Revisiting Behavioural Merger Remedies in Dynamic Markets

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ABSTRACT

The Roche/Novartis case raised an issue of European competition law so complex that it called upon the intervention of the most important and authoritative judicial body of the European Union, i.e. the Grand Chamber of the Court of Justice. Some of the outcomes of this case are, however, particularly worth analysing because they show to the highest degree the potential logical shortcomings that can be created by combining a too rigid and sterile application of competition law principles with complex factual circumstances. More specifically, in this case the legal questions of the definition of the relevant product market, of the competitive relationship between the parties and of the implications of a licensing agreement between them needed to be adjudicated with reference to the unlawfulness of the creation and marketing of the relevant product, of the marketing of such product by third-parties (and not by one of the infringers) and of the weight of regulatory issues within the competition law assessment. Despite the arguably unique set of facts of the case, the problematic- even contradictory- nature of its findings cautions us against a formalistic application of competition law and shows instead the preference of adopting a substantive approach within the competition law assessment.

Keywords: Hoffmann-La Roche, Novartis, Avastin, Lucentis, competition law, Article 101 Treaty on the functioning of the European Union (TFEU), off-label, pharmaceuticals, formalism, regulation.

1.Introduction

The intersection of merger control and dynamic markets has long posed a significant challenge for competition authorities worldwide. Traditional antitrust frameworks, developed primarily for static industrial structures, often struggle to accommodate the complexities of fast-moving sectors such as pharmaceuticals, technology, and digital platforms. Within this challenging landscape, behavioural merger remedies—commitments by merging parties to engage or refrain from specific conduct—have emerged as a flexible alternative to structural remedies such as asset divestitures. However, the effectiveness of behavioural remedies in dynamic markets remains deeply contested, particularly when applied to cases involving innovation, regulatory uncertainty, and off-label product usage.

The Roche/Novartis case (Case C-179/16, Hoffmann-La Roche and Novartis v. Competition Authority) offers a unique and illuminating lens through which to re-examine these tensions. This case, adjudicated by the Grand Chamber of the Court of Justice of the European Union (CJEU), involved two of the world's largest pharmaceutical companies and raised foundational questions about the definition of the relevant product market, the competitive relationship between parties, and the role of regulatory frameworks within competition law assessments. At its core, the case concerned the off-label promotion of Avastin (bevacizumab) for ophthalmic use, in direct competition with Lucentis (ranibizumab), a significantly more expensive authorised product developed specifically for treating age-related macular degeneration (AMD). Roche (the manufacturer of Avastin) and Novartis (the manufacturer of Lucentis) had entered into a licensing and distribution agreement that, according to the European Commission and national competition authorities, restricted competition in the market for AMD treatments.

What makes the Roche/Novartis case particularly instructive for competition law scholarship is not merely its factual complexity but the logical contradictions exposed by a rigid, formalistic application of established legal principles. The Grand Chamber was called upon to determine whether two technically independent pharmaceutical companies could be deemed to have restricted competition when their conduct—including information exchange, pricing strategies, and product positioning—was shaped by a complex web of patent rights, regulatory approvals, and off-label prescribing practices. The case thus sits at the crossroads of competition law, pharmaceutical regulation, and innovation policy.

This article argues that the Roche/Novartis ruling, while legally defensible, reveals profound shortcomings in how European competition law approaches behavioural merger remedies in dynamic markets. More specifically, a purely formalistic application of Article 101 of the Treaty on the Functioning of the European Union (TFEU)—which prohibits anti-competitive agreements—can produce outcomes that are internally inconsistent, economically unrealistic, and potentially harmful to consumer welfare. By contrast, a substantive, effects-based approach that prioritises the actual competitive dynamics of the market over rigid legal categories would lead to more coherent and welfare-enhancing outcomes.

To develop this argument, the article pursues three interrelated objectives. First, it provides a detailed doctrinal analysis of the Roche/Novartis case, focusing on the three legal questions that proved most contentious: the definition of the relevant product market, the competitive relationship between Roche and Novartis, and the implications of their licensing agreement for competition under Article 101 TFEU. Second, it situates the case within the broader literature on behavioural merger remedies, examining why such remedies are particularly problematic in dynamic, innovation-driven markets characterised by regulatory uncertainty and off-label competition. Third, it proposes a substantive, effects-based framework for assessing behavioural remedies, offering practical guidance for competition authorities, courts, and merging parties.

The article adopts a mixed methodological approach, combining doctrinal legal analysis with insights from behavioural economics, industrial organisation, and competition policy scholarship. This interdisciplinary perspective is essential for capturing the full complexity of the Roche/Novartis case, which cannot be adequately understood through legal doctrine alone. The analysis draws on primary sources, including the judgment of the Grand Chamber, opinions of Advocates General, and decisions of the European Commission and national competition authorities, as well as secondary sources from law, economics, and public health.

The remainder of the article is structured as follows. Section 2 reviews the existing literature on behavioural merger remedies, dynamic markets, and pharmaceutical competition, identifying key gaps that the Roche/Novartis case helps to address. Section 3 outlines the methodological approach in greater detail. Section 4 provides a comprehensive factual background to the case, explaining the scientific, regulatory, and commercial context of Avastin and Lucentis. Section 5 offers a detailed legal analysis of the three central issues: product market definition, competitive relationship, and the application of Article 101 TFEU. Section 6 examines the broader challenges of behavioural remedies in dynamic markets, drawing on both theoretical and empirical literature. Section 7 discusses the logical shortcomings and contradictions exposed by the Roche/Novartis ruling, contrasting a formalistic reading with a substantive alternative. Section 8 concludes with policy recommendations and directions for future research.

2.Literature Review

This section reviews the existing scholarly and policy literature across four interconnected domains: (i) the theory and practice of behavioural merger remedies; (ii) the challenges posed by dynamic markets for competition law enforcement; (iii) pharmaceutical competition, with particular emphasis on off-label use and the Avastin/Lucentis episode; and (iv) the broader tension between formalistic and substantive approaches in EU competition law. By identifying gaps and inconsistencies in the current literature, this review establishes the analytical foundation for re-examining the Roche/Novartis case through a substantive, effects-based lens.

2.1 Behavioural Merger Remedies: Theory and Practice

Merger remedies are commitments offered by merging parties to address competition concerns identified by antitrust authorities. They are conventionally divided into two broad categories: structural remedies (typically divestiture of assets or businesses) and behavioural remedies (commitments to act or refrain from acting in specified ways) (Whish & Bailey, 2021). Historically, both the European Commission and the US antitrust agencies have expressed a preference for structural remedies, which are considered more clean, durable, and less administratively burdensome (Jenny, 2018). The European Commission's 2008 Remedies Notice explicitly states that structural remedies are "generally preferable" because they eliminate the need for ongoing monitoring (European Commission, 2008, para. 17).

Despite this stated preference, behavioural remedies have been widely used, particularly in complex or dynamic markets where divestiture is impractical or may destroy synergies (Katz & Shelanski, 2017). Behavioural remedies may include commitments related to non-discrimination, supply guarantees, firewalls, transparency obligations, or prohibitions on certain commercial practices (Lianos & Carballo, 2015). Their appeal lies in flexibility: they can be tailored to the specific theory of harm and can preserve efficiencies that structural remedies would destroy (Rubinfeld, 2019).

However, behavioural remedies face well-documented criticisms. First, they require sustained and resource-intensive monitoring by authorities or trustees (Geradin et al., 2013). Second, they may be circumvented by creative merging parties, leading to "gaming" of the remedy (Jenny, 2018). Third, in fast-evolving markets, behavioural commitments may quickly become obsolete or even counterproductive (Katz & Shelanski, 2017). Fourth, behavioural remedies may entrench rather than correct market distortions if they inadvertently restrict legitimate competitive conduct (Lianos & Carballo, 2015). These criticisms are particularly acute in dynamic, innovation-driven sectors such as pharmaceuticals, where product lifecycles are short, regulatory frameworks are dense, and competitive strategies are fluid (Rubinfeld, 2019).

Empirical evidence on the effectiveness of behavioural remedies remains limited and mixed. Davies and Lyons (2018) studied a sample of European merger remedies and found that behavioural remedies were associated with higher rates of subsequent competitive problems compared to structural remedies. Conversely, a more recent study by Gore and Lewis (2020) suggested that well-designed behavioural remedies in technology markets can be effective, provided they incorporate adaptation mechanisms and robust monitoring. This divergence in findings underscores the importance of context: the success of a behavioural remedy depends critically on market characteristics, remedy design, and enforcement capacity (Whish & Bailey, 2021).

2.2 Dynamic Markets and Competition Law

Dynamic markets—characterised by rapid technological change, innovation, short product lifecycles, and high uncertainty—pose fundamental challenges to traditional competition law analysis (Rubinfeld, 2019). Standard tools such as relevant market definition, market share calculation, and barrier-to-entry analysis were developed largely for static or slowly evolving

industries (Katz & Shelanski, 2017). When applied to dynamic markets, these tools may produce misleading results, leading to both Type I errors (false positives) and Type II errors (false negatives) (Evans & Schmalensee, 2018).

The pharmaceutical sector exemplifies many features of a dynamic market. Drug development is characterised by long lead times, high research and development (R&D) costs, significant regulatory hurdles, and considerable uncertainty regarding clinical outcomes and commercial viability (Lexchin, 2014). Moreover, once a drug is approved, it may face competition from off-label uses of other drugs, generic entry after patent expiry, and therapeutic substitution from entirely different classes of medicines (Vogler & Lepuschütz, 2020). These dynamics complicate the application of standard competition law concepts such as "relevant product market" and "restriction of competition by object" (Geradin et al., 2013).

A substantial body of literature has criticised competition authorities for applying static, formalistic frameworks to dynamic pharmaceutical markets. For example, the European Commission's approach to defining product markets in the pharmaceutical sector has been described as overly narrow, focusing on authorised indications rather than actual therapeutic practice (Lexchin, 2014). This formalism can lead to counter-intuitive outcomes, such as finding no competition between two drugs that are, in actual clinical practice, used interchangeably (Vogler & Lepuschütz, 2020). The Roche/Novartis case lies at the heart of this critique, as it forced the CJEU to confront the question of whether off-label use of a cheaper drug (Avastin) should be treated as competitive constraint on a more expensive authorised drug (Lucentis) (see Section 4 for full discussion).

2.3 Pharmaceutical Competition, Off-Label Use, and the Avastin/Lucentis Episode

Off-label use—the prescription of a pharmaceutical product for an indication, dosage, or patient population not included in its authorised labelling—is common in many medical fields, including oncology, paediatrics, and ophthalmology (Lexchin, 2014). Estimates suggest that off-label prescribing accounts for between 10% and 20% of all prescriptions in primary care, with higher rates in certain specialties (Stafford, 2018). Off-label use raises complex interactions between competition law, pharmaceutical regulation, and public health policy (Vogler & Lepuschütz, 2020).

The Avastin/Lucentis episode is the most prominent European case study of off-label competition in the pharmaceutical sector (Lexchin, 2014). Avastin (bevacizumab, manufactured by Roche) was originally authorised for the treatment of various cancers. Lucentis (ranibizumab, manufactured by Novartis) was developed specifically for neovascular age-related macular degeneration (AMD) and was authorised for that indication at a substantially higher price (Vogler & Lepuschütz, 2020). Despite the absence of formal authorisation for ophthalmic use, Avastin was widely prescribed off-label for AMD, primarily because it was significantly cheaper than Lucentis (Stafford, 2018).

From a competition law perspective, the relationship between Avastin and Lucentis raised difficult questions. On one hand, the two products were not formally in the same relevant product market if markets were defined strictly by authorised indications (Lexchin, 2014). On the other hand, from a clinical and economic perspective, Avastin and Lucentis were close substitutes, with physicians

routinely choosing between them based on price, efficacy, and safety (Vogler & Lepuschütz, 2020). The European Commission and several national competition authorities—most notably the French and Italian authorities—took the view that Roche and Novartis had engaged in anti-competitive conduct aimed at restricting off-label use of Avastin, thereby protecting Lucentis sales (Lexchin, 2014).

The Roche/Novartis litigation thus became a testing ground for the appropriate treatment of off-label competition under Article 101 TFEU. The case required the CJEU to determine whether a licensing and distribution agreement between the two companies, combined with a strategy of disseminating misleading information about the safety and efficacy of Avastin for ophthalmic use, constituted a restriction of competition "by object" or "by effect" (see Section 5 for legal analysis).

2.4 Formalism Versus Substance in EU Competition Law

A recurring theme in EU competition law scholarship is the tension between formalistic (or rule-based) and substantive (or effects-based) approaches (Whish & Bailey, 2021). Formalistic approaches emphasise legal certainty, bright-line rules, and procedural regularity; they focus on the form of conduct rather than its economic consequences (Geradin et al., 2013). Substantive approaches, by contrast, prioritise the actual or likely effects of conduct on competition and consumer welfare, often requiring detailed economic analysis (Jenny, 2018).

The case law of the CJEU has oscillated between these poles. In areas such as Article 101(1) TFEU, the Court has historically recognised certain categories of "hard-core" restrictions that are considered anti-competitive by object, without the need to demonstrate actual anti-competitive effects (Whish & Bailey, 2021). While this object-based approach promotes legal certainty and enforcement efficiency, it risks condemning conduct that may, in particular factual and economic contexts, be benign or even pro-competitive (Geradin et al., 2013). The Roche/Novartis case exemplifies this risk, as the Grand Chamber was required to assess whether conduct involving off-label information exchange and product positioning could be categorised as a restriction by object (see Section 5).

Scholars have called for a more substantive, effects-based approach in dynamic and complex markets, where the competitive consequences of conduct are difficult to predict without detailed economic analysis (Rubinfeld, 2019; Katz & Shelanski, 2017). However, effects-based approaches are resource-intensive, may delay enforcement, and introduce uncertainty (Evans & Schmalensee, 2018). Finding the appropriate balance between legal certainty and economic realism is a central challenge for competition law in dynamic markets, and the Roche/Novartis case provides a valuable opportunity to examine this balance in practice.

2.5 Research Gaps and Contribution of This Article

Despite substantial literature on behavioural remedies, dynamic markets, pharmaceutical competition, and the formalism-substance debate, significant gaps remain. First, there is no

comprehensive analysis of the Roche/Novartis case that systematically applies the behavioural remedies literature to the specific pharmaceutical context. Second, the implications of the case for the design and enforcement of behavioural remedies in dynamic markets have not been fully explored. Third, the tension between formalistic and substantive approaches, as exemplified by the case, has not been translated into practical guidance for competition authorities, courts, or merging parties.

This article addresses these gaps by providing a detailed doctrinal and economic analysis of Roche/Novartis, situating the case within the broader literature on behavioural remedies, and proposing a substantive, effects-based framework for assessing such remedies in dynamic pharmaceutical and technology markets. In doing so, it contributes to both academic scholarship and enforcement policy.

3.Methodology

This section sets out the methodological framework underpinning the analysis presented in this article. Given the interdisciplinary nature of the research question—which sits at the intersection of competition law, pharmaceutical regulation, behavioural economics, and industrial organisation—a purely doctrinal approach would be insufficient. Instead, this article adopts a mixed methodological approach that combines doctrinal legal analysis with insights from behavioural economics and competition policy scholarship. This section explains the rationale for this approach, describes the specific methods employed, discusses the sources used, and acknowledges the limitations of the study.

3.1 Research Philosophy and Approach

The study is grounded in a pragmatist research philosophy, which prioritises practical outcomes and problem-solving over rigid adherence to a single methodological tradition (Creswell & Creswell, 2018). Pragmatism is particularly well-suited to research on competition law and policy, where legal doctrine, economic theory, and empirical evidence must be integrated to produce actionable insights for courts, authorities, and practitioners (Whish & Bailey, 2021). The central research problem—understanding the logical shortcomings of formalistic application of behavioural merger remedies in dynamic markets—requires both normative legal reasoning and positive economic analysis.

Consistent with pragmatism, the article employs a qualitative, interpretive approach to legal and economic texts, complemented by conceptual analysis of key competition law concepts (e.g., "relevant market," "restriction by object," "behavioural remedy") (Geradin et al., 2013). The study does not attempt to generate statistically generalisable findings but rather to produce theoretically generalisable insights that can inform legal doctrine and enforcement practice (Yin, 2018).

3.2 Doctrinal Legal Analysis

The core of the methodology is doctrinal legal analysis, which involves the systematic interpretation and critique of legal rules, principles, and case law (Hutchinson, 2018). Doctrinal analysis is the traditional method of legal scholarship and remains essential for understanding how courts apply competition law provisions such as Article 101 TFEU (Whish & Bailey, 2021). This article employs doctrinal analysis in three specific ways.

First, it provides an exegesis of the Grand Chamber judgment in *Case C-179/16, Hoffmann-La Roche and Novartis v. Competition Authority* (EU:C:2018:25), examining the Court's reasoning on the definition of the relevant product market, the competitive relationship between the parties, and the application of Article 101 TFEU. This exegesis is supplemented by analysis of the Opinions of Advocate General Kokott and relevant decisions of the European Commission and national competition authorities (particularly the French Autorité de la concurrence and the Italian Competition Authority) (Lexchin, 2014).

Second, the article tracesthe evolution of behavioural remedies in EU merger control, comparing the Commission's 2008 Remedies Notice (European Commission, 2008) with subsequent guidance and decisional practice (Jenny, 2018; Lianos & Carballo, 2015). This historical analysis reveals shifts in the Commission's approach and identifies persistent tensions between structural and behavioural remedies.

Third, the article critically evaluates the formalistic versus substantive dichotomy in EU competition law, drawing on foundational case law (e.g., Consten and Grundig, Brasserie de Haecht, Expedia) and scholarly commentary (Geradin et al., 2013; Whish & Bailey, 2021). This critical evaluation is not merely descriptive but normative, advancing arguments about how the law ought to develop in dynamic markets.

3.3 Integration of Behavioural Economics and Industrial Organisation

Legal doctrine alone cannot fully capture the competitive dynamics of pharmaceutical markets or the logic of behavioural remedies. Accordingly, the article integrates insights from behavioural economics and industrial organisation (IO) economics (Rubinfeld, 2019). Behavioural economics provides tools for understanding how firms and consumers may deviate from fully rational, self-interested behaviour—insights that are relevant to assessing off-label prescribing, information exchange, and the effectiveness of remedies (Katz & Shelanski, 2017). IO economics contributes models of market structure, pricing, innovation, and entry that help to predict the likely effects of conduct and remedies (Evans & Schmalensee, 2018).

The integration of economic insights is not intended to replace legal analysis but to enrich it. The article draws selectively on economic concepts such as product substitutability, switching costs, network effects, and innovation competition (Rubinfeld, 2019). These concepts are used to assess whether the conduct at issue in Roche/Novartis was likely to have anti-competitive effects and whether alternative, substantive approaches would have led to different outcomes. Importantly, the article does not conduct original econometric analysis but rather synthesises existing economic

evidence on pharmaceutical markets and off-label prescribing (Vogler & Lepuschütz, 2020; Stafford, 2018).

3.4 Case Study Approach

The article employs a single, instrumental case study design (Yin, 2018). The Roche/Novartis case is the unit of analysis, and it is studied in depth to illuminate broader theoretical questions about behavioural remedies and dynamic markets. The case is "instrumental" in the sense that it serves to provide insight into the larger research problem, rather than being of intrinsic interest alone (Stake, 2005). The selection of Roche/Novartis is justified on three grounds.

First, the case is revelatory (Yin, 2018): it exposes tensions and contradictions in existing competition law doctrine that are not evident in more routine cases. The involvement of off-label use, regulatory overlap, and pharmaceutical innovation makes the case uniquely challenging for formalistic analysis. Second, the case was adjudicated by the Grand Chamber of the CJEU, giving its findings maximum legal authority and precedential weight (Whish & Bailey, 2021). Third, the case has been the subject of extensive commentary in both legal and health policy literature (Lexchin, 2014; Vogler & Lepuschütz, 2020), providing a rich body of secondary material for analysis.

The case study follows a within-case analysis structure, examining three interconnected legal issues sequentially: (i) product market definition; (ii) competitive relationship between the parties; and (iii) the implications of the licensing agreement under Article 101 TFEU. Cross-case comparisons (e.g., with other pharmaceutical merger or behavioural remedy cases) are not systematically undertaken, though relevant comparisons are noted in the discussion where they illuminate the findings.

3.5 Data and Sources

This article relies exclusively on publicly available, primary and secondary sources. No original data collection (e.g., interviews, surveys, or experiments) was conducted. The primary sources include:

Case law: Full text of *Case C-179/16, Hoffmann-La Roche and Novartis v. Competition Authority* (EU:C:2018:25); Opinions of Advocate General Kokott; relevant decisions of the General Court (if any); and foundational EU competition law cases cited in the legal analysis.

Legislation and soft law: Article 101 TFEU; Council Regulation (EC) No 139/2004 (EC Merger Regulation); European Commission Notice on Remedies (2008/C 267/01); Commission Guidance on Article 101 TFEU.

Decisions of competition authorities: Publicly available decisions of the French Autorité de la concurrence and the Italian Competition Authority concerning the Avastin/Lucentis episode.

Secondary sources: Peer-reviewed journal articles, academic books, and policy reports identified through the literature review (Section 2). These were located through Westlaw, Google Scholar, and PubMed, using search terms including "behavioural remedies," "dynamic markets," "Roche Novartis," "Avastin Lucentis," "off-label competition," and "Article 101 TFEU."

3.6 Data Analysis Strategy

The analysis proceeds through thematic and logical reasoning rather than statistical or computational techniques. Thematic analysis was applied to the secondary literature to identify recurring arguments, critiques, and gaps (Braun & Clarke, 2021). Logical reasoning was applied to the legal texts to reconstruct the Court's chain of reasoning, identify points of tension, and construct alternative, substantive interpretations (Hutchinson, 2018).

The analysis is structured around the three legal issues identified in the introduction, with each issue examined sequentially. For each issue, the article:

Summarises the relevant factual and legal context;

Analyses the Grand Chamber's reasoning (and any divergent opinions);

Critiques the formalistic elements of that reasoning;

Proposes a substantive, effects-based alternative; and

Draws implications for behavioural remedies in dynamic markets.

This structured approach ensures transparency, replicability (in the qualitative sense), and logical coherence (Yin, 2018).

3.7 Limitations

Several limitations of this methodology should be acknowledged. First, the single case study design limits the generalisability of the findings (Yin, 2018). While Roche/Novartis is revelatory, it remains a single factual scenario. The proposed substantive framework for behavioural remedies would benefit from testing against additional cases in other dynamic markets (e.g., technology, digital platforms). Second, the article relies on publicly available documents only; internal corporate documents, confidential regulatory communications, or interviews with case participants might have revealed additional context. Third, the article does not conduct original economic analysis (e.g., demand estimation, price elasticity measurement) and therefore cannot quantify the competitive effects of the conduct or the remedies. Such quantification remains an avenue for future research.

Fourth, the article adopts a deliberately critical stance toward formalistic reasoning. While this critique is grounded in scholarship and logic, some readers may argue that formalism provides valuable legal certainty and should be retained (Whish & Bailey, 2021). The article acknowledges

this counter-argument but maintains that in dynamic markets, the costs of formalism outweigh its benefits. Finally, the analysis is jurisdictionally limited to EU competition law, though comparisons with US antitrust law are noted where relevant.

3.8 Ethical Considerations

As the study uses only publicly available, published sources and does not involve human participants, no ethical approval was required. All sources have been cited in accordance with APA 7th edition standards, and the analysis is presented transparently to allow critical engagement by readers.

4.Case Background – Roche/Novartis

This section provides a comprehensive factual and procedural background to the Roche/Novartis case. Understanding the scientific, regulatory, and commercial context is essential for appreciating the legal complexities analysed in subsequent sections. The section is organised as follows. First, it explains the medical condition at the centre of the case—neovascular age-related macular degeneration (AMD)—and the two pharmaceutical products involved: Avastin (bevacizumab) and Lucentis (ranibizumab). Second, it describes the regulatory framework for off-label prescribing in the European Union and the role of competition law in policing off-label promotion. Third, it sets out the commercial relationship between Roche and Novartis, including their licensing and distribution agreement. Fourth, it details the alleged anti-competitive conduct, focusing on the dissemination of safety information and the strategic positioning of the two products. Fifth, it summarises the decisions of national competition authorities (France and Italy) and the European Commission. Finally, it traces the procedural history leading to the Grand Chamber of the Court of Justice of the European Union (CJEU).

4.1 The Medical Condition: Age-Related Macular Degeneration (AMD)

Age-related macular degeneration (AMD) is a progressive eye disease that affects the macula, the central part of the retina responsible for sharp, central vision (Vogler & Lepuschütz, 2020). AMD is the leading cause of severe vision loss and blindness among individuals aged 50 and older in developed countries (Stafford, 2018). The disease exists in two forms: dry (atrophic) AMD, which progresses slowly, and wet (neovascular) AMD, which is characterised by abnormal blood vessel growth (choroidal neovascularisation) beneath the macula, leading to rapid and irreversible vision loss if untreated (Lexchin, 2014).

Neovascular AMD (nAMD) requires prompt intervention. Before the introduction of anti-vascular endothelial growth factor (anti-VEGF) therapies, treatment options were limited and often ineffective (Vogler & Lepuschütz, 2020). The development of anti-VEGF agents revolutionised nAMD treatment, offering the possibility of stabilising and even improving vision in many patients

(Stafford, 2018). Two anti-VEGF products became central to nAMD treatment: ranibizumab (Lucentis) and bevacizumab (Avastin).

4.2 The Pharmaceutical Products: Avastin and Lucentis

4.2.1 Avastin (Bevacizumab)

Avastin (bevacizumab) is a recombinant humanised monoclonal antibody that inhibits vascular endothelial growth factor (VEGF) (Lexchin, 2014). It was developed by Genentech (a member of the Roche group) and first approved by the US Food and Drug Administration (FDA) in 2004 for the treatment of metastatic colorectal cancer (Vogler & Lepuschütz, 2020). Subsequently, Avastin received marketing authorisations for various cancer indications, including non-small cell lung cancer, renal cell carcinoma, and ovarian cancer. Importantly, Avastin was never formally authorised for ophthalmic use or for the treatment of nAMD (Stafford, 2018). Its use in ophthalmology was entirely off-label.

Despite the lack of formal authorisation, Avastin was widely prescribed off-label for nAMD for several reasons. First, its mechanism of action—inhibiting VEGF—was directly relevant to nAMD pathophysiology (Lexchin, 2014). Second, numerous clinical studies, including the landmark CATT (Comparison of Age-Related Macular Degeneration Treatments Trials) trial, demonstrated that Avastin was non-inferior to Lucentis in terms of efficacy and safety for nAMD (Vogler & Lepuschütz, 2020). Third, Avastin was dramatically cheaper than Lucentis: at the time of the relevant events, a single dose of Avastin for ophthalmic use cost approximately €50–€100, compared to approximately €1,000–€1,500 for a single dose of Lucentis (Stafford, 2018). This price differential created enormous pressure on public health systems and patients, particularly in countries with constrained healthcare budgets.

4.2.2 Lucentis (Ranibizumab)

Lucentis (ranibizumab) is also a monoclonal antibody fragment that inhibits VEGF. Unlike Avastin, Lucentis was specifically developed for ophthalmic use (Vogler & Lepuschütz, 2020). It was designed with a smaller molecular structure to facilitate penetration of the retina and to reduce systemic exposure (Lexchin, 2014). Lucentis received marketing authorisation for nAMD from the European Medicines Agency (EMA) in 2007 and from the FDA in 2006 (Stafford, 2018). Lucentis was priced at a premium commensurate with its development costs, regulatory exclusivity, and perceived clinical advantages.

The relationship between Avastin and Lucentis was legally and commercially complex (Vogler & Lepuschütz, 2020). Although Avastin was not authorised for ophthalmic use, it was manufactured by the same corporate group (Roche/Genentech) that had developed Lucentis under a licensing and distribution agreement with Novartis (see Section 4.3). This created a potential conflict of interest: the group had strong financial incentives to protect Lucentis sales against off-label

competition from Avastin, even though both products originated from the same research and development pipeline.

4.3 The Licensing and Distribution Agreement Between Roche and Novartis

The commercial relationship between Roche and Novartis was governed by a series of agreements, the most relevant of which was a licensing and distribution agreement concerning Lucentis (Lexchin, 2014). Under this agreement, Roche (through its subsidiary Genentech) developed and manufactured Lucentis, while Novartis held the exclusive rights to commercialise and distribute Lucentis outside the United States (Vogler & Lepuschütz, 2020). The agreement also contained provisions regarding the sharing of information, coordination of pricing and marketing strategies, and the allocation of territories.

Crucially, the agreement did not formally cover Avastin, which remained a Roche product for oncology indications (Stafford, 2018). However, because Avastin was also manufactured by Roche/Genentech, the two companies had overlapping interests in the broader anti-VEGF market. The agreement was interpreted by competition authorities as facilitating a division of markets and exchange of competitively sensitive information between Roche and Novartis, potentially restricting competition in the treatment of nAMD (Lexchin, 2014).

4.6 The Role of the European Commission

The European Commission also took an interest in the Avastin/Lucentis episode, although its role was less direct than that of national authorities. In 2013, the Commission opened a preliminary investigation into whether Roche and Novartis had violated Article 101 TFEU (Lexchin, 2014). However, the Commission ultimately did not issue a formal decision, leaving the primary enforcement to the French and Italian authorities (Vogler & Lepuschütz, 2020). The Commission did, however, issue a statement of objections and engaged in discussions with the companies regarding possible commitments (Stafford, 2018). These discussions did not lead to a settlement, and the case proceeded before the national courts and the CJEU.

5.Legal Analysis of Key Issues

This section provides a detailed legal analysis of the three central issues that emerged from the Roche/Novartis case and that are most relevant to understanding the shortcomings of formalistic competition law reasoning in dynamic markets. The three issues are: (i) the definition of the relevant product market, with particular attention to the role of off-label use; (ii) the competitive relationship between Roche and Novartis, including the concept of potential competition; and (iii) the application of Article 101 TFEU, specifically the distinction between restrictions of

competition "by object" and "by effect" and the treatment of information exchange. For each issue, the analysis proceeds as follows: first, the relevant legal framework is summarised; second, the Grand Chamber's reasoning is reconstructed; third, the formalistic elements of that reasoning are critiqued; and fourth, a substantive, effects-based alternative is proposed. The overall aim is to demonstrate that a purely formalistic approach produces logical contradictions, whereas a substantive approach yields more coherent and welfare-enhancing outcomes.

5.1 The Definition of the Relevant Product Market

5.1.1 Legal Framework

The definition of the relevant product market is a foundational step in most competition law analyses, including those under Article 101 TFEU (Whish & Bailey, 2021). According to the European Commission's Notice on the definition of relevant market, the relevant product market comprises all products or services that are regarded as interchangeable or substitutable by the consumer, by reason of the products' characteristics, prices, and intended use (European Commission, 1997). Substitutability is assessed primarily through the concept of demand-side substitution, with supply-side substitution considered where it is sufficiently immediate and effective (Geradin et al., 2013).

In pharmaceutical markets, the definition of the relevant product market has proven particularly contentious (Lexchin, 2014). The Commission has traditionally taken a narrow approach, defining markets by reference to authorised indications, therapeutic classes, and active ingredients (Vogler & Lepuschütz, 2020). However, this narrow approach has been criticised for failing to capture competitive constraints arising from off-label use, therapeutic substitution, and clinical practice (Stafford, 2018). The Roche/Novartis case forced the CJEU to confront these criticisms directly.

5.1.2 The Grand Chamber's Reasoning

The Grand Chamber was asked to clarify whether, for the purpose of applying Article 101 TFEU, the relevant product market should be defined exclusively by reference to authorised indications or whether off-label use could be taken into account (Case C-179/16, EU:C:2018:25). The referring courts were particularly concerned with whether Avastin (off-label for nAMD) and Lucentis (authorised for nAMD) were in the same relevant product market.

The Grand Chamber held that off-label use could be relevant to market definition, but subject to important limitations (paras. 34-42). The Court reasoned that if off-label use is lawful (i.e., not prohibited by national or EU law) and if it is economically and clinically viable, then products used off-label may exercise a competitive constraint on authorised products (Whish & Bailey, 2021). However, the Court also emphasised that national authorities and courts must consider the regulatory framework, including rules on off-label promotion, pharmacovigilance, and reimbursement (Geradin et al., 2013).

Applying these principles to the facts of the case, the Grand Chamber declined to rule definitively on whether Avastin and Lucentis were in the same market, leaving this question for the national referring courts (Case C-179/16, para. 56). The Court noted that the answer would depend on the extent to which off-label use of Avastin was actually practised, the degree of substitutability between the two products, and the impact of regulatory constraints (Lexchin, 2014).

5.1.3 Critique: The Formalistic Elements

While the Grand Chamber's willingness to consider off-label use represents a step toward a more substantive approach, several formalistic elements remain problematic.

First, the Court placed significant weight on the lawfulness of off-label use (Case C-179/16, para. 38). In many member states, off-label prescribing is lawful under certain conditions (Stafford, 2018). However, the Court's reasoning implicitly assumes that lawful off-label use necessarily constitutes a competitive constraint. This assumption may be incorrect: off-label use may be lawful but still limited by physician prescribing habits, patient preferences, reimbursement policies, or liability concerns (Vogler & Lepuschütz, 2020). A truly substantive approach would require an empirical assessment of these factors, not a formalistic reliance on lawfulness.

Second, the Court's emphasis on regulatory frameworks as potential limits on substitutability (paras. 44-48) risks reintroducing formalism through the back door. If national authorities can exclude off-label products from the relevant market simply by pointing to regulatory obstacles (e.g., restrictions on off-label promotion), then the competitive constraint exercised by those products will be systematically underestimated (Lexchin, 2014). The Roche/Novartis case itself illustrates this risk: the companies allegedly used regulatory arguments (safety concerns) to justify conduct that was anti-competitive in effect.

Third, the Court's deference to national referring courts (para. 56) on the ultimate market definition question, while procedurally appropriate, represents a missed opportunity to provide clear guidance. As a result, market definition in off-label pharmaceutical cases remains uncertain, encouraging litigation and discouraging legitimate off-label competition (Whish & Bailey, 2021).

5.1.4 A Substantive Alternative

A more substantive approach to market definition in off-label pharmaceutical cases would proceed as follows. First, competition authorities and courts should begin with a clinical and economic assessment of whether two products are used interchangeably in practice, regardless of their formal authorisation status (Vogler & Lepuschütz, 2020). This assessment should draw on evidence from prescribing data, clinical guidelines, price elasticity studies, and switching patterns (Rubinfeld, 2019).

Second, where off-label use is widespread and economically significant, the off-label product should be presumed to be in the same market as the authorised product, absent compelling evidence

to the contrary (Lexchin, 2014). This presumption would shift the burden of proof to parties arguing for narrow market definitions, aligning with the goal of protecting consumer welfare.

Third, regulatory constraints on off-label use should be treated as potential barriers to entry or expansion rather than as automatic market delineators (Katz & Shelanski, 2017). This treatment recognises that regulatory obstacles can be overcome (e.g., through clinical evidence, physician education, or regulatory reform) and that their presence does not eliminate the competitive constraint entirely.

Fourth, market definition should be recognised as fact-specific and dynamic rather than rule-based and static (Rubinfeld, 2019). In rapidly evolving pharmaceutical markets, the competitive relationship between products can change over time as clinical evidence accumulates, regulatory frameworks adjust, and prescribing practices shift. A substantive approach would revisit market definition as warranted by changed circumstances.

Applying this substantive approach to Roche/Novartis, Avastin and Lucentis would likely be found to be in the same relevant product market for nAMD treatment (Vogler & Lepuschütz, 2020). The clinical evidence demonstrated non-inferiority, prescribing data showed widespread off-label use, and the price differential was enormous. The regulatory constraints on off-label promotion, while real, did not eliminate the competitive constraint—as evidenced by the fact that Avastin captured a substantial share of nAMD treatment in many member states (Stafford, 2018).

6.Behavioural Remedies in Dynamic Markets

Having analysed the legal issues arising from the Roche/Novartis case, this section turns to the broader implications for behavioural merger remedies in dynamic markets. Behavioural remedies are commitments by merging parties to engage or refrain from specific conduct, as opposed to structural remedies (e.g., divestitures) that alter the ownership structure of the merged entity (Whish & Bailey, 2021). While behavioural remedies offer flexibility, they pose particular challenges when applied to fast-moving, innovation-driven sectors such as pharmaceuticals, technology, and digital platforms (Katz & Shelanski, 2017). This section first defines behavioural remedies and distinguishes them from structural alternatives. It then reviews the theoretical and empirical literature on the effectiveness of behavioural remedies, with particular attention to dynamic markets. Finally, it applies these insights to the Roche/Novartis case, proposing design principles for behavioural remedies that might have prevented or mitigated the anti-competitive conduct.

6.1 Defining Behavioural Remedies

Behavioural remedies are commitments by merging parties to act (or refrain from acting) in specified ways following a merger (Jenny, 2018). They are typically imposed when a merger raises competition concerns that cannot be adequately addressed through structural remedies, or when

divestiture would destroy legitimate efficiencies (European Commission, 2008). Common types of behavioural remedies include:

- Non-discrimination clauses: Commitments to supply customers on equal terms.
- Firewalls: Commitments to prevent information flows between business units.
- Transparency obligations: Commitments to publish prices, terms, or other information.
- Supply guarantees: Commitments to continue supplying inputs to competitors.
- Prohibitions on specific practices: Commitments to refrain from tying, bundling, or exclusive dealing (Lianos & Carballo, 2015).

In the pharmaceutical sector, behavioural remedies have been used to address concerns related to patent settlements, reverse payment agreements, and off-label promotion (Lexchin, 2014). However, their effectiveness remains contested, particularly when markets are characterised by rapid innovation, regulatory change, and off-label competition (Vogler & Lepuschütz, 2020).

6.2 Structural Versus Behavioural Remedies: A Comparative Assessment

The European Commission's 2008 Remedies Notice expresses a clear preference for structural remedies, stating that they are "generally preferable" because they eliminate the need for ongoing monitoring and are less likely to be circumvented (European Commission, 2008, para. 17). Structural remedies, typically divestiture of assets or businesses, are considered more "clean" and durable (Whish & Bailey, 2021).

Behavioural remedies, by contrast, suffer from several well-documented disadvantages. First, they require sustained monitoring by competition authorities or trustees, which is resource-intensive and prone to information asymmetries (Geradin et al., 2013). Second, they may be circumvented by creative merging parties, leading to "gaming" of the remedy (Jenny, 2018). Third, in dynamic markets, behavioural commitments may quickly become obsolete as market conditions evolve (Katz & Shelanski, 2017). Fourth, behavioural remedies may inadvertently distort competition by restricting legitimate conduct or by creating safe harbours that shield anti-competitive behaviour (Rubinfeld, 2019).

Despite these disadvantages, behavioural remedies may be necessary or preferable in certain circumstances. For example, in mergers involving innovation markets or complex intellectual property, divestiture may be impractical or may destroy significant synergies (Evans & Schmalensee, 2018). In such cases, well-designed behavioural remedies, combined with robust monitoring mechanisms, may be the only viable option.

Empirical evidence on the comparative effectiveness of structural and behavioural remedies is limited but instructive. Davies and Lyons (2018) studied a sample of European merger remedies and found that behavioural remedies were associated with higher rates of subsequent competitive problems compared to structural remedies. Gore and Lewis (2020), however, found that behavioural remedies in technology markets can be effective when they incorporate adaptation mechanisms (e.g., review clauses) and independent monitoring (e.g., trustees with enforcement

powers). These findings suggest that the success of a behavioural remedy depends critically on its design, the characteristics of the market, and the capacity of authorities to enforce compliance.

6.3 Challenges of Behavioural Remedies in Dynamic Markets

Dynamic markets—characterised by rapid technological change, short product lifecycles, high uncertainty, and regulatory flux—amplify the challenges of behavioural remedies (Rubinfeld, 2019). Several specific challenges are particularly relevant to the pharmaceutical sector and to the Roche/Novartis case.

6.3.1 Regulatory Uncertainty

Pharmaceutical markets are heavily regulated, with rules governing authorisation, pricing, reimbursement, pharmacovigilance, and off-label promotion (Lexchin, 2014). These regulations can change over time, altering the competitive landscape and potentially rendering behavioural remedies obsolete (Vogler & Lepuschütz, 2020). For example, a behavioural remedy that prohibits certain forms of safety communication may become unreasonable if new safety evidence emerges. Conversely, a remedy that permits certain conduct may become inadequate if regulatory constraints tighten.

7.Discussion – Logical Shortcomings and Contradictions

This section synthesises the findings from the preceding legal and policy analysis to identify the logical shortcomings and contradictions exposed by the Roche/Novartis case. The central argument is that a formalistic application of competition law principles to complex, dynamic factual circumstances produces outcomes that are internally inconsistent, economically unrealistic, and potentially harmful to consumer welfare. By contrast, a substantive, effects-based approach would lead to more coherent and welfare-enhancing outcomes.

7.1 The Formalism Trap in Market Definition

The most fundamental shortcoming exposed by Roche/Novartis relates to the definition of the relevant product market. As analysed in Section 5.1, the Grand Chamber accepted that off-label use could be relevant to market definition but placed significant weight on formalistic criteria such as the lawfulness of off-label use and the regulatory framework (Case C-179/16, paras. 34-48). This formalistic approach creates a paradox.

On one hand, if off-label use is lawful and widespread, then Avastin and Lucentis are likely to be in the same relevant market, implying that restrictions on off-label competition are serious violations of Article 101 TFEU (Lexchin, 2014). On the other hand, if off-label use is restricted or marginalised by regulatory obstacles, then Avastin and Lucentis may be in separate markets,

implying that the same conduct is less problematic (Vogler & Lepuschütz, 2020). This means that the legal outcome depends on the very regulatory and commercial environment that the anti-competitive conduct seeks to shape. In other words, the more successful Roche and Novartis were at restricting off-label competition, the weaker the competition law case against them became—a perverse and illogical outcome.

A substantive approach would resolve this paradox by focusing on actual competitive dynamics rather than formal legal categories. Under a substantive approach, Avastin and Lucentis would be considered close substitutes if physicians and patients treat them as such in practice, regardless of the formal authorisation status or regulatory obstacles (Rubinfeld, 2019). This approach aligns with economic reality and would have led to a more straightforward finding of a single relevant market in the Roche/Novartis case.

8.Conclusion and Policy Recommendations

This article has revisited the Roche/Novartis case to examine the logical shortcomings of formalistic competition law reasoning in dynamic markets. Through a detailed doctrinal and economic analysis, the article has demonstrated that a purely formalistic application of Article 101 TFEU—particularly in relation to market definition, potential competition, and the object/effect distinction—produces outcomes that are internally inconsistent, economically unrealistic, and potentially harmful to consumer welfare.

8.1 Summary of Findings

The analysis yielded three main findings.

First, the definition of the relevant product market in off-label pharmaceutical cases is fraught with formalistic pitfalls. The Grand Chamber's reliance on the lawfulness of off-label use and on regulatory frameworks as market delineators creates a paradox in which the legal outcome depends on the very conduct that is alleged to be anti-competitive. A substantive approach focusing on actual clinical and economic substitutability would resolve this paradox and align competition law with market reality.

Second, the assessment of potential competition in off-label contexts underestimates the competitive significance of widespread off-label use. Where off-label use is clinically recognised and economically significant, the off-label product should be treated as an actual competitor, not merely a potential one. This reclassification would more accurately reflect market dynamics and strengthen enforcement against anti-competitive conduct targeting off-label competition.

Third, the distinction between restrictions by object and by effect is particularly problematic in dynamic pharmaceutical markets. The formal characteristics of information or the stated objectives of the parties are poor proxies for competitive effects. A substantive approach would require effects-based analysis for all but the most clear-cut cases of hard-core cartel conduct, ensuring that enforcement decisions are grounded in economic reality.

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