Markus Fjeldstad Reve, Associate

simonsen vogtwiig

# Denigration in the Pharmaceutical Sector as an Abuse of Dominant Market Position

## 1 Introduction

As the pharmaceutical industry keeps growing, so too do the new possible abuses of dominant market positions. One particular form of abuse on the rise, particularly in the life science sector, is the practice of denigration, which in essence is a measure implemented by undertakings who seeks to obtain a competitive benefit by speaking ill of competing products, services or competitors in general.

This article seeks to identify and examine the condition under which denigration in the pharmaceutical industry may constitute an abuse of a dominant market position under Article 102 of the Treaty on the Functioning of the European Union ("**TFEU**")[1], based on the general principles of EU competition law and guidance applicable in relation to that provision, as well as case law and decisions made by national courts, national NCAs and the EU Commission.

Denigration under Article 102 TFEU (hereinafter "**Article 102**") is still a nascent form of abuse, with little case law from the Court of Justice of the European Union ("**CJEU**"). Therefore, National Competition Authority ("**NCA**") decisions and Commission enforcement provide the primary reference points. A comparative review of the conditions applied in these sources allows for an extrapolation of the underlying conditions governing the application of Article 102 in denigration cases.

## 2 The Susceptibility of the Pharmaceutical Sector to Denigration Practices

Before reviewing the conditions for applying Article 102 to denigration cases, it is necessary to examine what denigration is, and why the pharmaceutical industry is particularly susceptible to denigration practices.

Denigration, or disparagement, refers to a dominant undertaking spreading false or misleading information about competitors or their products. This conduct may undermine competition on the merits and have an exclusionary effect, ultimately harming the market. However, not all information dissemination is illegitimate – factual communication can benefit the market by highlighting genuine product differences or valid safety concerns.

Denigration practices are a particularly effective means of limiting competition in the pharmaceutical sector. Past cases suggest that such conduct is most damaging in markets that were previously monopolistic but have recently, or are in the process of being, opened to competition.

In these markets, the incumbent typically enjoys strong brand recognition and trust among end-users due to its prior monopoly. When faced with new competitors, the incumbent may exploit this position to undermine rivals through denigration. This strategy is less impactful in markets with established competition, where no single actor dominates trust or information. Furthermore, this tactic is less harmful in markets with pre-established competitors, as the incumbent does not enjoy the same position as the primary source of information on the relevant product category. While especially relevant in pharmaceuticals, similar patterns have been observed in sectors like telecommunications and energy.

[1] See Consolidated version of the Treaty of the Treaty on the Functioning of the European Union, available at https://eur-lex.europa.eu/eli/treaty/tfeu_2012/oj/eng.

The pharmaceutical industry is unique in the sense that it does not only open up to competition from a monopolistic market structure once, like the aforementioned sectors might. Pharmaceuticals are, generally, covered by stringent patents and regulatory protections which prevent other market operators from creating similar products. This creates a monopoly situation within each therapeutic area until the patent expires, upon which other pharmaceutical companies may produce similar drugs using the same compound and formulation, known as generics. When the patent on a drug of an originator (original producer of a drug) expires, an analogous situation to that of a legal monopoly disappearing may be observed. Therefore, denigration practices may be especially prevalent in this sector.

Another related key reason the pharmaceutical industry is especially susceptible to denigrating practices is the information asymmetry in the market. A review of NCA decisions demonstrates that because the incumbent pharmaceutical undertakings are perceived as an authoritative source of information on the product or therapeutic area in question, combined with the general insufficient knowledge of pharmacology among prescribing physicians, the incumbent undertaking is in a situation well-suited for an effective denigrating campaign, as the prescribing physicians are primed to head the advice of the incumbent.

As such, denigration and the pharmaceutical sector go hand in hand, and just like previous case law, we expect the majority of future case law on denigration to relate to pharmaceuticals. This may, of course, have a propagating effect, as competitors and legal professionals may particularly look to denigration arguments in cases relating to pharmaceuticals, because the parallels to the case law which does exist will be strong.

# 3 Denigration Case Law

## 3.1 CJEU Case Law

Denigration has become an increasingly relevant competition law issue under Article 102 at the national level, especially within certain Member States. However, denigration has so far not been assessed under Article 102 by the EU courts, with only one case regarding denigration reaching the European Court of Justice ("**ECJ**"), where the Court applied Article 101 TFEU (hereinafter "**Article 101**") on the prohibition on anti-competitive agreements.

In case C-179/16 *Hoffman-La Roche,* two pharmaceutical companies – Roche and Novartis – entered into an agreement to denigrate a product produced by Roche (*Avastin*) in order to promote the sales of the significantly more expensive product produced by Roche, but licensed and marketed by Novartis (*Lucentis*). The Court found that this agreement was an infringement of Article 101, as it 'by object' restricted competition and could not be justified.

However, the application of Article 101 in the *Hoffman-La Roche* case may be attributed to the particular facts of the case. After all, there was an agreement between multiple undertakings which by object restricted competition. While the Court could have resolved the case by applying the doctrine of collective dominance under Article 102, Article 101 appeared as the most applicable legal background. A 'typical' denigration case involves one undertaking which decides to disparage an actual or potential competitor or their product. Therefore, Article 102 is the most relevant provision of EU competition law to apply.

## 3.2 National Competition Authorities

No authoritative sources preclude recognising denigration as abusive conduct under Article 102. In fact, different national competition authorities have applied EU law in their own national proceedings relating

to denigration as abuse. At the forefront of this legal development is the French Competition Authority ("**FCA**"), which has issued four fines to different pharmaceutical companies for violation of Article 102, and the equivalent provision in French national law, for denigration practices.

In the following, the conditions – the specific legal test – for denigration in the pharmaceutical sector under Article 102 based on findings from the FCA and the French courts, will be reviewed. To do this however, it is first necessary to give a brief introduction to the facts of the four key cases from France, before the specific legal test laid out in those cases are explored in detail.

One of the latest cases handled by the FCA is the *Avastin-Lucentis* case[2] handed down in 2020, related to the same matters of fact as the *Hoffman-La Roche* case of the ECJ. However, the FCA applied Article 102 under the doctrine of collective dominance, not Article 101, like the ECJ did in *Hoffman-La Roche*. The decision of the FCA was annulled by the Paris Court of Appeals in 2023[3], where the court found no violation of Article 102 or the equivalent French provision, arguing that the information provided by Roche and Novartis was accurate and not liable to mislead or discourage HCPs based on false information. This decision has been appealed to the Court of Cassation, which overturned the Paris Court of Appeal decision, citing errors in their legal reasoning.[4]

The FCA has given three other decisions on denigration within the pharmaceutical industry as well. In *Subutex*[5] from 2013, pharmaceutical undertaking Shering-Plough was fined for, *inter alia*, denigrating a generic competitor to its originator drug, by communicating differences between the products regarding appearance, dissolution and excipients, highlighting the 'psychiatric instability' of the patient population and the 'risk of misuse and trafficking' of the *Subutex* generic.

In *Plavix*[6] from 2013, Sanofi-Aventis was found to have abused its dominant position by denigrating competing generic products, by creating doubts regarding the efficacy and innocuousness of generic competitors of their own medicine, *Plavix*. The decision was upheld by both the Paris Court of Appeals and the Court of Cassation.[7]

Finally, in *Durogesic*[8] from 2017, Janssen-Cilag and parent company Johnson & Johnson had delayed entry of a generic version of their drug *Durogesic*. The undertakings had sent unjust and incorrect info to the French Agency for Medical Safety of Health, including denigrating statements regarding the efficacy and safety of competing generic products, with the aim of convincing the health authorities to refuse to grant, at a national level, generic status to competing drugs, despite such status on the European level. Furthermore, Janssen-Cilag orchestrated a major campaign to denigrate generic competitors of *Durogesic* among office and hospital-based HCPs by using misleading language, seeding doubt regarding the efficacy

[2] Dec. 20-D-11 of 9 September 2020.

[3] Paris Court of Appeal 16 February 2023.

[4] Court of Cassation on 25 June 2025, Judgment No. 411 FS-B.

[5] Dec. 13-D-21 of 18 December 2013. Other popular names include *Shering-Plough* and *Arrow Générique*.

[6] Dec. 13-D-11 of 14 May 2013. Other popular names include *Sanofi-Aventis*.

[7] Paris Court of Appeal on 18 December 2014 (Summary decision to the Court: no. 13-D-11 rendered on 14 May 2013 by the Competition Authority) and the Court of Cassation on 18 October 2016, Judgment No. 614 FS-B.

[8] Dec. 17-D-25 of 20 December 2017. Other popular names include *Janssen-Cilag*.

and safety of competing generic products. The decision was upheld by both the Paris Court of Appeals and the Court of Cassation.[9]

# 4 The Specific Legal Test for Denigration in the Pharmaceutical Sector under Article 102 as Defined Through National Case Law

## 4.1 Introduction

In their assessments, the FCA and French courts developed four conditions which they argue need to be fulfilled in order for denigration to be considered a *prima facie* abuse of a dominant position as outlined in Article 102.

This assessment may resemble that of a new 'specific legal test', which is a set of requirements the Commission assesses when examining commonly employed potentially abusive measures. Essentially, the FCA has developed a specific legal test to be applied in denigration cases under Article 102. This specific legal test bears a resemblance to other abusive conducts prohibited by Article 102, but the distinct nature of denigration necessitates a customised approach. However, the specific legal test is built on the same considerations as any other consideration of abusive conduct, *inter alia* the position of the dominant undertaking, the extent of the alleged abuse, and the conditions of the market.

According to French case law, there are four cumulative conditions which must be fulfilled: there must be (i) denigration of a competitor's product with a view to obtain a commercial interest, one must (ii) establish a link between the denigration and the dominance of the denigrating undertaking, (iii) the veracity of the claim must be assessed, and (iv) the conduct must be liable to influence the structure of the market.

## 4.2 First Condition: Denigration of a competitor's product with a view to obtain a commercial interest

Firstly, there is a need to demonstrate the denigration of a competitor's product with the aim of obtaining a commercial advantage. In an industry where market actors are dependent on the trust of prescribers and consumers, like the pharmaceutical industry, denigration has, as held above, particularly negative effects on the market and is thus a useful tool in obtaining such a commercial interest. This was noted explicitly in the *Plavix* case.[10]

In *Durogesic,* the FCA refers to the *Plavix* case and holds that denigration consists of "publicly discrediting an identified person, product or service" which is "distinguished from criticism insofar as it emanates from an economic actor who seeks to benefit from a competitive advantage by penalising his competitor."[11] Essentially, this condition requires that the public speech concerned targets rival products or companies, and that it is negative. However, it is also necessary to demonstrate an element of intent to disparage – the undertaking must have had a "coherent strategy, generally discernible in the statements in question, as well as in internal documentation".[12]

[9] Paris Court of Appeals the 11 July 2019 (albeit with a lowered fine from 25mEUR to 21 mEUR) and confirmed in the Court of Cassation on 1 June 2022.

[10] Dec. 13-D-11 of 14 May 2013 *Plavix*, paras. 375-376.

[11] Dec. 17-D-25 of 20 December 2017 *Durogesic*, para. 530 (our translation)

[12] Dec. 17-D-25 of 20 December 2017 *Durogesic,* paras. 114 *et. seq.*

It is only natural that it is necessary to demonstrate actual denigration towards a competitor or their products. After all, there is no point in applying a specific legal test for denigration cases if no denigration may be proven.

However, a weakness of having to demonstrate a "view to obtaining a commercial interest" is that this requirement potentially contradicts the objectivity of Article 102. Because Article 102 is objective, meaning it applies irrespective of the intentions of the undertaking, there should be no need to demonstrate a willingness of an undertaking to abuse a dominant position. Well-intentioned measures which aim to compete on the merits may also constitute abusive conduct.

As a corollary to the objectiveness of Article 102, it would, therefore, be possible for a pharmaceutical company to disseminate information about the efficacy or safety of a competing generic competitor in good faith, and yet still act in violation of Article 102. This situation is presumably rare, and not relevant in any of the French cases on denigration, which may explain why the FCA and the French courts considered it a requirement for denigration.

In our opinion, and contrary to the view presented in *Durogesic,* it cannot be a requirement for the application of Article 102 to denigration cases that the undertaking had a view to obtain a commercial interest. The underlying principles and aims of competition law – hereunder the functioning of the internal market and effective competition – apply even in cases where no intent to abuse a dominant position may be demonstrated, further strengthening this perspective.[13]

However, a distinction must be drawn between common criticism and denigration. Any potentially negative references to competing producers or their products cannot be considered prohibited abuse. Therefore, there is reason to hold that assessing the intention of the undertaking is a tool needed to differentiate denigration from common criticism.

While exclusionary intent is not a necessary element of an abuse because an abuse is 'an objective concept'[14], it is not a wholly irrelevant factor. Evidence as to the intent of the undertaking may be useful in interpreting its conduct. As the Court of Justice held in *Tomra*, "[…] the existence of any anticompetitive intent constitutes only one of a number of facts which may be taken into account in order to determine that a dominant position has been abused."[15]

A more suitable approach than proving a commercial intent, which also ensures that the underlying principles of competition law are attained, may be to take a more objective approach and assess the extent, gravity, and nature of the statements to distinguish between the common criticism and cases of denigration, keeping in mind intent as a factor in this assessment. By applying this test instead, the assessment steers clear of possibly infringing the objectivity of Article 102 and is, furthermore, easier for an external party to assess than only proving intent.

[13] See, to this effect, *inter alia* C-307/18 *Generics (UK),* para. 166, with reference to C-209/10 *Post Danmark I*, para. 42.

[14] C-179/16 *Hoffmann-La Roche,* para. 91.

[15] C-549/10 P *Tomra*, para. 20.

### 4.3 Second Condition: Establish a link between the denigration and the dominance of the denigrating undertaking

Secondly, there is a need to establish a link between the denigration and the dominance of the denigrating undertaking. There is no need to demonstrate an actual effect on the market, but rather assess whether the conduct, in its materialised scope and potential, is likely to influence the market structure.[16]

A relevant factor to this assessment is the extent of the denigration itself, and whether the conduct was implemented at a consistent and systematic manner. Using the example of the *Durogesic* case, Janssen-Cilag created a major campaign to falsely disparage generic versions of their drug among HCPs by using misleading language to create doubt about the efficacy and safety of those generics. Because Janssen-Cilag was the incumbent undertaking, which was a trusted producer of medical patches containing fentanyl, their measures were effective and created an actual effect on competition. Therefore, the FCA considered the requirement of a causal link be fulfilled.[17]

Interestingly, when the Belgian Competition Authority ("**BCA**") in *Test Achats / Novartis et Roche*[18] investigated the Avastin-Lucentis situation in Belgium, they applied a similar legal test to that of the FCA but held that there is no need to demonstrate a causal link between the dominant position of the undertaking and the abuse itself.[19] Essentially, according to the BCA, there is no need for the abuse itself to stem from the dominant position of the undertaking – it is sufficient that both conditions are fulfilled. In other words, according to the BCA, there is no need to demonstrate a causal link between the denigration campaign and the concrete negative effects on competition.[20]

### 4.4 Third Condition: The veracity of the claim

*Thirdly*, there is a question of whether the veracity of the claim must be assessed, or whether it is irrelevant to the finding of denigration prohibited by Article 102. In the *Plavix* case, the FCA held that in order to assess whether the conduct constituted denigration, it was relevant whether the public references were "[…] based on objective findings or unverified assertions"[21], and this was further followed up in *Durogesic*.[22]

The reason there is a question of whether the veracity of the claim is relevant to the assessment or not is because the French Court of Cassation in their rejection of an appeal regarding a denigration case between two manufacturers of gas-powered appliances and corresponding cartridges, provided that the denigrating undertaking may not argue that their conduct is not denigration because they were relaying accurate information.[23]

As the Court of Cassation is a high national court, their decisions are more relevant as a legal source in France than that of the FCA. However, the FCA has consistently, for many years after the decision from the Court of Cassation, held that the veracity of the claims is a relevant consideration. The decision from the

[16] Dec. 17-D-25 of 20 December 2017 *Durogesic,* para. 537.

[17] *Ibid.,* para. 538.

[18] BCA Decision PK-14-0026 (23-PK-02) *Test Achats / Novartis et Roche.*

[19] PK-14-0026 (23-PK-02) *Test Achats / Novartis et Roche,* paras. 573 *et. seq.*, citing T-321/05 *AstraZeneca,* para 267.

[20] *Ibid.,* paras 577 *et. Seq.*

[21] Dec. 13-D-11 of 14 May 2013 *Plavix,* para. 367.

[22] Dec. 17-D-25 of 20 December 2017 *Durogesic,* para. 532.

[23] *Cour de cassation,* Com. Dec. 12-19.790 of 24 September 2013.

Court of Cassation did not directly relate to Article 102, instead focusing on Article 1382 of the French Civil Code, which imposes liability for wrongful acts causing damage. This distinction may be of importance because the conditions for violations of Article 102 and the French Civil Code may differ due to their inherent function, or their underlying principles and aims.

Furthermore, the Danish Competition Authority ("**DCA**"), in their only case on denigration in the context of Article 102, does not apply a test of the veracity of the claim.[24] The case concerned ambulance services in Southern Denmark, where Danish company Falck lost a public tender for providing ambulance services to Dutch competitor BIOS. In response, Falck covertly denigrated BIOS by disseminating negative information, both internally to employees and publicly through the press. The aim was to prevent staff from joining BIOS, thereby undermining BIOS's ability to deliver the contracted services and enabling Falck to reclaim the contract.

In its assessment, the DCA did not consider the veracity of the claims put forwards by Falck – the DCA considered it irrelevant whether the claims were factual and accurate or not. In fact, the DCA found that some of the information might even have been correct, but the sheer covertness of the implementation of the denigration strategy was manipulative and misleading. Therefore, this Danish case appears somewhat unique, and as the case does not directly relate to the pharmaceutical industry, it is less directly applicable to the case study at hand. However, the case remains a necessary perspective to keep in mind when evaluating the norm of denigration under Article 102 in general.

It is also important to note that at the EU level, neither decisions from French courts nor NCAs are authoritative legal sources. To extrapolate the legal conditions for the application of denigration as an abuse of dominance, a general assessment based on EU law principles provides the best guidance. Furthermore, there may be differences in the conditions when applied to different sectors, such as the pharmaceutical sector.

In said sector, it is of vital importance for patient safety that all products have their described functions and that there is not a disparity between the claimed and actual quality and safety of the products. Therefore, there is a legitimate reason why other pharmaceutical undertakings may need to disseminate information regarding the safety profile of other products, even if they are direct or indirect competitors. There is therefore good reason to assume that information which is clear, complete, and unambiguous steers clear of the prohibition against denigration.[25] To be complete and unambiguous, the information must (i) relate to a matter of general interest; (ii) be sufficiently grounded in fact; and (iii) be expressed with an appropriate degree of restraint or caution.[26]

The assessment aims to *inter alia* ensure that information which is propagated is not harmful to consumers or competition. This underlines the importance of assessing the veracity of the claims provided. As such, there is good reason to consider the veracity of the claims put forward by the denigrating undertaking when assessing the legality of the conduct in relation to Article 102.

### 4.5 Fourth Condition: Liable to influence the structure of the market

*Lastly*, the denigrating conduct must be liable to influence the structure of the market, which for denigration practices amounts to exclusionary effects. As previously held, the pharmaceutical industry is

[24] See DCA Dec. 30 January 2019 (Journal no. 18/04542) *Falck.*

[25] See, as an antithesis to, Dec. 13-D-11 of 14 May 2013 *Plavix,* para. 378.

[26] See, to this effect, *inter alia,* Dec. 17-D-25 of 20 December 2017 *Durogesic*

prone to denigration because HCPs are particularly risk averse when prescribing medicines to patients if they have been exposed to negative statements relating to *inter alia* the quality or safety profile of a drug.127 Even potential impacts on, *inter alia,* HCP prescription patterns or consumer purchasing patterns may fall within the prohibition.[27]

This condition is somewhat similar to the requirement that the conduct "may affect trade between Member States", in the sense that it measures the actual or potential impact of the conduct on the structure and functioning of the market and the competitive landscape therein. Furthermore, the assessment has a side to the consideration of a causal link, because demonstrating a causal link between the denigration and the dominant position inherently requires an assessment of whether the measure was or could be an effective tool to exert abuse of dominance.

The concrete impact, whether actual or potential, on the market structure varies on a case-by-case basis. In *Plavix*, it was of relevance that the prescribing HCPs did not have sufficient knowledge of the pharmacological effects of different products. Furthermore, the generic producers who were subject to the denigration did not have the presence among or trust of the prescribing HCPs. The incumbent producer, who had held a statutory monopoly on the relevant treatment for decades, was well-known among HCPs, and they trusted their assessments, which the generic producers lacked the reach to rebut. Naturally, this resulted in lower sales of the generic variant of the originator drug, as the HCPs propagated their beliefs onto the end consumer, i.e., the patients within the relevant therapeutic area.

Many of these effects, which have been demonstrated in one or more of the French decisions on denigration[28], may be applicable more generally. It is, however, important to be mindful of how the concrete effects may vary between Member States – some Member States may, for example, be more or less susceptible to misleading information from the pharmaceutical industry because they have a stronger or weaker general trust and relationship to the industry. In fact, this could create a situation where the norm is, on an EU level, applied somewhat differently depending on the geographical scope of the market. This must be kept in mind when assessing denigration at an EU level, particularly.

# 5 The Specific Legal Test for Denigration under Article 102 TFEU as Defined by the EU Commission

## 5.1 Introduction

Keeping in mind the specific legal test outlined in national case law, it is relevant to consider the conditions applied by the Commission in their assessment of similar denigration situations within the pharmaceutical industry. Such a comparative analysis allows for a greater understanding of the different perspectives on denigration under Article 102 and is a useful tool for a pharmaceutical undertaking looking to assess the legality of its own denigrating measures.

As previously mentioned, the EU Courts have never tried denigration in the context of Article 102. However, the Commission has on two recent occasions investigated pharmaceutical companies for their denigration practices with reference to Article 102.

[27] See, to this effect, Dec. 13-D-11 of 14 May 2013 *Plavix,* para. 490.

[28] See, *inter alia,* Dec. 13-D-21 of 18 December 2013 *Subutex,* paras. 396-398.

### 5.2 Teva Copaxone

In a recent proceeding concluded in October 2024, the Commission found that Teva Pharmaceuticals Europe had abused their dominant market position through their misuse of divisional patents, and exclusionary disparagement.[29]

The case concerned denigration by Teva targeting generic competitors. Teva is the originator of glatiramer acetate (GA), an immunomodulatory drug for relapsing multiple sclerosis, marketed as *Copaxone*. With Teva's compound patent set to expire in 2015, Dutch generic manufacturer Synthon prepared to enter the market. According to the Commission Decision, Synthon's GA product was, at the time, the only authorized GA competitor in the EU. In order to prolong its own product exclusivity and delaying the launch of this generic competitor, Teva devised an elaborate, multifaceted strategy aimed at protecting *Copaxone* from competition.

Teva had *inter alia* disseminated information which emphasized clinically irrelevant differences in the molecular structures of the GA in *Copaxone* and Synthon GA. They further highlighted risks observed when using other glatiramer-related substances, incorrectly implying that these risks applied directly to Synthon GA as well. Teva also publicly questioned the scientific validity of the clinical trial which formed the basis for the finding of therapeutic equivalence between the two products.

With regard to this denigration, the Commission, when listing the particularities of the case, essentially creates a four-step specific legal test of their own. In essence, the Commission found that Teva had disparaged Synthon GA to hinder or delay its market entry and uptake, to prevent competition in the market. Key to the findings of the Commission was firstly that Teva had spread "objectively misleading information" on the efficacy, safety, and therapeutic equivalence of Synthon GA compared to *Copaxone*.[30] Secondly, Teva implemented effective mechanisms for spreading the misleading information to national health authorities, health insurance funds, and HCPs. Thirdly, their conduct was, actually or potentially, capable of having an exclusionary effect. Lastly, their conduct was not objectively justified.

Comparing the specific legal test of the Commission to the one employed by the FCA, there are clear similarities. Most notably, the Commission employs a requirement that the information must be objectively misleading. This corresponds to the consideration of the veracity of the claim, i.e., whether the information propagated was accurate and factual or whether it was false or liable to create a misleading impression. The Commission also considers the scope of the conduct while assessing the impact. By examining whether Teva has implemented "effective mechanisms" for spreading false information to relevant stakeholders, the Commission is essentially considering whether there is a sufficiently extensive denigration campaign while also highlighting that the campaign must be aimed at relevant stakeholders, which in turn will influence the market structure.[31]

### 5.3 Vifor (VI iron products)

The Commission has investigated one other case regarding denigration under Article 102, also within the pharmaceutical industry. In *Vifor (IV iron products)*, the Commission examined potentially anticompetitive denigration practices by Vifor Pharma.[32] The case ended in the Commission accepting the commitments offered by Vifor Pharma.

[29] AT.40588 *Teva Copaxone*

[30] See, *inter alia*, AT.40588 *Teva Copaxone,* para. 1469.

[31] *Ibid.,* Section 9.3.2

[32] See AT.40577 *Vifor (IV iron products)*.

Vifor disseminated false information about the safety of *Monofer*, a competitor to its own *Ferinject*, in the high-dose intravenous iron market. Although neither drug contains dextran – a compound linked to serious hypersensitivity risks – Vifor initially claimed *Monofer* contained dextran and later described it as "dextran-derived". This misrepresentation led HCPs to falsely perceive *Monofer* as significantly less safe than *Ferinject*.[33]

It is worth noting that the Commission, in its review of this case, applied a slightly modified specific legal test for denigration compared to the *Teva Copaxone* case, omitting the requirement to demonstrate that "effective mechanisms" were implemented. In the view of the Commission, it is sufficient that there exists dissemination of objectively misleading information, which is capable of having an exclusionary effect, which is not objectively justified.[34]

However, in its application to the case, the Commission highlights the extent of Vifor's conduct. The Commission recalls the different strategies employed by Vifor, including mobilising their sales force to disseminate false or misleading information, incorrectly attributing their perspectives to that of health authorities, incentivising HCPs to give false information during a Vifor-organised symposium, and how Vifor refined their messaging after some time from stating *Monofer* was dextran-based to stating it was dextran-derived, and therefore still had a similar risk profile to dextran-based drugs.[35]

While this assessment primarily relates to the assessment of whether there is dissemination of objectively misleading information, the Commission also appears to consider the extent of the denigration campaign. The Commission provides that "[a] disparagement campaign that methodically covers these main stakeholders and targets a material aspect of a prescription medicine such as its safety or efficacy is capable of [negatively affecting competition]."[36] Therefore, the extent of the denigration campaign is of relevance, although not necessarily an independent requirement. The condition from the *Teva Copaxone* case of requiring "effective mechanisms" is merely supplementary to the common condition of the conduct being capable of having an exclusionary effect. Indeed, if there is no effective mechanism for the dissemination of the false or misleading information, the impact on competition will be minimal, and the conduct may not actually or potentially have an exclusionary effect.

## 6 Conclusion

This article has assessed the conditions for denigration cases in the pharmaceutical industry to fall within the scope of Article 102 TFEU. Through an analysis of both national case law and decisions from the Commission, it has been revealed that denigration, although still in its early stages as a specific form of abuse under Article 102, may nonetheless fall within the ambit of the provision. Through a comparative analysis of the conditions applied in both national cases and Commission Decisions, the conditions for denigration under Article 102 have been clarified.

In essence, comparing the decisions of the Commission to that of most of the decisions from the FCA, it appears three main conditions must be assessed as part of the specific legal test for denigration as an abuse of a dominant market position incompatible with Article 102. Firstly, there has to be dissemination of objectively false or misleading information relating to a competing producer or their products and/or

[33] *Ibid.,* paras. 97-114.

[34] *Ibi*d., para. 83, with references therein.

[35] *Ibid.,* paras. 97-114.

[36] *Ibid.,* para. 87.

services. Secondly, the denigration must be capable of altering the competition within the market (i.e., have exclusionary effects). Finally, the conduct may not be objectively justified.

A notable difference between the cases is that while the FCA applies a requirement to demonstrate a commercial interest by the denigrating undertaking, the Commission does not apply such a condition. Omitting such a requirement harmonises, as held above, with the objectiveness of Article 102, and eases the burden of proof on the investigating organ. Furthermore, the causal link that the FCA requires but the Belgian Competition Authority rejects is not included in the legal test outlined by the Commission. The requirement of the conduct being capable of creating exclusionary effects is, however, a softer version of the requirement of a causal link. There is no need to prove an *actual* effect on the competition, but the conduct must be *capable* of having such an effect. Whether that capability stems from a causal link between the denigration and the dominant position, or whether such a potential effect may arise even in situations where there is no link between the conduct and the dominant position, like the BCA holds, is unclear, and is in any case exceedingly unlikely as far as actual situations concerns.

The Danish Competition Authority's lack of an assessment of whether the information disseminated was verifiable or not could potentially constitute an error in their legal assessment. However, in our opinion, considering the covertness of the conduct is not inherently incompatible with the doctrine outlined above. As the Commission held in *Vifor*, "[a] communication is misleading where, because of the manner in which it is presented, it is likely to mislead those who receive it."[37]

If information is presented in a way where the sender (i.e., the source of origin for the information) is concealed, but the channel through which it is presented is a reputable information provider (e.g., a newspaper, like in the *Falck* case), the information may seem more trustworthy or correct. Even if, as in the *Falck* case, the working conditions of one ambulance service provider is somewhat worse than that of another ambulance service provider, the mere fact that such information is propagated through trustworthy channels where the sender is concealed allows for an amplification of the effects that could not be achieved if the same information was disseminated directly. Essentially, the amplification of a small difference in quality through a covert dissemination channel could be considered to fall within the condition of false or misleading information and therefore constitute illegal denigration.

As such, denigration campaigns may take many forms, and yet still constitute abuse which falls within the prohibition outlined in Article 102. In any case, case law on denigration at both the national and EU level is sure to evolve over time, and as these cases mature, so will the specific legal test which is to be applied to denigration cases. For now, the findings above appear to be a well-founded starting point for assessing denigration under Article 102 TFEU.

[37] *Ibid.,* para. 85.