL:HR:2015:760 *{AIG7X).*

53 N.E. Groeneveld-Tijssens, *De verklaring voor recht,* Deventer: Kluwer 2015, no 39.

54 See no 9-14 of A-G Spier's opinion in ECLI:NL:PHR:2014:2733.

6.46 In this respect, Dutch civil procedural law only provides for the possibility of splitting compensation proceedings into main proceedings aimed at establishing liability and follow-up proceedings aimed at establishing the nature and extent of the damage. This possibility is created by Article 612 Rv on the one hand and by the Partial Disputes Procedure Act (Articles l019w-10l9cc Rv) on the other. Thus, when only a declaratory judgment is claimed that unlawful action has been taken without anticipating a damages assessment procedure or follow-up procedure - as in this case - the prohibition on splitting applies in full. The plaintiff who seeks a declaratory judgment that is not aimed at recovering damages must plead special circumstances that justify making a declaratory judgment sufficient. If the plaintiff fails to do so or if the circumstances do not justify the plaintiff sufficing with a declaratory judgment, the plaintiff should be declared inadmissible ex officio.[5] ' As stated above, FTV has not alleged any, or at least insufficient, circumstances that would justify FTV limiting itself to the bare declaration it seeks.

(c) AbbVie's interest in legal certainty (balancing of interests)

6.47 Moreover, it is undesirable to completely abandon the splitting ban, as Dutch civil procedural law was not designed for the mere legal recognition of a substantive right. Because the recognition of a substantive right does not automatically imply the possibility of realisation of that right, the party against whom a declaratory judgment is pronounced is often in uncertainty about its legal position vis-à-vis the other party.[56] With FTV having categorically excluded compensation for damages, it is unclear what the consequences for AbbVie would be if the claimed declaratory judgment were granted.

6.48 Groeneveld-Tijssens therefore rightly argues that because of this uncertainty that a declaratory judgment may entail, it is appropriate to be cautious in a claim that seeks a declaratory judgment only if the plaintiff could (also) have claimed an order for performance. AbbVie's legal claim, if upheld, would therefore disproportionately harm AbbVie's interests, while upholding FTV's claim will have no identifiable positive impact on the legal position of the Closely Related Group.

6.49 In addition, the parties should be protected from being sued by third parties merely to serve as examples in future cases against yet others. The present proceedings not only involve high costs and a considerable investment of time, but also result in damage to AbbVie through very negative, if not defamatory, public statements. Moreover, that damage is actively promoted by FTV as evidenced by the various publications incriminating to AbbVie issued by FTV around the issuance of the writ, **Production 5.**

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55 N.E. Groeneveld-Tijssens, *De verklaring voor recht,* Deventer: Kluwer 2015, no 81.

56 N.E. Groeneveld-Tijssens, *The Supreme Court and the declaratory judgment,* NTBR 2015/32.

(d) The importance of good justice

6.50 Finally, FTV's legal claim is also not in the interest of justice in general. The bare declaration that AbbVie acted unlawfully will, in the absence of an additional claim for damages, create much confusion as to what the implications of that declaration should be. This would open the door to more proceedings seeking the alleged implications, unnecessarily burdening the judiciary and compromising the interests of due process.

6.51 As FTV's legal claim essentially serves no (clear) purpose, the test of Section 3:303 of the Civil Code, which includes a balancing of the parties' interests, has not been met, as well as the requirements of due process or the interests of proper administration of justice in general.

D **Conclusion**

6.52 All that has been said above shows that FTV does not have a sufficient interest in its claims. Thus, FTV should be declared inadmissible in its claims. Already on this inadmissibility of FTV, Your Court could dismiss this case.

6.53 AbbVie will show below, in the alternative - and perhaps superfluously - that FTV is also inadmissible in its claims because it does not meet the admissibility requirements of Section 1018c(5) Rv, which include the requirements of Section 3:305a of the Civil Code.

7. PHARMA FOUNDATION INADMISSIBLE UNDER THE WAMCA

A Introduction

(a) Applicability of WAMCA

7.1 FTV takes the view that the claimed declaratory judgment should be assessed under the WAMCA, as in its view the present case involves a collective claim based on a series of events that occurred both before and after 15 November 2016. FTV believes there is a continuing tort because AbbVie's alleged excessive pricing of Humira occurred during the Relevant Period from 2004 to l5 October 2018. It is clear from the parliamentary history that in such a case, the law applicable is that in force at the time the last event to which the claim relates took place. To the extent that Your Court finds that FTV's claim can indeed be brought on the basis of the WAMCA, AbbVie has no objection to this, without, however, thereby waiving any right.

7.2 In particular, AbbVie's agreement to apply the WAMCA does not mean that AbbVie recognises that the alleged wrongful conduct should be considered as "one continuous tort". On the contrary, to the extent that any tort would be concluded at all, that tort would have consisted of a multitude of separate conduct.

7.3 Indeed, during the Relevant Period, different pricing (and reimbursement) regimes applied to Humira. In particular, between 2004, when Humira was introduced on the Dutch market, and 2012, the product was included in the outpatient system (the so-called Medicines Reimbursement System) where the product could be purchased from retail pharmacists. During this period, the maximum reimbursement for the product was regularly revised. In 2012, Humira was transferred to the so-called intramural system, which remained in place until biosimilars entered the market. Intramural means that the product can only be supplied and administered by hospitals. Moreover, in 2006, the Dutch system was reformed to a system of "regulated market forces", encouraging regulated competition between health insurers and healthcare providers.

7.4 In 2012, Humira and other products were switched to the "inpatient" system with the aim of saving additional costs. The idea behind this switch was that hospitals would be in a better position than pharmacists to negotiate discounts on these products. Since then, AbbVie (and its predecessor Abbott) has indeed entered into a large number of separate agreements with individual hospitals (and sometimes groups of hospitals). In each of these agreements, price terms for Humira were individually negotiated.

7.5 In view of the above, it is clear that the reimbursement and pricing conditions for Humira were constantly reviewed and applied as part of regulatory revisions to the reimbursement limit or developments in maximum price regulations or under individual agreements with hospitals and groups of hospitals. The relevant agreements entered into with hospitals had durations ranging from one to several years. It follows that AbbVie did not pursue a single pricing policy since 2004. On the contrary, AbbVie had to comply with revisions of maximum reimbursement limits and subsequently engaged in separate negotiations for the supply of Humira, each resulting in specific price conditions. Thus, these behaviours must be classified as separate behaviours each time.

7.6 As said, AbbVie has no objections to the application of the WAMCA, as FTV is not seeking compensation for damages in the present proceedings. However, in view of possible separate claims for damages (e.g. from health insurers) in relation to the subject matter of this case, this agreement to applicability the WAMCA, as stated above, should not be interpreted as acceptance by AbbVie that its pricing behaviour in relation to Humira during the Relevant Period would have been one continuous act (or tort).

(b) The admissibility decision under the WAMCA

7.7 Before the substantive hearing of the class action can take place, pursuant to section l0l8c(5) Rv, your Court must make a (positive) decision on each of the following criteria, namely that:

(i) FTV meets the admissibility requirements of Article 3:305a paragraphs 1 to 3 of the Civil Code;

(ii) FTV has made a sufficiently plausible case that pursuing this collective claim is more efficient and effective than bringing an individual claim; and

(iii) no summary evidence of the unsoundness of the collective claim was revealed at the time the proceedings were brought.

7.8 AbbVie will show and justify below that FTV has not met any of the above requirements so that it should be declared inadmissible.

7.9 Even if, as FTV argues, there would be the light regime of paragraph 6 of Article 3:305a of the Civil Code - which AbbVie expressly disputes - FTV's claim is inadmissible as the admissibility requirements of similarity and representativeness of Article 3:305a, paragraph 1 and paragraph 2, opening words, of the Civil Code are not met. FTV's argument that the 'light regime' of Article 3:305a paragraph 6 of the DCC applies because it did not bring a claim for damages but only a claim for a declaratory judgment with, according to it, a purely 'idealistic purpose', does not alter this. Indeed, these requirements apply just as much if the exceptional situation of Article 3:305a paragraph 6 of the Civil Code did apply. To the extent that FTV thereby implies that the action is essentially a public interest action with an idealistic purpose, AbbVie disputes this.

7.10 In what follows, AbbVie will first conclude that the light regime of Article 3:305a(6) BW does not apply. It will then discuss the admissibility requirements of Article 3:305a of the Civil Code which FTV does not meet. Then AbbVie will explain that pursuing this class action is not more efficient and effective than bringing an individual claim. Finally, AbbVie will explain why FTV's claims have been found to be summarily unsound.

B **'FTV' does not** fall **under the 'light regime' of Article 3:305a(**6) **BW**

7.11 The 'light regime' of Article 3:305a(6) of the Civil Code applies if there is (i) a collective action with an idealistic purpose and a very limited financial interest' or (ii) when the nature of the collective action gives rise to it. When applying the so-called 'light regime', the collective action cannot be aimed at obtaining monetary damages.

7.12 According to FTV, it can invoke the 'light regime' because its claim is allegedly for an idealistic purpose and does not seek monetary damages.[5] ' However, it appears from the parliamentary history that a reliance on the exception should not be granted when the requested declaratory judgment serves only as a prelude to a class action for damages. '[5]

7.13 AbbVie has concrete reason to doubt the purity of FTV's motive in bringing its legal action. Given the interruption letters sent by the health insurers to AbbVie, it is plausible that the present proceedings actually serve as a prelude to future class actions brought by insurers and/or hospitals. In this regard, AbbVie refers to what it has argued in section 6.7, where it explains that FTV is in fact a

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57 Subpoena para 5.18.

58 Parliamentary Papers II 20l6f 17, 34608, no 6.

claim which, according to its own contentions, belongs to the domain and interest of insurers.

7.14 Moreover, the present action should be classified as a group action. Collective actions can be divided into group actions and general interest actions (i.e. actions with an idealistic purpose). Deputy P-G Langemeijer and A-G Wissink describe these categories of collective actions in their opinion in the *Urgenda* case as follows[5] ':

> *"Group actions involve the representation of the combined interests of a certain or definable number of individuals. In' algeriieen belaitgacties it concerns the representation by a legal person of fixed algentene interests, which are iinot ittdividualisable because they" belong to a much larger group of persons, which is diffuse and ottdetermined."*

7.15 Jongbloed also argues that the distinction between group actions and general interest actions lies in the fact that in group actions, the persons whose interests are at stake can be individualised as opposed to general interest actions. This is because the interests in general interest actions are of such a general nature that they are part of almost everyone's existence.[60] In other words, in the case of a general interest action, it represents an abstract interest that can apply to anyone, whereas a group action concerns a constituency that is in principle reducible to i n d i v i d u a l s .

7.16 As stated above, AbbVie disputes that the present case involves a public interest action with an idealistic purpose. After all, FTV claims to stand up for *"All persons who (may) be entitled to legally insured basf's care in Neclerlancl. The majority of ele persons whose interests ele legal representations are intended to protect will therefore htin habitual verbli'jf place in the Netherlands."* In view of the representativeness requirement, these natural persons may be individualised into insurance beneficiaries resident in the Netherlands during the Relevant Period. Thus, FTV's constituency is reducible to individuals so that in the present case it is a group action and not an idealistic action.

7.17 In view of the above, the light regime of Article 3:305a(6) of the Civil Code, under which FTV would not have to comply with the requirements of Article 3:305a(2)(a) to (f) of the Civil Code, does not apply. Consequently, FTV must also comply with the requirements of Article 3:305a(2)(a) to (e) of the Civil Code, which relate to transparency and *governance* rules regarding interest organisations.

S9 Opinion of Deputy P-G Langemijer & A-G Wissink for HR 20 December 2019, ECLI:NL:HR:2019:2006, *NJ* 2020/41 m.nt. J.Spier *(State of the Netherlands v Urgenda Foundation).*

60 A.W. Jongbloed, in: GS Vermogensrecht, Art. 3:305a BW, ann. 8.1 (online, current until 20-10-2020). See, e.g., also C.J.J.M. Stolker, in: T&C Civil Code, Art. 3:305a BW, aant. 1(e) (online, current until 15-02-2021) and AsserfRensen 2-III 2017/197.

C **FTV does not meet the admissibility requirements of Art 3:305a BW**

(a) FTV does not meet all requirements of Art 3:305(2)(a - f)

(i) FTV's constituency has ***no*** *mogelijkheicl of* ***influence*** *on the decision-making process as be':loelcI* in *Article 3:305a lief* 2 *sub b BW*

7.18 To begin with, FTV does not have an appropriate and effective mechanism for the participation of, or representation of, the constituency in decision-making within FTV within the meaning of Article 3:305a(2)(b) of the Civil Code. Interest groups have the freedom to determine for themselves how the constituency can influence decision-making.[6] ' However, FTV neither states nor substantiates that its constituencies can influence its policy, let alone the present proceedings.

7.19 It is also not clear from FTV's website whether and how its supporters can have sufficient say in FTV's decision-making, or whether affiliates are given any opportunity at all to comment on certain decisions. According to FTV's website, interested parties can only click on a general and unspecified *"Aloe mee"* button where they have the option of signing a letter of support and/or making a donation. This *"Aloe mee"* button is not specifically intended to support the present proceedings, but to express support for FTV in general. This is not sufficient to comply with Article 3:305a(2)(b) of the Civil Code.

(ii) FTV is not financially) sufficiently independent ex Article 3:305a(2)(c) BW

7.20 It is not further clear from the Subpoena whether FTV has the required degree of financial independence, or at least FTV does not or insufficiently state this.

7.21 Thus, it is not clear whether FTV has sufficient resources to conduct these proceedings. FTV recently published its annual report for 2022 on its website. Nothing can be seen from that regarding the funding of these proceedings. It follows from FTV's 2021 annual report that FTV received grants worth EUR 144.312.18, and that it had C 63,000 in cash on 31 December 2021. How much FTV has in cash now and from what source is not insightful. Similarly, it is not insightful whether FTV has sufficient control over the established claim. Thus, FTV in any case does not comply with paragraph 5 of Section 3:305a of the Dutch Civil Code.

7.22 In doing so, it is likely that FTV is funded by a litigation funder. If this is the case, it is cnicial to examine the influence of the funder on the proceedings and to assess whether the arrangement with the litigation funder does not impede the careful representation of the interests of the persons who are part of the Closely Associated Group. This is all the more insistent given the general requirement of adequately safeguarded interests."

6I Parliamentary Papers II 2016/17, 34608, no. 3, pp. 19-20.

62 Parliamentary Papers II, 2016-2017 session, 34 608, no. 3, p. 20.

7.23 If there is a funding agreement between FTV and a litigation funder, AbbVie requests Your Court to order FTV under Section 22(l) Rv to produce the funding agreement and if requested, on the understanding that by application of Section 22(2) Rv only Your Court will take cognisance of the funding agreement. '[6]

(b) No similar interests that lend themselves to bundling

7.24 Pursuant to Article 3:305a paragraph 1 of the Civil Code, a foundation or association with full legal capacity may institute legal proceedings aimed at protecting similar interests of other persons, insofar as it promotes these interests pursuant to its articles of association. That requirement is satisfied if the interests which the legal action seeks to protect lend themselves to bundling, so that efficient and effective legal protection can be promoted on behalf of the interested parties. It is thus required that the disputes and claims raised can be adjudicated in a single procedure without having to consider the special circumstances on the side of the individual interested parties.

7.25 Unlike FTV argues, the interests of the Closely Defined Group that FTV purports to represent are too diffuse and insufficiently similar. It is therefore not possible to group these interests together, preventing the action from leading to efficient and effective legal protection. Indeed, FTV is not only limited to representing the interests of individuals who have not used Humira (for whatever reason), but also claims to represent the thousands of people who were treated with Humira during the Relevant Period and who received significant health benefits from that treatment with Humira.

7.26 Indeed, the Closely Defined Group that FTV claims to stand up for includes, in its own definition, *"any resident of Neclerlancl who is entitled to statutory insuredcle basic care"*. That is pretty much the entire Dutch population, plus non-Dutch nationals permanently residing in the Netherlands.

7.27 As such, the Closely Defined Group thus consists of individuals with diverse and even conflicting interests. It includes, for example, persons who received all the necessary legally insured basic care they needed, as well as persons who received Humira and benefited from an improvement in their health as a result; persons who - for whatever (policy) reason - did not receive the medical treatment or received a different medical treatment than they wished for or counted on. Furthermore, this group may also include persons who were entitled to legally insured basic care but did not use it, persons who are not insured or persons who are currently insured but were not during the Relevant Period.

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[63] In this regard, see also Rb. Amsterdam 9 November 2022, ECLI:NL:RBAMS:2022:6488 in which the court ruled that the three claim foundations had to allow inspection of the litigation funding agreement under section 22(1) Rv.

" HR 26 February 2010, ECLI:NL:HR:2010:BK5756 *(Foundation Baas in Eigen Huis/Plazacasa).*

7.28 The above illustrates that the interests of persons belonging to the Closely Defined Group are not necessarily aligned. Nor are they necessarily aligned with the general interest for which FTV claims to be standing in these proceedings. Pursuant to its articles of association, FTV promotes:[6] '

> *"the public interest {..... J by striving to ensure that medicines and other medical technologies are available on the market in a sustainable and socially rewarding iviy manner, iith which context, the foundation values fair pricing and distribution that is in concsteiitriiiitg not written ett unwritten iiatioital, European and international law."*

7.29 The answer to the question whether or not granting FTV's claims would have a positive effect on the interests of the individuals belonging to the Closely Associated Group is a question that goes beyond the scope of this conclusion and, in AbBVie's view, should be dealt with in the substantive phase of the proceedings (if it were to come to that). In this regard, AbbVie merely wishes to note that it disputes that the results FTV hopes to obtain through these proceedings would benefit Dutch health insurance policyholders. On the contrary.

7.30 AbbVie is limited at this stage of the proceedings to arguing that FTV neither motivates nor demonstrates how the principle of regulating maximum profits of drug companies - which seems to be FTV's main driver
- would be in the interest of Dutch medically insured patients. The possible practical negative effects including, for example, inhibiting innovation or limiting the availability of medicines in the Netherlands were not considered by FTV. However, these effects are highly relevant in any discussion on drug pricing and reimbursement. Accordingly, AbbVie reserves the right to fully explain these effects if proceedings proceed to the substantive hearing of FTV's claims.

7.31 For the purpose of the proceedings at the admissibility stage, it is sufficient to note that the Closely Defined Group - as defined by FTV - is far too heterogeneous and, as a result, the consequences of the adjudication of FTV's claims will not be the same for all, let alone beneficial to all. As a result, FTV's claims do not purport to represent similar interests that *"lend themselves to buncleling"* and thus promote efficient and effective legal protection for the benefit of its constituencies.

7.32 The above implies that, since the requirement of similarity is also not met in view of the diversity of interests, there is no commonality of the questions of fact and law to be answered. The latter, however, is a requirement, as the Supreme Court held in *Foundation in Own* Boss v JaeacaJa:[66]

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65 Production 14 of the Summons, Article 2 of FTV's articles of association.

66 HR 26 February 2010, ECLI:NL:HR:2010:BK5756 *(Stichting Baas in Eigen Huis/Plazacasa),* para 4.2.

> *"In this way, the issues and claims raised by the action can be dealt with in a single procedure, without the need to take into account the particular circumstances of the individual interested parties".*

7.33 This similarity requirement is also supported in the legislative history of the 'old' Article 3:305a of the Civil Code, which already contained this requirement:[67]

> *"It is therefore possible that although there is a common disputeputtt, the questions of law and fact involved in that disputeputtt must be answered differently for each individual. The question whether the nature of the claim and of the interests involved make bundling possible is then one of the criteria against which the admissibility of a collective action should be assessed."*

7.34 The relevant facts and circumstances on the side of the individuals belonging to the constituency should therefore be similar enough to allow the claims to be adjudicated within one set of proceedings. If the questions to be answered in the proceedings are not sufficiently common, it is also not more effective and efficient to settle them collectively, and therefore section 1018c(5)(b) Rv is also not satisfied. The question of whether the allegedly excessive pricing for Humira violates an unwritten standard of care does not allow itself to be answered in one set of proceedings in this case for the persons belonging to the Closely Described Group.

7.35 After all, there will be facts and circumstances potentially relevant to the illegality question, which will vary from person to person of the Closely Defined Group. This precludes a class action. For example, for those who benefited from the use of Humira, the wrongfulness question whether or not a standard of care was violated towards them will be answered based on different facts than for those who never used Humira. Similarly, persons who required medical care, whether it consisted of pharmaceutical treatments or other forms of care, and always received all necessary care, or persons who required a form of care that was in any case part of the healthcare budget during the Relevant Period, have no interest in the present action.

7.36 The prevailing doctrine is that the concept of illegality is inherently relative in nature. In other words, when assessing unlawfulness, one must assume that violation of a standard is only considered unlawful towards a specific particular (type of) person and in relation to a specific (type of) interest." Within the legal system of Section 6:162 of the Civil Code, a conduct is therefore not considered to be

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67 Parliamentary Papers II 1991-1992, 22 486, no. 3, p. 27.

68 K.J.O. Jansen, GS Unlawful act. Article 163 Book 6 BW, no. 1.4.2; in fact, the concept of illegality has a relative character. This was also stated in so many words in the Supreme Court judgment of 30 September 1994, *NJ* ï 996// 96, m.nt. C.J.H. Brunner *(Staat/Shell),* in which the Supreme Court pointed to the 'close connection between unlawfulness and relativity requirement'.

considered generally unlawful, but only in the specific context in which it occurs and in relation to one or more particular individuals.

7.37 The specific circumstances of the individual case should thus be taken into account when determining the unlawful act. Thus, the District Court of The Hague considered in *Milieuclefensie and* Stichting *Aclerni'Staat:*

> *"The same applies to the persons for whose gebwtdeld interest Milietidefetisie eit Adem are acting. For them, it applies boveitdieii that the question o(the State by not complying with the PMI0 resPective NO2 limit values on ll juiti 2011 and 1 January 2015 has acted unlawfully jeeeits persons for ivieits bundled interest vii in these proceedings, can only 'vordeti beamsvoord on the basis of the concrete circumstances of the individual eeval, which can be very different for each person. However, concrete circumstances have not been stated. Of importance are, for example, the specific locations where exactly the exceedances occurred, to what concrete harmful consequences the failure to comply with the standards for PMI0 and NO2 on 1 January 2011 and 1 January 2015 led, and the question of whether the requirement vati causal link between the State's breach of this obligation and the damage has been met. This oiilosmakeli.ike sameithang with the special omstandiehedeit of the iitdividual cases, means that on this point there is an interest that does not allow itself to be sufficiently generalised to be pereketid to the pelijksoortype interests to which Article 3:305a of the Civil Code has the uncle. Compare HR 13 October 2006, ECLI.-NL:HR:2006.-AW2080 (Vie d'Or j. These collective proceedings on the basis of Article 3:305a of the Civil Code do not lend themselves dtis to the (further) determination of whether the partition fixed the first obligation is oitrechtniatig jegetts Milieudefettsie and Adem."*
>
> (Underlining lawyer)

7.38 In the present case, within the group of persons belonging to the Closely Defined Group, there are also very different situations, with the result that the facts and circumstances cannot be generalised as such in these proceedings. As a result, the alleged unlawfulness of AbbVie's conduct cannot be adjudicated in a single proceeding.

7.39 The interests that FTV claims to be defending do not lend themselves to bundling for this reason either. After all, the issues in dispute and claims raised by the legal action cannot be adjudicated in a single proceeding without also having to consider the particular circumstances on the side of the individual interested parties.

(c) FTV is insufficiently representative

(i) Inleicling

7.40 With the increased responsibilities of interest representatives under the WAMCA, the government considered it necessary to tighten the admissibility requirements in Section 3:305a of the Civil Code. The purpose of that tightening is to prevent a

class action would (i) become unmeritorious, (ii) be used as a prelude to a class action for damages, or (iii) be frivolously brought with the primary purpose of inflicting harm on the opposing party.[6] '

7.41 Article 3:305(l) BW stipulates that the interests of those for whom the legal entity claims to stand up must be sufficiently safeguarded. Article 3:305a paragraph 2 BW further specifies and strengthens these requirements.

7.42 The representativeness requirement, included in paragraph 2 of Article 3:305a of the Civil Code, constitutes one of the tightened admissibility requirements. It also acts as a clarification of the guarantee requirement set out in Article 3:305a(1) of the Civil Code.'[0] Subject to the representativeness requirement, interest representatives must be sufficiently representative, given the constituency and the size of the claims represented.[7] ' The term 'the constituency' does not appear to be explicitly defined in Article 3:305a of the Civil Code or in the parliamentary history. The common interpretation is that 'the constituency' refers to the number of persons within the group concerned who actually actively support the collective action.

7.43 With the requirement of representativeness, the legislator intended to prevent an interest organisation from bringing an action without sufficient support from its supporters. Thus, not every interest organisation can claim to defend the interests of victims of allegedly unlawful actions. Only when it appears that the interest organisation clearly stands up for a sufficiently large part of the group of affected victims, it may bring proceedings on behalf of that group.'[2]

7.44 To assess whether the interest organisation is sufficiently representative, (i) the interest organisation must provide an accurate description of the group of victims for whom it claims to stand up, (ii) the interest organisation's constituency must consist of a significant proportion of the total number of victims, (iii) the size of the constituency's claims must be substantial in relation to the claims of all victims, and (iv) the constituency must actually actively support the collective action. Only when a sufficient number of persons have agreed to belong to the constituency of the interest group can one speak of the required 'support of a constituency'."

7.45 In the following, AbbVie will demonstrate that FTV has not sufficiently demonstrated that it has a sufficient constituency. Moreover, the endorsements that FTV claims to have are insufficient to assume representativeness. Before explaining this in more detail, AbbVie will first explain

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69 Parliamentary Papers II 2016/2017, 34608, no. 3, p. 16.

70 Parliamentary Papers II 2016/2017, 34608, no. 3, p. 18.

71 See Article 3:305a(2) opening words of the Civil Code.

72 Parliamentary Papers II 2016/2017, 34608, no. 3, pp. 18- 19, where the legislator states, *"It must be clear in advance that they [advocates] quantitatively stand up for a sufficiently large proportion of the group of affected victims."*

73 Ditto.

that - contrary to FTV's argument - the requirement of representativeness also applies in full to purely idealistic actions.

(ii) The representativeness requirement applies in full to' idealistic actions

7.46 Even if Your Court should unexpectedly rule that the present action is of an idealistic nature, the representativeness requirement applies in full." The legislator considered it undesirable for the representativeness requirement not to apply to such actions. The omission of the requirement would create the possibility of certain claims being easier to bring. This could lead to an unjustified increase in the number of legal proceedings and 'juridification'.[75]

7.47 That the representativeness requirement also applies to idealistic collective actions was also explicitly confirmed by the Minister for Legal Protection in the transposition proposal for Directive EU 2020/1828 on representative actions for consumers.[7] ' It is therefore incorrect that in lower case law the representativeness requirement has sometimes not been applied at all to idealistic actions. Moreover, application of the representativeness requirement in all collective actions prevents the incentive for interest representatives to frame all collective claims as idealistic, when in reality purely property law interests are at stake.

7.48 FTV argues that it is sufficiently representative by citing its expertise, experience and other work it has done, as well as the statements of support it claims to have received. FTV also argues that the representativeness requirement should not be unnecessarily high in a non-commercial action. However, it does not provide any substantiation for this claim.

7.49 In this connection, FTV merely refers to the parliamentary history of the representativeness requirement of Section 7:907(3)(f) of the Civil Code, which applies to a request for a declaration of commitment of a collective settlement." It follows from the parliamentary history of Section 7:907(3) of the Civil Code that no definite interpretation of the representativeness requirement can be given, and that the representativeness of an interest organisation can be derived from, among other things:

> *"the other activities carried out by the organisation to promote the interests of the disadvantaged, or the number of disadvantaged persons who are members of the organisation, or the extent to which the disadvantaged themselves consider the organisation to be representative".*

7J This is also confirmed by Sweerts & Hackeng in *"Eéit for all and allett by ééit: on representativeness in collective action law",* NTBR 2022/23,

75 Parliamentary Papers II 2018/2019, 34608, no 14 *{Amendment van Gent).*

76 Parliamentary Papers II 2021/2022, 36034, no. 3, p. 25 *"Incidentally, even for this type of idealistic vorderiiigen, organisations must always sheet meet the requirements in paragraph 1 (association or foundation), paragraph 2, opening words (representativeness j and paragraph 3 (no ivinstoogmerk directors, sufficient itan-ve baitd with the Netherlands and consultation obligation) of Article 3:305a."*

77 Paragraph 5.19 of the Subpoena and Parliamentary Papers II 2003/2004, 29 414, 3, p. 15.

(Underlining lawyer)

7.50 However, the parliamentary history of the WAMCA nowhere refers to the representativeness requirement of Section 7:907 (3) (f) of the Civil Code. Even if inspiration could be drawn from the latter representativeness requirement when testing the representativeness requirement of Article 3:305a, paragraph 2, of the Civil Code, this does not affect the fact that the viewpoints as explained in paragraph 7.44 above must also be met in the case of idealistic actions. These viewpoints are particularly quantitative in nature. This means that an interest group must not only be able to demonstrate a "theoretical representativeness" of the group it claims to stand up for, but must have a sufficiently large "constituency" that actually and actively supports the collective action.

7.51 With that quantitative criterion, the points of view correspond to some extent to the criteria of Section 7:907a (3) (f) of the Civil Code. For instance, under that article, an interest organisation must also disclose how many injured parties have joined the interest organisation. However, FTV does not comply with this either, or at least FTV completely fails to state anything or provide any clarity about this in the Summons.

(iii) ***No*** *voldoencle constituency*

7.52 As mentioned, sufficient representativeness of an interest association requires that the constituency of the interest association consists of a substantial proportion of the total number of victims, and the size of the claims of the constituency in relation to the claims of all victims must also be substantial. Whether the number of persons in the constituency and their claims are large enough will vary from case to case and can only be determined in relation to the number of victims. The parliamentary history of Article 3:305a paragraph 2 BW shows that this can be tested: *'on basfs of ele at' an association's affiliated members or by means of the number of gedtipeerclen clat has actively signed up for the vorclering*'. '[7]

7.53 According to case law, the complete absence of a constituency is problematic." It also follows from case law that an unspecified and small constituency offers little prospect of achieving the admissibility threshold. The District Court of The Hague, for instance, ruled in a summary proceedings that an unspecified constituency, consisting of such a small number of persons, is not sufficient to assume representativeness necessary to p a s s the admissibility threshold.'[0]

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78 *Ditto.*

79 See, for example, the judgment of the Amsterdam Court of Appeal of 9 September 202 l (ECLI:NL:GHAMS:202 l:34l8), in which the court of appeal tested the admissibility requirements in the context of a request for a preliminary witness examination on cross-border issues. In doing so, the court found that the interest group SMMT had not made it clear that it actually had a constituency. The statement by SMMT's lawyer that the Jewish community supports the foundation was "wholly insufficient" to demonstrate the interest organisation's representativeness.

80 Rb. Den-Haag (Vzngr.) 23 November 2021, ECLI:NL:RBDHA:2021:12811 r.o. 3.7.

7.54 As it is at the very least unclear whose interests are served by FTV's action, as the interests in question are too diffuse, it cannot be concluded that FTV has a sufficient constituency. FTV also fails to demonstrate that this action is truly in the interest of the group it claims to represent.

(iv) Lack of sufficient constituency support

7.55 FTV merely states that on its website information, as mentioned in Article 3:305a(2)(d) of the Civil Code, can be found, including: *"an overview of ele manner in which persons for the protection of whose interests ele legal action extends may join' ele legal entity and wi joe how to* terminate *this affiliation*."

7.56 However, FTV's website does not show this. Individuals can only 'participate' by signing a statement of support. However, this does not make it clear whether persons are 'participating' in the action against AbbVie or whether persons are thereby only supporting FTV in general. Thereby, FTV itself writes on its website the reasons that persons signing a statement of support can use as comments to their statement of support." In this way, FTV in no way demonstrates whether and, if so, how many persons from the Closely Described Group have joined this action, nor does it in any other way reveal that it actually has a (sufficiently substantial) constituency. Given the extensive and very heterogeneous group that FTV claims to represent in its Summons, namely: *"every resident of Neclerland who is entitled to statutory insured* basic care", this is all the more pressing.

7.57 Relevant in this context is the case of *Stichting The Privac y Collective* (TPC)." In it, the Amsterdam District Court ruled that TPC was not sufficiently representative because it could not prove how many of the aggrieved *actually* supported the action, as well as the extent of the claims it represented. TPC's constituency consisted of individuals who had clicked a fike button. According to the Amsterdam District Court, these individuals did not qualify as a constituency that actually supported the action. This conclusion was partly determined by the lack of sufficient information for the *'likers'*. The screen lacked essential information about the nature and purpose of the action, it did not state which parties the action was directed against, and it was not clear that clicking on the support button meant that the person registered himself as a duped person for the collective action or would automatically belong to the supporters of the interest group. The Court therefore ruled that the mere clicking of the support button did not mean that a valid expression of support was thereby obtained as intended by the statutory representativeness requirement.

7.58 Even in the present case, it is not clear whether, if someone signs a statement of support on FTV's website, that person registers himself as an aggrieved person for the collective action at issue, and thus whether he automatically joins FTV's constituency

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81 Par. 5.22 of the Summons.

82 See in this context: https://farmaterverantwoording.nl/doe-mee/#data.

83 Rb. Amsterdam 29 December 2021, ECLI:NL:RBAMS:2021:7647 *(Stichting The Privac y Collective).*

belong." This means that the statements of support on FTV's website should be seen as general statements of support for the organisation itself and not as statements of support for this particular case. 'Logically, support can only be obtained if it is clear to the supporter exactly what is being supported.'[5] That information is completely missing from FTV's website. Therefore, in the absence of further details about FTV's supporters, it cannot be concluded that FTV has the support of a supporter that meets the legal requirements of Article 3:305a(2), introductory sentence, of the Civil Code.

7.59 As mentioned, it can be deduced from FTV's website that 174 statements of support have been signed. This number is negligible when set against the total number of people FTV claims to stand up for namely: *"all persons who are (or may be) entitled to statutory insured basic care in NeclerlanJ".* That is many millions of Dutch people.

7.60 It can also be seen from the statements of support on FTV's website that people abroad have also signed a statement of support. However, these do not belong to the Closely Related Group as it is at least required that one is resident in the Netherlands to (be able to) claim legally insured basic care. Thus, these statements of support cannot contribute to the representativeness of the FTV. Nor can statements of support from health insurers and (international) advocacy organisations contribute to FTV's representativeness. Indeed, the organisations supporting FTV cannot be seen as part of FTV's constituency. Their support means no more than that they are sympathetic to FTV's goals'[6] The endorsements from health insurers rather raises the question of whose interests FTV actually represents in the present proceedings.

7.61 In light of the foregoing, it can be concluded that FTV has not provided any, or at least insufficient, insight into the group it claims to stand up for and thus the individuals it claims to support it. However, such insight is essential to determine whether FTV meets the legal requirement of representativeness. This is even more pressing in the case of idealistic actions. After all, under Section 1018k Rv, a final judgment in a collective action is binding not only on the parties but on all members of the Closely Defined Group. All persons belonging to the Closely Defined Group may therefore be bound by a judgment without it having been established that they sufficiently support FTV.

7.62 Only the representativeness requirement protects against insufficient support in the group being sued. This protection cannot be derived from the other criteria applicable to the admissibility of advocacy groups.

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84 FTV's website shows that it has also filed a legal action against pharmaceutical company Leadiant.

85 Rb. Amsterdam 29 December 2021, ECLI:NL:RBAMS:2021:7647 *(Stichting The Privac y Collective).*

86 A constituency within the meaning of the WAMCA can only consist of aggrieved persons for whose interests a plaintiff in a WAMCA case stands up. The organisations supporting FTV's action are not. See in this context also Rechtbank Amsterdam 29 December 2021, ECLI:NL:RBAMS:2021:7647 *(Stichting The Privac y Collective))* r.o. 5.13.

7.63 Thus, the so-called participation right of paragraph 2 sub b of Article 3:305a of the Civil Code only leads to participation of active members of the constituency who are fully aware of the nature and scope of the collective action. This provision does not guarantee the representativeness of the advocate for all persons represented, including **non-active persons** and even persons who are not aware of the collective action. Moreover, it should be noted that, in the present case, FTV invokes the exception clause of Article 3:305a(6) of the Civil Code, under which the right of participation does not apply if such an appeal is upheld.

7.64 This once again underlines the great importance to be attached to the representativeness requirement, which must be met even in the case where the 'light regime' applies. FTV does not demonstrate in the Summons that the representativeness requirement has been met, and AbbVie disputes that this is the case. FTV should therefore be declared inadmissible on that ground too.

D **No efficient and effective collective action**

(a) Introduction

7.65 Pursuant to Section 1018c(5)(b) of the Dutch Code of Civil Procedure, substantive consideration of the collective claim will furthermore only take place if and after Your Court has ruled that FTV has made it sufficiently plausible (i) that pursuing this collective claim is more efficient and effective than bringing an individual claim, namely (ii) by the fact that the factual and legal questions to be answered are sufficiently common, as well as (iii) that the number of persons whose interests the claims are aimed at protecting is sufficient. This requirement effectively builds on the similarity requirement set out in Article 3:305a(1) of the Civil Code.

(b) Questions of fact and law insufficiently common

7.66 As explained in paragraphs 7.34 to 7.41 above, FTV does not meet that requirement. After all, individual circumstances must be taken into account when assessing whether wrongful conduct was committed against persons belonging to the Closely Defined Group. As mentioned, the Closely Defined Group includes persons whose interests do not coincide and are even mutually contradictory. For example, the Closely Defined Group includes individuals who have benefited from the drug Humira for one or more of its many indications (16). In these cases, anyway, there will be no question of healthy years of life lost, quite the contrary. In addition, if payment was made for Humira, it was made by health insurers and not by the users of the drug, given AbbVie's policy of never co-paying patients for Humira. However, if FTV's contentions in the Summons are to be followed, it does not represent the interests of those health insurers in these proceedings - at least not directly.

7.67 Thus, the interests for which FTV claims to be acting do not correspond to each other sufficiently to be 'bundleable'. As a result, the requirement set out in Section l0l8c(5)(b) Rv cannot be met in a general sense. Thus, contrary to FTV's contention, pursuing this collective action is not more efficient and effective as the questions of fact and law to be answered are not sufficiently common.

E Summary mischaracterisation of collective claims revealed

7.68 Finally, summary judgment shows that FTV's collective claims are unsound, with the result that the requirement set out in section l0l8c(5)(c) Rv has not been met.

(a) FTV's claimed declaration of entitlement is a political matter

7.69 As FTV itself argues, it is bringing this case to establish the illegality of the pricing of Humira during the patent period and because the government allegedly does not (and has not) made any moves to take action against AbbVie with regard to the allegedly excessive price AbbVie charged for Humira during the patent period."

7.70 To establish AbbVie's alleged illegality, the pricing of Humira during the patent period would have to be assessed. However, as already explained in detail in Chapter 5, there is an institutional infrastructure in the Netherlands designated to set both regulatory and policy on drug pricing and reimbursement. The minister is responsible for policy setting under the supervision of parliament and has been implementing the Medicines Vision since 2016 to promote the affordability and accessibility of medicines. In turn, the legislature is responsible for adopting the relevant legal regulations.

7.71 Your Court is thus essentially being asked to set a concrete standard beyond which drug prices would be excessive. This would amount to disrupting - and circumventing - the existing institutional infrastnicture, including the process initiated by the Minister, and further disregards the separation of powers. Especially given the reference to the government's alleged failure to act against excessive prices, FTV is thus expressly asking your court to fulfil the role of the legislature and create regulations as well as sit in the chair of the executive by implementing and developing policies. However, that is not the court's job and the court has no jurisdiction to do so.

7.72 FTV thus aims to create a rule through the courts that does not derive from law and is highly dependent on political decision-making. As explained, this is an issue that belongs to the political domain. It should therefore not be entrusted to the civil court, which, moreover, is not equipped to do so. This issue therefore goes beyond the judge's law-making role. This is all the more the case as the civil court can only make a binding decision between the parties to the proceedings (art. 236 Rv). Granting FTV's claim will have consequences for persons belonging to the Closely Defined Group, even those who do not (actively) support the action, because they will still be bound by the court's judgment because that rule will also apply to them despite the fact that they have never supported the current proceedings, and, as is probably true for many, were never aware of it.

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87 Paragraph 1.8 of the Summons.

(b) FTV does not fulfil its burden of proof in respect of the violations of European and Dutch competition law

7.73 FTV does not meet its burden of proof to substantiate its claim that AbbVie would have violated applicable Dutch and European competition law (Article 24 Mw and Article 102 TFEU). AbbVie will show in what follows that FTV has not formulated a detailed market definition, but instead bases its unsubstantiated allegations on hypotheses and even contradictory statements.

7.74 The burden of proposition and proof regarding a violation of competition law rests on the party alleging such a violation. This follows from Article 150 Rv, but also expressly from Article 2 of Regulation 1/2003 of 16 December 2002 on the implementation of the competition rules laid down in Articles 81 and 82 of the Treaty." Competition law, in particular the law on abuse of a dominant position, requires a legal and economic analysis of the relevant market, in order for the court to be fully aware of the market dynamics, for the parties to be able to have a debate in which each party can fully express its defence, and for the court to be able to make a reasoned judgment, the plaintiff must provide sufficient economic facts and analysis, which FTV has completely failed to do.

7.75 In the *IATA judgment,* the Supreme Court gave further interpretation to the duty to propose when invoking competition law infringement. In the IATA judgment, the Supreme Court considered that the party alleging a competition law infringement must substantiate this with relevant (economic) facts and circumstances to enable a sufficiently adequate and well-founded (economic) party debate and subsequent judgment. The court must be able to gain sufficient insight into the functioning of the relevant market to determine whether, and if so to what extent, free competition in that market has been distorted. Therefore, a party claiming a competition law violation cannot, in principle, discharge its burden of proof with a general description of competition law prohibitions accompanied by the assertion that those prohibitions have been violated in the relevant case."

7.76 In particular, the Supreme Court stressed in the /ArA judgment that sufficient insight must be provided into the facts and circumstances that are essential for the assessment of the alleged competition law infringement, such as careful market definition, the relevant market structure and characteristics, as well as the actual functioning of the relevant market(s) and the effects on it of the alleged infringements.

7.77 AbbVie will explain below that FTV has not demonstrated any of these elements. FTV has therefore failed to meet its burden of proposition and proof.

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88 Art. 2 of Regulation 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty **reads** as follows: "*In any national or Community proceedings applying Article 81 or arf Article 82 of the Treaty, the party or authority alleging an infringement of Article 81(1) or Article 82 of the Treaty shall has been committed, bear the burden of proving that infringement* fe".

89 Supreme **Court** 21 December 2012, ECLI:NL:HR:2012:BX0345 r.o. 3.6.1.

Consequently, it should be declared inadmissible in its claims, at least insofar as they are based on an alleged infringement of competition law.

(i) FTV does not clef ele market, nor does it provide an analysis of ':le market strtictutir and ele characteristics and the actual functioning of the relevant market

7.78 To establish abuse of a dominant position, a clear definition of a product and geographic market must first be made, on which an alleged dominant position can then be analysed.

7.79 The CJEU ruled in the *Continental* Can case that a careful market definition is 'essential' for the analysis of whether or not there is an abuse of a dominant position.'[0] Indeed, the concept of abuse of dominance rests on a firm having such power in a given market that it is able to act without being constrained by its customers and competitors. To assess such a situation, the relevant market must first be defined.

7.80 Case law has recognised that while market definition is essential in any abuse of dominance case, it is of even greater importance in the pharmaceutical industry, where the competitive dynamics are different from other markets." Defining markets in the pharmaceutical industry requires an in-depth economic analysis of the market, taking into account all factors that influence purchasing decisions.

7.81 As explained below, FTV fails to argue, let alone demonstrate, the existence of a relevant defined market.

7.82 For example, FTV attempts to define the market by stating that the product market during the Relevant Period should be defined "very narrowly" and that Humira may have even "possibly" formed its own product market. By proposing two alternative market definitions and by making purely hypothetical proposals ("possibly"/"possibly"), FTV does not delineate the market in accordance with the IATA measure. In the absence of a clear market definition, AbbVie cannot defend itself or at least insufficiently. Moreover, Your Court cannot reach a conclusion on market definition.

7.83 FTV's contention that the market should be (very) narrowly defined is unconvincing and, moreover, vague. Even if one were to accept that the market should be defined very narrowly, *quod non, it is* still impossible to understand which products (if any) FTV believes should be part of that market along with Humira.

7.84 Instead of providing a detailed market definition relevant to FTV's contention, FTV limits itself to selectively quoting individual passages from an ACM sector enquiry without drawing any conclusions. In this regard, AbbVie also wishes to stress that the ACM sector enquiry in question did not

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90 Case 6-72, Continental Can v Commission, [1973] ECR 215, §32.

9i Case T-321/05, AstraZeneca v Commission, EU:T:2010:266, at §183 and T-691/14, Servier and others v Commission, ECLI:EU:T:2018:922 at §l 385.

established that AbbVie was dominant, or that there was abuse of a dominant position, nor was that the purpose of that investigation.

7.85 Moreover, FTV's attempt to define the market is incomprehensible, as it takes contradictory positions on this point on several occasions. For example, FTV states that the market should be (very) narrowly defined and that the market could be so narrow that the market includes only Humira, but at the same time FTV notes that Humira and Pfizer's Enbrel (etanercept) are "close competitors" and serve a similar number of patients for the same therapeutic indications. This is a clear contradiction: indeed, the market cannot be limited to Humira alone if Humira and Enbrel are close competitors, as FTV itself claims. In fact, the ACM report relied on by FTV contains evidence that Humira competes with infliximab for certain therapeutic indications.

7.86 This contradiction is illustrative of the fact that FTV does not even attempt to provide a relevant market definition, let alone a coherent one. In view of the foregoing, it should be concluded that FTV has failed to meet the burden of proof and should be declared inadmissible in its claim insofar as it relates to abuse of dominance.

7.87 Having failed to define a relevant market, FTV also fails to demonstrate dominance in such a market. Moreover, FTV's attempt is too brief and lacks a credible analysis of the market conditions on the basis of which dominance could be established.

7.88 First, FTV's argument is limited to the hypothesis that the market could be limited *"zoti"* to Humira itself. As discussed above, that proposed definition is not credible and is contradicted by FTV's own contention. FTV does not even attempt to demonstrate dominance in its other hypothetical market definition that relies on a "very limited" market.

7.89 Second, FTV does not provide any analysis of competitive pressures in the alleged market, including the respective roles of actual and potential competitors, the specific circumstances of the pharmaceutical industry including the role of price regulation, the countervailing power of buyers or the prescription dynamics of medical professionals. These are fundamental elements that require proper analysis in a market abuse case.

7.90 Similarly, FTV's analysis does not include any relevant market analysis, such as, for example, a simple presentation of market shares. Based on FTV's contentions, Humira competed "closely" with Enbrel and had similar market shares to Enbrel, which - on its own - demonstrates the absence of dominance.

7.91 FTV' s flawed dominance analysis is entirely devoted to the price aspects of competition. Apart from the fact that such an analysis is insufficient, incomplete and misleading, it also contradicts FTV's own assertion that price is not a relevant factor in the choice of the drug to be administered, because that choice is made

made by the medical specialist and not by the patient himself." In light of the above, FTV has not put forward a coherent rationale for the existence of a dominant position.

(c) Conclusion

7.92 FTV attempts to allege an infringement of competition law, but fails to demonstrate such an infringement. Indeed, FTV fails even to define the relevant market. Instead, it proposes conflicting market definitions, without substantiating them at all in accordance with the IATA standard. FTV limits itself to citing general circumstances that are unconvincing and, moreover, contradict its own proposed market definitions. In doing so, it does not fulfil its obligation to state the case.

8. CONCLUSION

8.1 In view of all the above, Your Court lacks jurisdiction to hear FTV's claims against AbbVie Deutschland and AbbVie US. Furthermore, all that has been argued in this conclusion shows that FTV's claims against AbbVie are inadmissible as well as without merit. FTV's claims must therefore be dismissed in their entirety.

9. BENEFITS

To the extent that the court finds that AbbVie has any burden of proof, AbbVie , in addition to the productions already submitted with this submission, offers to further prove its contentions by all means in law.

WITH CONCLUSION

That it may please the court by judgment, so far as possible enforceable:

A. Declare itself incompetent to hear FTV's claims against AbbVie Deutschland and AbbVie US.

in the admissibility case:

B. Declare FTV inadmissible in its claims, or at least dismiss them in their entirety indicate; and

C. order FTV jointly and severally to pay the costs of the proceedings, including the follow-up costs, with the stipulation that if the aforementioned costs of the proceedings are not paid within seven days from the date of the judgment to be given in this matter, statutory interest will be payable on the outstanding amount of the costs of the proceedings from the eighth day until the day of full payment.

" Paragraph 4.141 of the Summons.

Lawyer 

This case will be handled by Mr G. te Winkel, Mr C.E. Drion and Mr G. Taspinar, Jones Day, Concertgebouwplein 20, 1071 LN Amsterdam (PO Box 51204, 2007 EE Amsterdam), telephone: 020 305 4200, fax: 020 305 4201, email: gtewinkelHjonesday.com / cdrionHjonesdav.com / gtaspinarW tonesdav.com.

JONESDAV

AMSTERDAM COURT
CIVIL JUSTICE DEPARTMENT, COMMERCE TEAM
CASE AND ROLL NUMBER: **C/13/730018** HA ZA **23-172**
DATE: 15 NOVEMBER **2023**

PRODUCTION LIST
AT
CONCLUSION OF REPLY
IN THE ADMISSIBILITY CASE

Production	*Description*	*Date*
Production 1	*Environmental, Social d' Governance* report AbbVie	2022
Production 2	FTV policy plan	29 December 2018
Production 3	Annual report VGZ	2022
Production 4	(a) Letter from CZ Group	13 October 2023
	(b) Letter from ONVZ Ziektekostenverzekeraar N.V.	13 October 2023
	(c) Letter from VGZ	13 October 2023
	(d) Letter from DSW	11 October 2023
	(e) Letter from Zorg en Zekerheid	11 October 2023
	(f) Letter from ASR Basis Ziektekostenverzekeringen N.V.	12 October 2023
	(g) Letter from Menzis	12 October 2023
	(h) Letter from Salland Zorgverzekeraar N.V.	12 October 2023
	(i) Letter Zilveren Kruis Zorgverzekeringen N.V.	12 October 2023
Production S	Overview of FTV press releases regarding AbbVie	N/A