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Abuse of Legal and Regulatory Procedures in the Pharmaceutical Sector: Sham Litigation, IP Strategies and the Protection of Compounding Pharmacies in EU and US Competition/Antitrust Law (Between Patent Rights and Patient Access)

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Table of Contents

Abstract

This thesis examines the extent of which EU and US competition/antitrust law address sham litigation and the abusive use of regulatory and intellectual-property procedures by dominant pharmaceutical firms, with particular consideration to the effects of such conduct on compounding pharmacies and patient access to medicines. It adopts a doctrinal and comparative methodology, with the main focus on Article 102 TFEU in the EU and on Sections 2 and 5 of the FTC Act in the United States. It will also situate both systems within the pharmaceutical regulatory frameworks governing compounding.

Chapter 1 explains the legal and practical role of compounding pharmacies in the EU and US, describing how they function as access-sensitive providers in situations involving shortages, therapeutic gaps, and individualized treatment needs. Chapter 2 analyzes the way EU competition law responds to misleading regulatory conduct, tactical use of intellectual property and administrative procedures, and related exclusionary measures. This analysis is primarly done through key cases such as *AstraZeneca*, *Servier*, and *Roxtec*. Chapter 3 then examines the US framework, focusing on *Noerr–Pennington*, the sham litigation and *Walker Process* exceptions, *FTC v. Shire ViroPharma*, and more recent litigation involving Eli Lilly and compounding pharmacies. Chapter 4 then compares both systems and considers their real-life effects on lawful compounding and patient access. Chapter 5 develops the policy recommendations and provides the final answer to the research question.

The main argument of the thesis states that both legal systems have the ability to tackle procedure-based exclusion, but neither is fully sufficient where strategic litigation and regulatory pressure affect compounding pharmacies. in comparison, EU law is better equipped to reach

misleading or strategically bundled procedural conduct under Article 102, especially in the cases where dominance and foreclosure can be shown. US law, by contrast, gives a greater safeguard for petitioning and litigation. This leads to a more proper safeguarding of legitimate rights enforcement but in turn, makes antitrust intervention more difficult unless the conduct is has clearly fraudulent or empirically unfounded actions. The thesis concludes that the preferable response is not to weaken legitimate patent, litigation, or regulatory rights, but instead to develop clearer enforcement standards and stronger coordination with medicine regulators so that those rights are not used tactically to suppress lawful competition and undermine patient access.

Abstract in Italian

Questa tesi esamina la misura in cui il diritto antitrust dell'UE e degli Stati Uniti affronta le controversie pretestuose e l'uso abusivo delle procedure regolamentari e di proprietà intellettuale da parte delle aziende farmaceutiche dominanti, con particolare attenzione agli effetti di tale condotta sulle farmacie galeniche e sull'accesso dei pazienti ai farmaci. Adotta una metodologia dottrinale e comparativa, concentrandosi principalmente sull'articolo 102 del TFUE nell'UE e sulle sezioni 2 e 5 del FTC Act negli Stati Uniti. Contestualizzerà inoltre entrambi i sistemi all'interno dei quadri normativi farmaceutici che disciplinano la preparazione galenica.

Il Capitolo 1 illustra il ruolo giuridico e pratico delle farmacie galeniche nell'UE e negli Stati Uniti, descrivendo come esse operino in quanto fornitori sensibili all'accesso ai farmaci in situazioni di carenza, lacune terapeutiche ed esigenze di trattamento individualizzate. Il Capitolo 2 analizza il modo in cui il diritto antitrust dell'UE risponde alle condotte regolamentari ingannevoli, all'uso tattico della proprietà intellettuale e delle procedure amministrative e alle relative misure escludenti. Tale analisi si basa principalmente su casi chiave come AstraZeneca, Servier e Roxtec. Il capitolo 3 esamina quindi il quadro normativo statunitense, concentrandosi sul caso Noerr-Pennington, sulle eccezioni relative alle cause fittizie e al processo Walker, sul caso FTC contro Shire ViroPharma e su controversie più recenti che coinvolgono Eli Lilly e le farmacie galeniche. Il capitolo 4 confronta poi i due sistemi e ne considera gli effetti concreti sulla preparazione legale di farmaci galenici e sull'accesso dei pazienti. Il capitolo 5 sviluppa le raccomandazioni politiche e fornisce la risposta finale al quesito di ricerca.

L'argomentazione principale della tesi afferma che entrambi gli ordinamenti giuridici sono in grado di affrontare le esclusioni basate su procedure, ma nessuno dei due è pienamente sufficiente laddove le contenziosi strategici e le pressioni normative incidono sulle farmacie

galeniche. Al contrario, il diritto dell'UE è più attrezzato per contrastare le condotte procedurali ingannevoli o strategicamente raggruppate ai sensi dell'articolo 102, soprattutto nei casi in cui si possano dimostrare la posizione dominante e la preclusione. Il diritto statunitense, invece, offre maggiori garanzie per le istanze e i contenziosi. Ciò porta a una tutela più adeguata dei diritti legittimi, ma al contempo rende più difficile l'intervento antitrust, a meno che la condotta non sia chiaramente fraudolenta o basata su prove infondate. La tesi conclude che la risposta preferibile non è indebolire i diritti legittimi in materia di brevetti, contenziosi o regolamentazione, bensì sviluppare standard di applicazione più chiari e un maggiore coordinamento con le autorità di regolamentazione dei farmaci, in modo che tali diritti non vengano utilizzati tatticamente per sopprimere la concorrenza legale e compromettere l'accesso dei pazienti alle cure.

Chapter 1 – Compounding Pharmacies and the Pharmaceutical Regulatory Framework in the EU and US

1.1 Introduction

This chapter provides the context necessary for the analysis for the rest of the thesis. The pharmaceutical sector is defined by a significant amount of regulation. In addition, the presence of patents, exclusive regulations and clinical information provides a significant amount of market power.[1] This signifies that disputes between originator pharmaceutical pharmacies and compounding pharmacies will not rely on price competition as much as maintaining the boundaries of lawful compounding. Understanding of this regulatory architecture is vital for assessing whether litigation and regulation will serve as legitimate enforcement or as exclusionary practices.[2]

There are four main objectives to this chapter. First, to clarify the legal definition of pharmacy compounding and to distinguish it from industrial manufacturing. The main attention to this will be a "boundary problem", which means there has to be a clearly defined difference between patient specific preparation and de facto manufacturing. Second, there will be an outline of the legal frameworks that determine when it is legal to compound, both in the USA and the EU.[3] For the US side, the requirement is to explain the statutory architecture created by the Federal Food, Drug, and Cosmetic Act (FDCA), as amended by the Drug Quality and Security Act (DQSA), with the distinction between section 503A pharmacies and section 503B outsourcing facilities.

[1] R Whish and D Bailey, *Competition Law* (11th edn, Oxford University Press 2024); A Jones and B Sufrin, *EU Competition Law: Text, Cases, and Materials* (Oxford University Press, latest edn).
[2] P Galli and MP Negrinotti, 'Competition Law' (Course syllabus, 2025–2026) 2 (Objectives).
[3] Food, Drug, and Cosmetic Act 1938 (as amended) 21 USC §§ 353a–353b; Drug Quality and Security Act 2013, Pub L No 113-54, 127 Stat 587.

Also, the FDA policy on shortages and "essentially copies" will be addressed.[4] For the EU side, we explain the purpose and goals of Directive 2001/83/EC and the scope of the magistral and officinal exemptions, as realized in national systems.[5] Third, the area of compounding within the pharmaceutical supply chain will be determined and the features that make compounders vulnerable to larger originator firms will be assessed. The main features would be regulatory fragility, reputational sensitivity and significant resource unevenness in legal disputes.

The creation of this framework for this chapter will explain why litigation and regulatory complaints have the ability to create strong anti-competitive effects in the pharmaceutical market, even before a legal decision is reached.[6]

1.2 What is pharmacy compounding?

1.2.1 Definition and core characteristics

Pharmacy compounding refers to the preparation, mixing and modification of a medical product by a pharmacist to meet a patient's specific needs.[7] It may encompass adjusting the dosage strength, dosage form, removing or substituting ingredients, or preparing a custom nonindustrial

[4] US Food and Drug Administration, *Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act* (Guidance for Industry, January 2018); US Food and Drug Administration, 'Compounding when Drugs are on FDA's Drug Shortages List' (webpage, content current as of 8 August 2025, accessed 4 March 2026).
[5] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [2001] OJ L311/67.
[6] H Hovenkamp, *Federal Antitrust Policy: The Law of Competition and Its Practice* (7th edn, West Academic)
[7] U.S. Food and Drug Administration, 'Human Drug Compounding' (13 February 2026) https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding accessed 7 April 2026.

product. This is done to ensure clinical suitability and patient care for when a standardized medicine cannot meet those needs.

There are several core differences that distinguish compounding with industrial scale drug manufacturing. First, compounding is patient oriented and justified by individual clinical use instead of a broader commercial distribution. Second, it usually is not industrial in scale, instead it is created within the framework of the pharmacy, with the pharmacist having the direct responsibility to prepare, document and assure the quality of the product. Third, the quality controls of compounded products are on a different standard than industrial drugs.[8] There are professional standards of traceability and pharmacy level quality practices, rather than a large-scale practice. This variance can be blurred with our boundary problem, where compounding pharmacies start resembling manufacturing systems. This can be seen with large scale batches, pharmacy wide standardizations, wide distribution systems, and even substitutions to authorized products instead of individualized specific need products.[9] This boundary is fundamental for the thesis, as many disputes in this sector involve the complaint that compounders have crossed this line.

1.2.2 Compounding vs industrial manufacture

Industrial medicines are primarily subject to a pre-market authorization, meaning that they can only be manufactured and distributed within a licensed and tightly supervised framework. This is

[8] Directive 2001/83/EC [2001] OJ L311/67, art 2(1) and art 3(1)–(2)

[9] US Food and Drug Administration, 'Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act' (Guidance for Industry, January 2018) https://www.fda.gov/regulatory-information/search-fda-guidance-documents/compounded-drug-products-are-essentially-copies-commercially-available-drug-product-under-section accessed 4 March 2026.

based on GMP systems[10] - good manufacturing processes- for large scale pharmaceutical production. In contrast, pharmacy compounding is usually permitted only within limited regimes/narrow exemptions that treat the preparation as a part of the pharmacy preparation. This signifies that the legality depends on specific conditions such as a patient-oriented purpose or a non-industrial supply. The quality is assured through pharmacy level standards, documentation and traceability, and professional quality rather than a full industrial manufacturing architecture.[11]

The key controversial issue is the boundary problem: when compounding begins to resemble manufacturing. This involves large-scale batching, standardization, wider distribution, or substitution for authorized products without a genuine individualized need. This distinction is extremely important because it determines the legality and the risk of enforcement. This distinction also helps explain why the originator companies can challenge compounding pharmacies through litigation and regulatory complaints, as they highlight their activity as de facto manufacturing.[12]

[10] European Commission, 'EudraLex – Volume 4 – Good Manufacturing Practice (GMP) guidelines' https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en accessed 4 March 2026;
[11] Directive 2001/83/EC [2001] OJ L311/67, art 6(1) ('No medicinal product may be placed on the market … unless a marketing authorisation has been issued'); Food, Drug, and Cosmetic Act 1938, 21 USC § 355(a) and §§ 353a–353b.
[12] US Food and Drug Administration, 'Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act' (Guidance for Industry, January 2018) https://www.fda.gov/regulatory-information/search-fda-guidance-documents/compounded-drug-products-are-essentially-copies-commercially-available-drug-product-under-section accessed 4 March 2026; Directive 2001/83/EC [2001] OJ L311/67, art 2(1) and art 3(2).

1.3 Why compounding exists (clinical and economic role)

1.3.1 Clinical role

Compounding exists to respond to individual needs of patients that normal standardized medications cannot fully meet. This includes a personalized dosing and formulas such as adjusting strength or changing route of administration. For example, if a patient cannot take a tablet but the medication is only available in tablet form, the compounded version of that medication would be in a form that the patient is able to take.[13] Compounding is also very relevant in pediatrics and geriatrics, where alternative dosage forms and flexibility can be vital. In addition, patients with allergies or intolerances can have the offending ingredients removed or substituted. For hospital situations, compounding can be the answer administration needs for specific patients that cannot take the commercial form.[14]

1.3.2 Economic/system role

Beyond tailoring to individual clinical reasons, compounding has a broader system role in maintaining access to treatment during shortages or supply distributions.[15] They act as a sort of safety mechanism to support patients when the standard commercial product is not readily available. Compounding also can affect the access dynamics of an authorized medicine, making

[13] Council of Europe Committee of Ministers, Resolution CM/Res(2016)1 on quality and safety assurance requirements for medicinal products prepared in pharmacies for the special needs of patients (adopted 1 June 2016) <https://rm.coe.int/168065c132> accessed 4 March 2026 ('medicinal products manufactured by the pharmaceutical industry are not always authorized or available to cover the special needs of individual patients');

[14] Resolution CM/Res(2016)1 (n 1) para 1 (scope includes 'community and hospital pharmacies') and para 3 ('needed by a specific patient or by specific population groups with particular needs').

[15] US Food and Drug Administration, 'Compounding when Drugs are on FDA's Drug Shortages List' (FDA webpage, content current as of 8 August 2025) <https://www.fda.gov/drugs/human-drug-compounding/compounding-when-drugs-are-fdas-drug-shortages-list> accessed 4 March 2026 ('when a drug is in shortage, patients and health care professionals may look to compounded drugs as an option').

it more accessible past the limitations of the authorized forms. For example, Ozempic has many compounded medication versions that expand on the scope of the commercial drug.[16] This leads to another issue: since they aren't authorized in the same industrial pathways as commercial medications, there are debates about compliance and safety that will be used in litigation narratives.[17]

1.3.3 Relevance to the thesis

These clinical and system roles help to explain the main central tension point of the thesis. The originator pharmaceutical companies often include in their litigation disputes the issues of patient safety, regulatory integrity, and misleading communications. The compounding pharmacies instead specify how their products expand access, continuity of care, and patient specific clinical needs. Since, legally, compounding is defined in a narrow and conditional space, litigation has to prove that the compounder has surpassed these boundaries or has not been compliant in the compounded processes.[18] This makes compounding pharmacies very vulnerable to strategic litigation and regulatory complaints, which can deter access to the market even before any

[16] National Library of Medicine. *DailyMed: OZEMPIC — semaglutide injection, solution*. Updated October 14, 2025. Accessed April 5, 2026

[17] US Food and Drug Administration, 'FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss' (FDA webpage, content current as of 4 February 2026) <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss> accessed 4 March 2026 ('unapproved versions do not undergo FDA's review for safety, effectiveness and quality before they are marketed'); FDA, 'Compounding when Drugs are on FDA's Drug Shortages List' (n 3).

[18] Directive 2001/83/EC [2001] OJ L311/67, art 3(1)–(2); Food, Drug, and Cosmetic Act 1938, 21 USC §§ 353a–353b; US Food and Drug Administration, *Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act* (Guidance for Industry, January 2018) <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/compounded-drug-products-are-essentially-copies-commercially-available-drug-product-under-section> accessed 4 March 2026.

decision is made. [19] The following sections therefore outline the EU and US legal frameworks that define when compounding is lawful, providing a basis for later chapters on the strategic use (and potential abuse) of legal and regulatory procedures.

1.4 EU framework (Directive 2001/83/EC/national implementation/reforms)

1.4.1 Baseline rule: marketing authorization and regulated manufacturing

As a baseline, EU pharmaceutical law is built on the principal that medical products intended for the market have to be subject to a marketing authorization requirement, and regulatory conditions for manufacturing and distribution, Directive 2001/83/EC expresses this general rule by stating that no medicinal product may be placed on the market in a Member State unless a marketing authorization has been issued by the competent authority. Also, if there has been an authorization granted based on the EU centralized procedure.[20] In terms of policy, this reflects the logic of public health: industrial medicine is standardized, distributed at scale, and therefore requires ex ante controls. There is a limited carve out for pharmacy preparations where the activity is more closely related to meeting the patient's specific needs, not in an industrial way.[21] In practical terms these exemptions create a space for compounding in a legal sense, albeit

[19] H Hovenkamp, *Federal Antitrust Policy: The Law of Competition and Its Practice* (7th edn, West Academic).

[20] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [2004] OJ L136/1.

[21] Council of Europe Committee of Ministers, Resolution CM/Res(2016)1 on quality and safety assurance requirements for medicinal products prepared in pharmacies for the special needs of patients (adopted 1 June 2016).

narrow and heavily conditional. The requirements from the definition operate as cumulative conditions: if they are not fulfilled then the preparation of the drug risks falling back to the general regime requirements. This is where the legal vulnerability arises, where disputes stating the activity isn't genuine pharmacy preparation as it has become standardized and/or widely supplied. As an example, large scale batching or a very large distribution can be used as arguments that will result in litigation.[22]

1.4.2 Magistral and officinal exemptions

Within this framework, Directive 2001/83/EC excludes from its scope certain pharmacy preparations, most prominently the magistral and officinal formulas. The Directive does not apply to medicinal products prepared in a pharmacy in accordance with a medical prescription for an individual patient (magistral formula), and it also does not apply to medicinal products prepared in a pharmacy in accordance with a pharmacopoeia and supplied directly to the patients served by that pharmacy (officinal formula). These exclusions reflect the idea that some medicines must be tailored for specific patients or prepared within a professional setting even when they are not authorized industrial products.

In practical terms, the exemptions create lawful space for compounding, but that space is narrow and conditional. The requirements contained in the definitions operate as cumulative conditions: if they are not fulfilled, the preparation risks falling back into the general regime (including marketing authorization and related licensing requirements). This is where the "legal vulnerability" arises: disputes often turn on claims that the activity is no longer a genuine

[22] P Minghetti and others, 'Regulatory framework of pharmaceutical compounding and actual developments of legislation in Europe' (2014) 117(3) *Health Policy* 328, 330–333.

pharmacy preparation because it has become too standardized or too widely supplied (for example, through large-scale batches or distribution beyond the patients served by the preparing pharmacy).[23]

1.4.3 National implementation and divergence

Since magisterial and official preparations are formed out of the Directive framework, the specific rules that govern pharmacy preparations are set on the national level. These include quality and safety standards, as well as operational limits. Therefore, member states retain a significant amount of power to define how these exemptions for compounding pharmacies function in reality. For example, conditions where hospitals may prepare in advance, the extent of permissible stock, the supply and distribution levels. This matters for the thesis because it adds an element of legal uncertainty as well as compliance risk. Consequently, additional scope for regulatory complaints and litigation strategies exists based on national boundaries.[24]

1.4.4 EU "Pharma Package" reforms

Recent EU reform proposals (the "Pharma Package") seek to modernize this pharmaceutical framework. This will emphasize patient access to medication and the security of the supply of that medication. The primary concern is shortages. The proposed new Directive (COM(2023)192) would continue treating pharmacy preparations as outside the general market-placement regime by maintaining exclusions for magistral and officinal formulas.[25]

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[23] Minghetti and others (n 3) 330–333.
[24] Resolution CM/Res(2016)1 (n 2).

[25] European Commission, Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC, COM(2023) 192 final, art 1(5)–(6);

However, it will also explicitly add that in justified cases, a hospital-serving pharmacy may prepare magistral products in advance on the basis of estimated prescriptions for a limited specific time frame. For the thesis, these reforms have significant importance because the scope of lawful preparation and the gray interpretations around it can now have the ability to expand or contract through legislative change. This has the possibility to increase incentives for strategic regulatory action by firms seeking to shape or exploit the ever-evolving boundaries.[26]

1.5 US framework (FDCA + DQSA + 503A/503B + FDA guidance)

1.5.1 Policy driver and shift toward federal oversight

In the United States pharmacy compounding historically has been treated as a practice of pharmacy subject to state law and the state pharmacy boards. This is as opposed to industrial drug manufacturers subject to full federal pre-market approval. However, over time, significant growth of large-scale compounding and some high-profile safety incidents has led to more federal regulation. This led to the Drug Quality and Security Act 2013 (DQSA), which amended the Federal Food, Drug, and Cosmetic Act (FDCA) and established a more explicit statutory architecture for compounding. Particularly it has reinforced the framework for "traditional" compounding under FDCA §503A (21 USC §353a) and created a distinct category of outsourcing facilities under FDCA §503B (21 USC §353b). These regulations have given the

[26] European Commission, Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, COM(2023) 193 final.

FDA clearer oversight tools for specific forms of compounding that sit at a closer level to industrial production.[27]

1.5.2 Section 503A (traditional compounding)

Section 503A is designed for traditional, patient-specific compounding. The core model of this regulatory system is that compounding is done by a state-licensed pharmacy (or physician) and linked to valid prescriptions for individual patients. There is an anticipatory element based on prescribing patterns as well. By meeting these specific conditions, the compounded drugs will fall within the exemptions from standard federal industrial regimes. The most important of these are new drug approval requirements and certain labelling and current good manufacturing practice (cGMP) obligations, However, it is important to note that these compounded medications are still subject to federal rules on adulteration and misbranding.[28]

A key function of the 503a section is to prevent compounding from becoming a pathway to market unapproved copies of the authorized industrial medication. Hence this means that there is a limit based on individual clinical need as opposed to broad commercial distribution. The restriction of products to become essentially copies of the commercial version is the most important regulation of this statute, since there is often high demand for copying that will become central in legal disputes.[29]

[27] 1. Food, Drug, and Cosmetic Act 1938 (as amended) 21 USC § 355(a) and §§ 353a–353b; Drug Quality and Security Act 2013, Pub L No 113-54, 127 Stat 587; US Food and Drug Administration, 'Human Drug Compounding' (webpage) <https://www.fda.gov/drugs/human-drug-compounding> accessed 4 March 2026.

[28] 2. Food, Drug, and Cosmetic Act 1938 (as amended) 21 USC § 353a; 21 USC §§ 351–352; US Food and Drug Administration, 'Human Drug Compounding' (webpage) <https://www.fda.gov/drugs/human-drug-compounding> accessed 4 March 2026.

[29] 3. Food, Drug, and Cosmetic Act 1938 (as amended) 21 USC § 353a;

1.5.3 Section 503B (outsourcing facilities)

Section 503B created a separate category of outsourcing facilities, which are intended to supply compounded drugs to healthcare institutions under a higher level of federal oversight. The difference between 503b facilities and 503a is that these facilities have the ability to compound drugs without individual restrictions. This is because their primary goal is to supply healthcare providers such as hospitals and clinics. This expanded operational model comes with stricter regulatory expectations. They have the obligation to register with the FDA and have to be subject to FDA inspections. In addition, they are largely expected to comply with cGMP requirements (or a closely equivalent quality system) and comply with additional obligations such as product reporting and specific labelling requirements.[30]

For the thesis, this matters greatly since 503b is at a much closer level to industrial manufacturing than 503a. This signifies that there is greater risk that the boundary between these is blurred and therefore a higher potential for possible legal challenges.

1.5.4 FDA guidance: shortages and "essentially copies"

FDA policy and guidance play an important role in defining the practical boundaries of lawful compounding, particularly through the interaction between compounding and drug shortages. When the FDA identifies a product as being in shortage, this can affect the extent to which compounders may supply products that would otherwise be treated as impermissible substitutes for sanctioned medicines. Conversely, when a shortage is resolved, the legal space for producing "copy-like" compounded products typically narrows. In parallel, the concept of "essentially

[30] 4. Food, Drug, and Cosmetic Act 1938 (as amended) 21 USC § 353b; US Food and Drug Administration, 'Outsourcing Facilities' (webpage) <https://www.fda.gov/drugs/human-drug-compounding/outsourcing-facilities> accessed 4 March 2026.

copies" (and related FDA interpretations) functions as a key boundary rule: it differentiates compounding justified by patient-specific clinical need from compounding that effectively serves as an unapproved substitute for an authorized commercial product. This regulatory framing is not only relevant to FDA enforcement; it also frequently appears in private litigation and public communications, where originator firms may allege that compounders are misleading patients and prescribers about regulatory status, safety, or equivalence—issues that become central in later case studies on litigation strategies targeting compounders.[31]

1.6 Compounding in the pharmaceutical supply chain

1.6.1 Supply chain map

The pharmaceutical supply chain can be described as a sequential stage connecting innovation to patient access. First R&D generates new therapies, which are protected by means of patents and regulatory exclusivities. Then the products move to manufacturing, wholesaling and distribution.[32] In the US there is an additional layer of market organization by payers and PBMs(intermediaries). These have a very strong influence over the reimbursement and access to

[31] 5. US Food and Drug Administration, 'Compounding when Drugs are on FDA's Drug Shortages List' (webpage) <https://www.fda.gov/drugs/human-drug-compounding/compounding-when-drugs-are-fdas-drug-shortages-list> accessed 4 March 2026; US Food and Drug Administration, 'Drug Shortages' (webpage) <https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages> accessed 4 March 2026; US Food and Drug Administration, 'Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act' (Guidance for Industry, January 2018) <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/compounded-drug-products-are-essentially-copies-commercially-available-drug-product-under-section> accessed 4 March 2026.

[32] 1. European Commission, Pharmaceutical Sector Inquiry: Final Report (Commission Staff Working Document) SEC(2009) 952 (8 July 2009) <https://edz.bib.uni-mannheim.de/www-edz/pdf/sek/2009/sek-2009-0952-en.pdf> accessed 4 March 2026.

formulas.[33] In both the EU and US, prescribers determine patient demand through their prescribing. Ultimately, pharmacies will provide the patients with the medication, along with compounding pharmacies being on this level of the supply chain. They specifically prepare patient specific products in cases where the authorized drug is unavailable, not suitable, or has supply issues. Displayed below is a figure showing the normal pharmaceutical flow from R&D to the patient (the payers and PBMS would be in between distributors and prescribers for the US):

1.6.2 Where market power sits (and why it matters)

In this chain, the originator pharmaceutical companies show a significant amount of market power at different points. The most obvious ones would be for patents and regulatory exclusivities. These create legal barriers to entry, and delay competitors from entering the market.[34] Furthermore, these originator firms often control the key clinical evidence narrative around a product. This is the main distinction between "approved" medicines and "unapproved" preparations. The approved medications are supported by clinical trials and regulatory review. This shapes the way regulators, prescribers, and patients perceive alternative sources of the same

[33] 2. Federal Trade Commission, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies (Interim Staff Report, July 2024) <https://www.ftc.gov/reports/pharmacy-benefit-managers-report> accessed 4 March 2026.
[34] 4. R Whish and D Bailey, Competition Law (11th edn, Oxford University Press 2024); European Commission, Pharmaceutical Sector Inquiry: Final Report (SEC(2009) 952) (n 1) (discussion of reliance on patents/exclusivities and obstacles to entry).

type of medicine. [35] Thus, the brand reputation and the ability to set the safety and quality narrative behave not only as marketing assets, but as strategic advantages. This is expressly prominent in this sector as trust and regulatory legitimacy is very imperative.

Compounding pharmacies, in contrast, tend to be structurally weaker actors in this market. Often, their operations run on a limited scale, permissions to operate within a narrow regulatory space, and often lack the financial resources to sustain prolonged litigation. In addition, they are highly sensitive to reputation. Allegations with safety, illegal processes, or incorrect or misleading information they provide can deter providers and patients from using them. This can occur even before any legal decision is made. Since compounding pharmacies' market power is asymmetrical compared to originator firms, the firms have strong incentive to apply legal pressure to these pharmacies. They do this through complaints to regulators, warming campaigns or litigation around safety and misleading public arguments. This dynamic is appropriate for the thesis since it helps to explain how strategic litigation and regulatory complaints have the ability to generate exclusionary effects in practice, even without a definitive ruling on the merits.[36]

1.7 Structural vulnerability of compounders to litigation and regulatory complaints

Compounding pharmacies operate within a regulatorily fragile space. This means that their ability to compound is lawful only if it remains within strict and oftentimes cumulative

[35] 5. Directive 2001/83/EC [2001] OJ L311/67, art 6(1) and art 3(1)–(2); Food, Drug, and Cosmetic Act 1938 (as amended) 21 USC § 355(a) and §§ 353a–353b.

[36] 6. H Hovenkamp, Federal Antitrust Policy: The Law of Competition and Its Practice (7th edn, West Academic); P Areeda, L Kaplow, AS Edlin and CS Hemphill, Antitrust Analysis: Problems, Text, and Cases (Aspen, latest edn);

conditions. These conditions can be patient-specific, limits on scale and/or distribution. Therefore, there is ample chance to consent to the legality of compounding. Since compounding is not authorized in the same pathway as industrial manufacturers, the allegations that a compounder has exceeded the permitted boundaries or has failed with the compounding standards become a powerful tool of pressure. Even in the cases where the underlying conduct is defensible, simply the existence of a credible regulatory challenge can create large uncertainty for compounders.

This fragility is reinforced by reputational and resource asymmetries. Due to the fact that compounding pharmacies are highly reputable-sensitive, accusations involving safety, quality, or "misleading" communications can affect prescriber and patient demand even before any court or regulator reaches a decision.[37] In contrast, pharmaceutical companies generally have a greater capacity to deal with prolonged legal disputes. This signifies that there is a cost asymmetry that can deter compounders from fully defending themselves. In this context, repeated complaints, petitions, or lawsuits may generate "procedural leverage". This means that the burden of responding to the process itself can impose costs and delay and therefore is able to function as a form of pressure regardless of the final outcome. Finally, litigation and regulation closely cooperate, because private suits frequently rely on regulatory compliance narratives. This means if preparation will fall within lawful compounding parameters. Therefore, regulatory ambiguity

[37] 3. Council of Europe, Resolution CM/Res(2016)1 (n 1); US Food and Drug Administration, 'Human Drug Compounding' (webpage) <https://www.fda.gov/drugs/human-drug-compounding> accessed 4 March 2026.

can be translated into courtroom leverage. These dynamics are directly relevant to the later analysis of sham litigation and abuse of regulatory procedures.[38]

1.8 Mini conclusion and transition to Chapter 2

This chapter has demonstrated that compounding is a form of pharmacy preparation that can support access and continuity of care where standardized authorized medicines are unavailable or unsuitable. However, it has to operate within a narrow and conditional legal space. In the EU, this space is structured around the general marketing-authorization model and the magistral/officinal exemptions, implemented through national rules. In the US, it is structured around the FDCA as amended by the DQSA, including the distinction between 503A and 503B compounding and related FDA policy. For both systems, the blend of regulatory delicateness, reputational sensitivity, and resource asymmetries helps explain why strategic litigation and regulatory complaints can have significant real-world effects on compounding activity even before any decision on the merits. Against that background, Chapter 2 turns to EU competition law and asks the central question for the EU part of the thesis: when does the strategic use of legal and regulatory procedures by a dominant undertaking cross the line into an abuse under Article 102 TFEU?

[38] 4. H Hovenkamp, Federal Antitrust Policy: The Law of Competition and Its Practice (7th edn, West Academic);

Chapter 2: Abuse of legal and regulatory procedures in EU competition law: AstraZeneca, Servier, Roxtec and related practice under Article 102 TFEU

2.0 Chapter aim, contribution, and roadmap

This chapter establishes the EU baseline for the thesis by explaining how Article 102 TFEU [39] regulates a specific category of exclusionary conduct: the abuse of legal and regulatory procedures by dominant pharmaceutical firms. There is a prominent level of regulation and concentration within the pharmaceutical sector. On one hand, originator companies normally will hold substantial IP portfolios and market power. On the other hand, however, compounding pharmacies tend to serve a more practical function. These involve actions such as preparing personalized medicines, addressing shortages, and filling therapeutic gaps where authorized products are unavailable or not suitable. In response, oftentimes originator firms will decide to employ procedural strategies such as: stating compounders have been misleading to patent or regulatory authorities, manipulating the pathways of marketing and exclusivity, creating weak or instrumental litigation, or creating litigation that is coordinated with public disparagement. These methods are used with the intention to disturb the balance between patent-driven innovation and access by increasing the compounder's costs and additionally delaying or deterring entry.

The chapter's contribution has two main points. First, it clarifies the doctrinal toolkit for scrutinizing such conduct under Article 102 (dominance, abuse, and the competitive significance of "procedural" foreclosure), using a prominent EU competition law textbook account as an organizing reference point.[40] Second, it will develop a typology of procedural abuses and apply it

[39] Consolidated Version of the Treaty on the Functioning of the European Union [2012] OJ C326/47, art 102.

[40] Richard Whish and David Bailey, *Competition Law* (11th edn, OUP 2024);

with three anchor case studies—AstraZeneca, Servier, and Roxtec. Then, it will widen to other related EU and national practices. The chapter will conclude with a compound framework that will be used again in the US chapter and later, the comparative/applied chapter.[41]

2.1 Article 102 TFEU toolkit for "procedural abuse"

2.1.1 Core elements: dominance, abuse, effects, and standard of proof

Article 102 TFEU applies to where (i) an undertaking holds a dominant position on a relevant market, (ii) it engages in "abuse", and (iii) the conduct is at least capable of restricting competition and affecting trade between Member States.[42] The assessment of dominance in the market is done via shares in the market. However, for the context of pharmaceuticals structural features such as regulatory barriers to entry, IP protection, and dependence on administrative authorizations are also determined to find out market dominance.[43] "Abuse" by itself, is an objective concept.[44] The focus is then on the nature of the conduct and how this conduct impacts the competitive process, as opposed to evaluating moral blame.

For the abuse of exclusion, we determine enforcement on an effects based level. Here, the authorities have to determine whether the firm is capable of foreclosing competitors, taking into account all of the specific circumstances: market structure, duration, scale, and the mechanism of foreclosure. In some areas, EU practice still might use form-based shortcuts. However, the procedural strategies are normally assessed through how these practices affect the competitor

[41] Alison Jones, Brenda Sufrin and Niamh Dunne, *Jones & Sufrin's EU Competition Law: Text, Cases & Materials* (8th edn, OUP 2023).
[42] Consolidated Version of the Treaty on the Functioning of the European Union [2012] OJ C326/47, art 102.
[43] Robert O'Donoghue and A Jorge Padilla, *The Law and Economics of Article 102 TFEU* (Hart Publishing 2020).
[44] Case 85/76 *Hoffmann-La Roche & Co AG v Commission* [1979] ECR 461, para 91 ("the concept of abuse is an objective concept");

firms, while still recognizing that tactics distorting regulatory decision-making can be especially problematic. Additionally, the capability is assessed in markets that involve a heavy use of procedures. This capability is proven more by showing how the procedure works as opposed to just the price and output data. The enforcement must see if exclusionary consequences were foreseeable. Key indicators for these include internal documents, sequence and timing, misleading or inconsistent submissions, and evidence of delayed entry, higher compliance costs, or chilled competition.[45]

2.1.2 Procedural abuse: tension between competition law and procedural/constitutional rights

In this chapter "procedural abuse" refers to the use of legal or regulatory procedures, such as through the courts, patent offices, medical agencies, pricing bodies, not to explicitly remove their rights to compete, but instead to hinder them. This exclusionary mechanism is done to generally delay, inflate costs, create uncertainty, or have a chilling effect.

The category of abuse is a sensitive subject, especially in the pharmaceutical market. EU competition law must not turn legitimate access to the courts and regulators as a source of liability, because it hinders the actions of effective judicial protection and the right to be heard.[46] However, article 102 would in fact be undermined if dominant firms can successfully impede on their rivals simply by creating exclusion through legal procedural form. Therefore, the important task is to distinguish rights-vindication and good-faith participation in public processes from manipulative or misleading conduct that distorts outcomes.

[45] Communication from the Commission—Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings (Text with EEA relevance) [2009] OJ C45/7;

[46] Charter of Fundamental Rights of the European Union [2012] OJ C326/391, art 47.

Pharmaceutical regulation will highlight and amplify these exact issues. Since administrative steps determine entry, the legal effects of authorizations, exclusivities, substitution rules, reimbursement, competitive pressure are naturally filtered with these bottlenecks for entry. [47] Therefore, small procedural interventions can have the potential to have large market wide effects, both for compounding pharmacies and patient access.

2.1.3 Abusive litigation gatekeeper: ITT Promedia and "wholly exceptional circumstances"

When alleged abuse involves the court proceedings or even just the threat of them, EU law now applies a restricted gatekeeper, associated with the ITT Promedia case. Litigation by a dominant undertaking will constitute an abuse only in "wholly exceptional circumstances", reflecting the importance of access to courts. With this restriction, two conditions are required: 1) that the action must be unfounded, meaning that it cannot reasonably be regarded as an attempt to defend or establish rights, instead it only serves to harass. 2. It has to form a part of a plan that has the goal to eliminate competition. This means it has to involve a more broad exclusionary strategy against a rival.[48]

This is the threshold that the EU is cautious about. Article 102 is reluctant to condemn litigation as abusive because there are many genuine, complex and even socially valuable legal disputes, especially regarding IP and regulations. However it is important to note that this gatekeeper does not allow dominant firms to abuse where litigation is one instrument among others as a strategy

[47] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products [2009] OJ L152/1.
[48] Case T-111/96 *ITT Promedia NV v Commission* [1998] ECR II-2937 ("it is only in wholly exceptional circumstances that the fact that legal proceedings are brought is capable of constituting an abuse").

to foreclose competition. These other ones involve actions such as misleading submissions to authorities, IP-office procedural gaming, coordinated communications.

2.1.4 Objective justification and "competition on the merits" in procedure-heavy markets

Routinely, allegations of procedural abuse trigger "objective justification" arguments. This is where the dominant firms claim that their conduct reflects regulatory compliance (patient safety, pharmacovigilance duties, truthful labelling), legitimate protection of IP, or the exercise of lawful procedural entitlements (filing applications, challenging approvals, seeking injunctions). The main question regarding article 102 is not if these reactions are conceivable abstractly but whether they explain with credibility the conduct and whether the means are appropriate and proportional.

The pharmaceutical market is a very procedure heavy one, therefore the distinction between competition on merits and exclusionary manipulation often is an issue of good faith. Good faith and genuine engagement with regulation is generally permissible, as opposed to misleading statements, selective disclosures, and weaponized filing sequence. Even litigation without a realistic vindication can be perceived in bad faith. Where prima facie exclusionary mechanism is shown, the undertaking must substantiate its claimed justification.

Through these complex procedures many plausible alternative narratives are created. Therefore, focus on the analysis should be based on evidence (internal documents and timing), foreseeability of exclusionary consequences, and whether less restrictive avenues were available to achieve the claimed objective.[49]

[49] Communication from the Commission—Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings [2009] OJ C45/7;

2.2 Typology of abusive legal and regulatory procedures (classification grid)

To keep our EU analysis consistent across our case studies of AstraZeneca, Servier, Roxtec and the "related practice" section, and to create a bridge to the applied discussion on compounding pharmacies in Chapter 4, a reusable typology of procedural exclusion under Article 102 TFEU.[50] The underlying idea of this typology is that in a highly regulated and concentrated sector, competitive outcomes can be shaped by: how dominant firms use public procedures and private enforcement. Public procedures can be characterized by authorizations, exclusivities, and reimbursement. Private enforcement is characterized by IP/unfair-competition litigation.[51] The proposal already identifies the core strategic behaviors this chapter tracks: misleading information to authorities, manipulation of marketing authorizations or exclusivity, weak/instrumental litigation, and coordinated communications disparaging rivals (including compounders and generics). The following types are described below:

Type A — Misleading representations to public authorities.

This category covers situations where a dominant undertaking makes inaccurate, incomplete, or strategically framed submissions to public decisionmakers, including patent/SPC offices, medicines agencies, and reimbursement bodies. The central competitive concern is that misinformation (or selective disclosure) can distort administrative decision-making in a way that allows exclusivity to be obtained or maintained, or that slows competitors' regulatory pathways. In practice, the evidential markers tend to be documentary and procedural rather than purely economic: inconsistencies across parallel filings, selective disclosure of material facts, and

[50] European Commission, *Pharmaceutical Sector Inquiry: Final Report* (Commission Staff Working Document, SEC(2009) 952, 8 July 2009) paras 4, 7 and 16;

[51] Lauren E Battaglia, 'Drug Reformulation Regulatory Gaming in Pharmaceuticals: Enforcement & Innovation Implications' (2011) 7(2) *European Competition Journal* 379.

internal records indicating knowledge, intent, and the foreseeability of exclusionary consequences. A particularly important feature is the "procedural automatic effect" problem: once a decision is triggered by the authority's process (for example, a grant, a term, or a regulatory status consequence), the market impact can be immediate and difficult for rivals to neutralize. [52]

Type B — Regulatory switching/withdrawal tactics.

Type B captures strategic changes to marketing authorization status, product presentation, or market presence. These involve strategies such as withdrawals, deregistration, or reintroductions timed around entry by generics or close alternatives. The exclusionary mechanism is not necessarily deception, but the way a regulatory move can interfere with reference-product dependence, substitution, parallel trade, or reimbursement positioning.[53] The typical analytical question is whether the strategy predictably raises rivals' entry costs or delays their route to market, particularly in the cases where the dominant firm cannot provide a plausible benefit to the patient or compliance rationale for the timing and design of the switch.

Type C — Strategic use of IP-office procedures.

This type concerns the procedural exploitation of patent-office mechanisms—such as divisionals, oppositions, and sequencing— in order to create legal uncertainty or a "thicket" effect around a product. The foreclosure mechanism is usually to delay via a path of created uncertainty: competitors face extended clearance burdens and prolonged dispute timelines, which can deter

[52] Commission Decision of 15 June 2005 relating to a proceeding under Article 82 of the EC Treaty and Article 54 of the EEA Agreement (Case COMP/A.37.507/F3 — *AstraZeneca*) (notified under document number C(2005) 1757) [2006] OJ L332/24, art 1(1).
[53] Case C-457/10 P *AstraZeneca AB and AstraZeneca plc v Commission* EU:C:2012:770, paras 149–155.

investment and slow launch decisions.[54] Evidence for this typically includes repeated late or staggered filings, weak claims deployed defensively, and portfolio management documents that describe the objective in terms of delaying or complicating entry rather than protecting genuine innovation.

Type D — Sham/vexatious litigation and threats.

Type D addresses court actions, interim measures, and warning-letter campaigns where the dominant undertaking's procedural recourse functions with the primary intention to delay or chill entry, rather than to vindicate rights in good faith. The mechanism involves raising rivals' legal risk and costs and discouraging supply, substitution, or commercial expansion. Analytically, this category is intricately linked to the "manifestly unfounded" idea and to whether the litigation/threats have an integration into a broader plan to eliminate competition, rather than being an isolated legal dispute.[55]

Type E — Hybrid multi-channel strategies.

Finally, Type E is focused on coordinated strategies that combine elements of the previous Types A–D with communications/denigration and regulatory complaints. There is a cumulative competitive effect: delay, uncertainty and reputational harm can together produce foreclosure even if there is no single channel that would be sufficient on its own. [56] The evidential emphasis is therefore focused on coordination and sequencing: cross-referenced internal strategy

[54] Summary of Commission Decision of 31 October 2024 relating to a proceeding under Article 102 of the Treaty on the Functioning of the European Union (Case AT.40588 – *Teva Copaxone*) (notified under document number C(2024) 7448 final) [2025] OJ C, C/2025/1680.
[55] Case T-111/96 *ITT Promedia NV v Commission* [1998] ECR II-2937.
[56] Autorità Garante della Concorrenza e del Mercato (AGCM), Provvedimento n 30737, A538 – *Sistemi di sigillatura multidiametro per cavi e tubi* (18 July 2023)

documents, consistent narratives across different forums, and a common objective that links administrative actions, enforcement tactics, and market-facing messaging.

2.3 Case study I - AstraZeneca (EU foundational procedural abuse case)

2.3.1 Background and Case Decision-making Logic

The AstraZeneca case is one of the foundational EU authorities on the misuse of regulatory procedures by a dominant pharmaceutical company. It concerned Losec, AstraZeneca's blockbuster anti-ulcer medicine and one of the first proton pump inhibitors. The Commission found that, between 1993 and 2000, AstraZeneca used two sets of public procedures to shield Losec from competition after the core period of exclusivity was ending. First, it gave misleading information to various national patent offices in order to obtain supplementary protection certificates (SPCs) that extended the protection for Losec. Second, it deregistered with selective process the marketing authorizations for Losec capsules in Denmark, Norway and Sweden after launching a tablet version. This made it harder for generic firms to rely on the simplified approval route and complicated parallel trade. In 2005 the Commission fined AstraZeneca €60 million; in 2010 the General Court decided that they would largely uphold the decision, while reducing the fine because the Commission had not proved effects on parallel imports in Denmark and Norway. [57]

What makes AstraZeneca especially important is the reasoning behind the outcome. The courts did not specifically say that asserting IP rights is abusive as such. Instead, they focused on the

[57] Case C-457/10 P *AstraZeneca*

fact that a dominant firm had used administrative mechanisms in a such a way that departed from competition on the merits. The Court of Justice confirmed that if representations to public authorities are misleading or not must be assessed concretely. This is done by looking at the circumstances of the case rather than requiring proof of bad faith with a narrow subjective sense. It also stressed that dominant undertakings have a special responsibility to not use regulatory procedures to make market entry more difficult without objective justification. Overall, the case turned on the combination of dominance, the distortion of public procedures, and the exclusionary effect on generics and parallel traders. That is the reason why AstraZeneca became a leading precedent for the proposition that formally lawful regulatory steps can still amount to abuse under Article 102 when they are used strategically to foreclose rivals.

2.3.2 Regulatory and market context

Competition in the pharmaceutical sector is channeled through both regulatory and IP choke points in a highly concentrated and regulated sector. A generic to a drug cannot simply be added to the market: there must be authorization given under a pathway based on Directive 2001/83/EC [58] and clear the remaining exclusivities. Supplementary Protection Certificates (SPCs) can extend effective patent protection, therefore manipulation in SPC files can translate into extra time without generic competition.[59]

Parallel traders likewise depend on the continuing regulatory status of the reference product and

[58] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [2001] OJ L311/67.
[59] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (Codified version) [2009] OJ L152/1.

on the free-movement logic that allows medicines marketed in one Member State to be placed on another, subject to conditions. [60]

Therefore, AstraZeneca is an exemplary "authority-facing" abuse case, since the alleged exclusionary conduct did not take form in terms of pricing or supply strategies, but instead of strategic interactions of the public procedures. These involved misleading recommendations to patent offices in order to obtain or maintain SPCs, as well as deregistration of marketing authorizations for its drug loss, in order to obscure generic entry and parallel imports.[61]

2.3.3 Abuse theory 1 – Misleading information to obtain/maintain exclusivity (SPC/patent-related)

The first theory regarding AstraZeneca is concerning the type A procedural abuse: a pattern of misleading representations made to the national patent offices. This is in the context of Supplementary Protection Certificate (SPC) applications for omeprazole (Losec). The framework for SPCs involves a requirement for applicants to provide the number and date of the first authorization to place the product on the market. If different, then what is required is the number and date of the first authorization in the European Community. [62] This directly affects whatever SPC applications will be granted or not, as well as its duration.

In June of 1993, AstraZeneca circulated centralized instructions for SPC filings across several jurisdictions, relying on a list of pricing-publication that signified 21 March 1988 as the initial

[60] Consolidated Version of the Treaty on the Functioning of the European Union [2012] OJ C326/47, arts 34–36; Case C-457/10 P *AstraZeneca AB and AstraZeneca plc v Commission* EU:C:2012:770, para 145.
[61] Commission Decision of 15 June 2005 relating to a proceeding under Article 82 of the EC Treaty and Article 54 of the EEA Agreement (Case COMP/A.37.507/F3 — AstraZeneca) (notified under document number C(2005) 1757) [2006] OJ L332/24
[62] Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products [1992] OJ L182/1, art 8(1)(a)(iv) ('if this authorization is not the first authorization for placing the product on the market in the Community, the number and date of that authorization').

date. This means they linked their filings according to price publication/"effective marketing". Therefore, this meant that that date was signified as the first authorization date, instead of clearly presenting the earlier authorization history. When patent offices decided to question this matter, the response of AZ was not clear. They continued to defend their "effective marketing" theory and, strategically sometimes amended certain arguments in one jurisdiction, while at the same time preserving arguments in others to keep litigation options open. Contemporary internal documents showed that AZ had awareness of these factual and legal vulnerabilities for their position, yet they continued persisting with the approach.[63]

The key issue is why this falls outside of competition based on merits, since technically, it occurs within a formal legal procedure. Article 102 does not prohibit patent or SPC protection in and of itself. Instead, it targets the distortion of public decision-making via misleading conduct, where the foreseeable effect is to strengthen dominance by excluding rivals. The conduct was treated as a single and continuous abuse by The Commission. This means that the abuse was a strategy designed to face authority in a way to secure SPC protection that was either: unavailable but hidden via misrepresentations, or of longer duration than stated.[64]

The exclusionary mechanism is a straightforward one in the pharmaceutical market. Since SPC protection delays generic entry, it creates legal uncertainty that can lead to a chilling of investment and an acceleration of defensive litigation. The SPCs are explicitly linked to delayed entry and therefore the intended balance between originators and generics is stressed, thus the manipulation of the inputs to SPC duration is competitively significant.

[63] Commission Decision (n 19).

[64] Case C-457/10 P *AstraZeneca* (n 19) para 63 (confirming that misleading submissions to authorities enabling grant of an SPC 'constitutes a practice falling outside the scope of competition on the merits').

AstraZeneca shows what proof looks like in procedural cases: internal documents (knowledge/intent), timing and sequencing across jurisdictions, the foreseeability of exclusivity effects, and a counterfactual showing that (i) SPCs would have been refused or shorter and (ii) generic entry would likely have occurred earlier absent the misleading representations.[65]

2.3.4 Abuse theory 2 – Misuse of marketing authorization procedures (withdrawal/deregistration and parallel trade)

The second AstraZeneca abuse theory concerns Type B procedural abuse: the strategic use of marketing authorization (MA) procedures to obstruct entry.

This was characterized by the commission as a single and continuous abusive conduct by AstraZeneca requests to surrender (deregister) the MAs for Losec (omeprazole) capsules in Denmark, Norway and Sweden. In addition, they also withdrew capsules from the market and replaced them with the Losec tablets, a new product. This was an authority facing procedure, as opposed to competing via pricing or output. This is because AZ sought to change what the legal status of the reference product was right at the moment generic competitors were preparing to enter the market.[66]

This regulatory lever matters since under the EU framework, at the time Directive 65/65, later codified in Directive 2001/83/EC, the generic entry is dependent on abridged procedures that allow the reliance on the originator company's dossier once the exclusivity/data-protection period has expired. The General Court's found that the deregistration of the MA for the original product had the ability to prevent applicants for "essentially similar" products from having to

[65] Sebastian Moore and Rachel Montagnon, 'AstraZeneca's SPC and deregistration practices "abuses of dominant position"' (2010) 5(10) *Journal of Intellectual Property Law & Practice* 687.
[66] Commission Decision (n 19), art 1(2); Case T-321/05 *AstraZeneca* (n 19); Case C-457/10 P *AstraZeneca* (n 19).

conduct the full pharmacological, toxicological and clinical trials. The result of this pushes rivals into a slower and more cumbersome route and therefore delays entry. The CJEU accepted this finding.[67] Also affected were the parallel traders: in Sweden, the grant and maintenance of a parallel-import license was dependent on the continued existence of an MA for the reference product. This signifies there was a clear and direct link between deregistration and obstacles to parallel imports.[68]

Therefore, the pathway to foreclosure is procedural but concrete. Since the status of MA was removed, the dominant firm (AZ) was able to increase the regulatory burdens of their rivals, extend timelines, and create uncertainty around supply and substitution. On objective justification, AZ argued that the withdrawal of MA was a lawful regulatory option motivated by business reasons and compliance considerations. However, The CJEU nevertheless stated that the possibility to withdraw the MA is not a "property right" and that a dominant firm, with its special responsibility, cannot use deregistration in such a way to prevent or make it more difficult for other firms to enter, unless there can be demonstrable legitimate interests or objective justifications. In these specific circumstances, the after expiry of exclusivity protecting AZ's dossier investment- the courts found no sufficient justification. Therefore, they treated this conduct as falling outside "competition on the merits."[69]

2.3.5 AstraZeneca takeaways

The case of AstraZeneca provides a reusable set of doctrinal criteria for identifying procedural abuse under Article 102 TFEU in the highly regulated pharmaceutical markets. These following

[67] Case C-457/10 P *AstraZeneca* (n 19) paras 151–155.
[68] Case C-457/10 P *AstraZeneca* (n 19) para 145; Case C-15/01 *Paranova Läkemedel and Others* [2003] ECR I-4175; Case C-113/01 *Paranova* [2003] ECR I-4243.
[69] Case C-457/10 P *AstraZeneca* (n 19) paras 149–150 ('the possibility … of deregistering a MA is not equivalent to a property right').

points will be used as a checklist in the later case studies and will be used once again for Chapter 4's applied analysis on compounding pharmacies:

1. Authority-facing conduct can be considered "abuse". Article 102 reaches conduct that operates through public procedures (patent/SPC offices, medicines agencies), not only through market instruments such as price or supply.

2. Deception and lack of transparency is a key separator. A dominant firm may use procedures, but misleading information or strategically incomplete disclosure that distorts decision-making can fall outside "competition on the merits".

3. There has to be foreseeability of regulatory consequences. Liability is supported where the exclusionary impact (e.g., extended exclusivity, delayed entry, loss of a regulatory reference) is reasonably foreseeable given the procedure's legal effects.

4. The regulatory causation is very relevant to the outcome. The analysis must explain the mechanism: how the procedural step alters legal status and thereby delays or deters competitors (generics, parallel importers) through concrete regulatory pathways.

5. The capability of foreclosure is important, not necessarily proof of actual effects. In procedure-heavy markets, "capability" can be established by the regulatory structure plus case-specific evidence (timing, internal documents, competitor entry plans), even if quantifying consumer harm is difficult.

6. The objective justification is tightly policed, as the "Lawful option" is not enough: the dominant firm must show a credible, proportionate justification (e.g., genuine safety/compliance reasons) and not merely a strategic exclusion rationale.

7. The choice of remedy follows the mechanism of action. Effective intervention targets the procedural distortion (e.g., stopping misleading filings, preventing regulatory obstruction), because the competitive harm arises from institutional effects rather than conventional price conduct.

2.4 Case study II - Servier (Perindopril): portfolio strategy, market definition, and procedural ecosystem

2.4.1 Background and Case Decision-making Logic

The Servier litigation arose out of efforts to protect perindopril, a major cardiovascular medicine, after the main patent on the active ingredient had largely expired in 2003. Generic manufacturers were preparing to enter, but they still faced a web of secondary patents, especially process patents linked to the production of the active ingredient. According to the Commission, Servier first acquired the most advanced source of non-protected technology in 2004, even though it never used that technology, and then entered into a series of patent settlements with generic companies between 2005 and 2007. In those agreements, the generics accepted delayed entry or agreed to stop challenges in exchange for value from Servier, including cash and other commercial benefits. In 2014 the Commission treated this as both a set of unlawful "pay-for-delay" arrangements under Article 101 and, taken together with the technology acquisition, part of an exclusionary strategy under Article 102, imposing total fines of about €427.7 million.[70]

[70] Commission Decision of 9 July 2014 relating to a proceeding under Articles 101 and 102 of the Treaty on the Functioning of the European Union (Case AT.39612 — *Perindopril (Servier)*) (notified under document C(2014) 4955 final).

The key reason the case led to antitrust liability is that the authorities did not treat the settlements as simply ordinary compromises of uncertain patent disputes. The view instead was that the generic firms were genuine potential competitors because they had taken concrete preparatory steps toward entry and Servier's patents were not seen as insurmountable barriers. On that basis, payments or other transfers from Servier were understood not as compensation for legitimate dispute resolution, but as inducements to stay out of the market and preserve monopoly rents. The Court of Justice's 2024 judgments largely confirmed that logic: it maintained the findings against Niche/Unichem, Matrix/Mylan, Teva, Lupin and Biogaran (the generic manufacturers that had agreements. They also held that General Court had relied on incorrect grounds when they rejected the Commission's relevant market analysis for the abuse claim. They also restored the Commission's case against Krka(another generic) in a substantial part, while still sending one remaining Krka issue back to the General Court. The broader conclusion is that patent settlements cross the Article 101/102 line when their real function is market exclusion rather than genuine dispute settlement.[71]

2.4.2 Procedural posturing and Ongoing Questions

The case of Sevier is an interesting one. It tests Article 102 where the alleged abuse is not a single misleading filing- but instead a multi-pronged portfolio strategy. This strategy involved patent-related settlements and a technology acquisition aimed at delaying generic entry. On 9 July 2014 Commission decided (AT.39612) that several settlement agreements infringed Article 101. In addition, Servier, through technology acquisition and five settlements, had implemented an exclusionary strategy infringing Article 102 on their drug perindopril and related technology

[71] Court of Justice of the European Union, Press Release No 107/24 (27 June 2024).

markets.[72] However, in 2018 the General Court annulled the Article 102 infringement(while largely upholding article 101 infringement), mainly since it due to the rejection of the Commission's market definition/dominance analysis.[73] Then, on 27 June 2024, the Court of Justice set aside the market-definition reasoning and remitted the Article 102 part to the General Court.[74] As of February 2026, the remitted case (T-691/14 RENV) is still pending, so this chapter will treat the Article 102 questions as still unresolved.[75] However, much of the Article 101 "pay-for-delay" analysis now is settled.

2.4.3 Market definition and dominance in pharma: why it matters for procedural abuse

In pharmaceutical "procedural abuse" cases, market definition is very consequential. This is because this determines if the alleged strategist is dominant, as well if Article 102's "special responsibility" logic is triggered. The main problem is deciding between a narrow market, which would be defined at the level of a single active substance, or a broader market defined at the level of a therapeutic class. The substitutability is determined by prescribing realities of doctors and pharmacists. Since doctors have a duty to follow clinical guidelines and patient-specific risk profiles, the substitution powers may be limited for the pharmacist. In addition, reimbursement systems have the ability to weaken price-based switching. However, therapeutic alternatives possibly can still constrain demand via non-price factors such as tolerability, side effects, prescriber preferences.

Servier gives us a clear example on how the legal outcome is able to turn on this economic or

[72] Summary of Commission Decision of 9 July 2014 relating to a proceeding under Articles 101 and 102 of the Treaty on the Functioning of the European Union (Case AT.39612 — Perindopril (Servier)) (notified under document C(2014) 4955) [2016] OJ C393/7.
[73] Case T-691/14 Servier and Others v Commission EU:T:2018:922 (Judgment, 12 December 2018);
[74] Case C-176/19 P *Commission v Servier and Others* EU:C:2024:549 (27 June 2024).
[75] Case T-691/14 RENV *Servier and Others v Commission* (pending, as at February 2026).

medical evidence (switching patterns, medical comparability, and the role of price in prescriber choice). In this case, the Commission defined a finished-products market at the molecule level of their product, perindopril. [76]This was supporting a finding of dominance therefore, it enabled the characterization of Servier's conduct-settlements and a technology acquisition-as an exclusionary strategy. Later, when the General Court annulled the Article 102 finding, their reasoning (inter alia)was that the Commission did not demonstrate a perindopril-only market where other medicines in the same therapeutic class could exert non-price competitive pressure. On appeal, the Court of Justice set aside that specific market-definition reasoning and remitted the Article 102 issues for reconsideration.[77]

The link is clear and direct for procedural abuse claims. One one hand, a narrow market often tends to yield high shares and stronger inferences of market power, therefore making entry-delay tactics more harmful. On the other hand, a broader therapeutic market makes dominance harder to establish, and thus the same conduct can be seen as less capable of foreclosing competition.

2.4.4 "Single strategy" theory under Article 102: when multiple acts become one abuse

When the authority can demonstrate that seemingly separate events are not fact, not isolated incidents but instead components of an overall exclusionary strategy, the Article 102 analysis often becomes much stronger. Legally, the logic signifies that a dominant undertaking may commit a single and continuous infringement/abuse where several acts are linked by 3 factors. (i) a common exclusionary aim, (ii) complementarity (each measure strengthens the others), and (iii) continuity in time and market context (the same competitive threat, same product/market,

[76] Summary of Commission Decision of 9 July 2014 relating to a proceeding under Articles 101 and 102 of the Treaty on the Functioning of the European Union (Case AT.39612 — Perindopril (Servier)) (notified under document C(2014) 4955) [2016] OJ C393/7.

[77] Case C-176/19 P *Commission v Servier and Others* EU:C:2024:549 (27 June 2024).

and a coherent sequence). This avoids an approach where each step appears defensible when assessed alone, but the true pattern predictably delays entry or raises rivals' costs.[78]

Servier is a useful lens for this since the Commission treated their actions as one strategy, instead of separate isolated cases. Both their technology acquisition and the reverse-payment settlement's aims were to remove the nearest sources of competition and therefore was characterized as a single and continuous infringement of Article 102. Looked at individually, they might not be abusive, but when combined their significance increases greatly. In a more recent enforcement, the same strategy is assessed: in Teva (Copaxone), the Commission stated that patent-procedure misuse and a systematic disparagement campaign were "complementary" and together amounted to a single and continuous infringement of Article 102.[79] The case discussed previously, AstraZeneca, also provides an earlier template, where a pattern of misleading representations to patent offices and the steps they took related to that was treated as a single and continuous abuse. The strategy does not mean that individually lawful acts, such as patent filings, settlements, acquisitions, litigation, regulatory complaints, etc, become unlawful automatically. Instead, the chapter will treat them in two different steps: first, to ask whether each act has a plausible "rights-vindication/compliance" rationale; second, to assess whether, taken together, this bundle uses means other than competition on the merits. Some examples include creating persistent legal uncertainty, distorting regulatory pathways, or chilling entry. This "strategy" approach will be reused later for Roxtec, Teva, and for the applied chapter on conduct affecting compounding pharmacies.

[78] Case T-286/09 RENV *Intel Corporation v Commission* EU:T:2022:19 (Judgment, 26 January 2022) (noting the analysis of an 'overall strategy' and 'single and continuous infringement' under Article 102).
[79] Summary of Commission Decision of 31 October 2024 relating to a proceeding under Article 102 of the Treaty on the Functioning of the European Union (Case AT.40588 – Teva Copaxone) (notified under document number C(2024) 7448 final) [2025] OJ C, C/2025/1680.

2.4.5 Servier takeaways for the thesis

With the addition of Servier, there is a materially distinct layer to the thesis included beyond AstraZeneca. While the AstraZeneca case is a comparatively clean authority-facing abuse centered around deception and regulatory causation (misleading SPC filings and MA deregistration), Servier displays how Article 102 becomes fragile to analyze when the alleged abuse is a multifaceted portfolio strategy. Patent disputes, settlement agreements, and a technology acquisition have to be assessed not as isolated events, but instead as an overall plan to delay the entry of generics. Therefore, in this setting, the market definition is not a preliminary technicality but now a dispositive lever. Since in a molecule-level market one can support dominance and make entry-delay tactics appear capable of foreclosure. Meanwhile, in a more broad therapeutic market, one can dissolve dominance and dismantle the Article 102 theory. Additionally, Servier highlights complexity of evidence, such as medical substitutability, prescriber behavior, and the interaction between IP/legal timelines and competitive constraints. Lastly, it showcases the practical interface between Articles 101 and 102: the same background circumstances and context (patent settlements and lifecycle management) can raise dual concerns, but the legal tests, burdens, and remedial narratives are different, requiring a consideration in the separation of analysis for the thesis.[80]

[80] Damien Neven and Georges Siotis, 'The judgment of the Court of Justice in perindopril (Servier), Case AT.39612: a comment on market definition' (2025) 16(1) *Journal of European Competition Law & Practice* 53.

2.5 Case study III - Roxtec (national practice): trademarks, litigation, and communications as foreclosure

2.5.1 Background and Decision-making Logic

The Roxtec case shows how similar exclusionary logic can appear outside pharmaceuticals. Roxtec had developed a modular cable and pipe sealing system protected by European patent EP 0429916B1, which expired in October 2010. During the patent period Roxtec built a leading position worldwide. The Italian Competition Authority (AGCM), following a complaint by Wallmax and a formal investigation opened in 2021, examined Roxtec's conduct in the market for modular cable/pipe sealing systems. In its 2023 decision, the AGCM found that this was a European market and that Roxtec held very high market shares, around the 72% to 85% range over several years, which supported a finding of dominance. The authority therefore approached the case not as a routine IP dispute between equals, but as the conduct of a dominant firm dealing with its closest competitive threat after patent expiry.[81]

The AGCM concluded that Roxtec had implemented a single, complex exclusionary strategy from at least July 2015 onward. That strategy included strategic EU trademark filings for the "bullseye" appearance of its modules, extensive litigation against Wallmax in several jurisdictions, and disparaging or misleading communications to customers about Wallmax and ongoing disputes. The authority attached particular importance to the fact that EUIPO bodies had already treated the essential sign as reflecting the technical function of the product, meaning trademark law could not be used to recreate perpetual protection for a technology that had entered the public domain. It also relied on internal documents showing an intention to reduce

[81] Autorità Garante della Concorrenza e del Mercato (AGCM), Provvedimento n 30737, A538 – *Sistemi di sigillatura multidiametro per cavi e tubi* (18 July 2023) paras 1, 391, 393 and 396–397.

Wallmax's activity to a minimum and to avoid leaving written traces about certain communications. For the AGCM, the problem was consequently not any single lawsuit or filing in isolation, but the cumulative use of trademarks, litigation and denigration as non-merits tools to prolong exclusivity after patent expiry. On that basis, it found a single abuse of dominance under Article 102 and imposed a fine of €15,117,795. [82]

2.5.2 Why Roxtec belongs in a pharma-focused thesis

Initially the question of why the case of Roxtec belongs in a pharma-focused thesis. Through careful evaluation, it demonstrates that in a non-pharma setting, the same analytical structure that often appears in medicines markets: IP rights and procedural tools that can be used as competitive levers, as opposed to only as legal protections. In the pharmaceutical industry, patents/SPCs, regulatory submissions, and safety-framed communications can delay or deter entry. In this case, Roxtec shows how a dominant firm can similarly combine administrative IP actions (trademarks), enforcement threats and litigation, and public communications to raise rivals' costs, create legal uncertainty, and chill market participation.[83] This makes Roxtec a clear example of a Type E "hybrid multi-channel strategy" in the typology: multiple individually lawful channels become problematic when coordinated toward foreclosure. It therefore provides a useful comparator for later analyzing compounder-related disputes in Chapter 4.

[82] AGCM, Provvedimento n 30737, A538 – *Sistemi di sigillatura multidiametro per cavi e tubi* (18 July 2023) para 1 and 'DELIBERA' (a)–(c).
[83] Autorità Garante della Concorrenza e del Mercato (AGCM), Provvedimento n 30737, A538 – *Sistemi di sigillatura multidiametro per cavi e tubi* (18 July 2023);

2.5.3 Conduct and legal characterization

For the Roxtec case (AGCM, Case A538), the authority treated the questioned behavior as coordinated acts of conduct instead of a single act. The three principal categories identified were: (i) strategic use of administrative IP procedures, (ii) enforcement actions and litigation, and (iii) communications with derogatory features. Concretely, Roxtec was engaged in a "deposito strategico di marchi UE" (strategic EU trade mark filings). It then used these filings as a basis for contentious proceedings against Wallmax (and its distributors in some instances), and adopted "modalità denigratorie" in communicating those actions to customers. The AGCM explicitly defined these elements as "un'unica e complessa strategia escludente" (a single, complex exclusionary strategy) , therefore as contrary to Article 102 TFEU.[84]

Due to raising rivals' costs, chilling entry/expansion, and reputational harm, the foreclosure narrative was able to be defined. The decision was able to rely largely on internal documents displaying an exclusionary objective. Roxtec's own legal leadership stated that "continu[ing] fighting Wallmax" and "reducing their activities to minimum" was a main goal, as well as internal emails noting that the "proceedings" were slowing the activities of rivals. The AGCM also was able to link the litigation and IP claims to practical burdens for Wallmax (defense costs, forced commercial/technical adjustments). And in addition, there were significant and obvious customer-facing effects: Roxtec's communications strategy included controlled, often oral-only messaging to customers, "packages" of information, and instructions not to leave written traces. This is the exact type of conduct the AGCM viewed as consistent with a discrediting plan and to deter switching.

Roxtec also argued that the "sham litigation" threshold was not met for the ITT Promedia point

[84] AGCM, Provvedimento n 30737 (n 37).

of the case.[85] This is since they stated it was manifestly unfounded and part of a plan. The AGCM responded since the case was viewed and assessed as part of a broader exclusionary strategy in which the litigation formed one component, as opposed to something abstract.[86] This was supported by the inspection record and evidence of exclusionary intent.

2.5.4 Roxtec takeaways for compounding-pharmacy disputes

Multi-channel foreclosure is the key lesson displaced here. Roxtec shows how a dominant firm can combine IP procedures, enforcement/litigation, and customer communications into one exclusionary scheme. In pharma, the same package can appear as patent/enforcement threats with regulatory complaints and targeted messaging to prescribers, pharmacies, or payors.

Another takeaway is that "Safety" narratives have the potential to function like denigration. Where communications imply that a rival's product is unsafe or non-compliant, the effect can be to chill converting and deter supply, even before any regulator or court reaches a conclusion. This maps closely onto disputes involving compounded medicines, where allegations are often framed in patient-safety terms.[87]

The third takeaway is that procedural pressure raises rivals' costs. Even weak or repetitive claims can impose legal costs, uncertainty, and compliance burdens, which is especially acute for smaller compounding pharmacies.

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[85] Case T-111/96 *ITT Promedia NV v Commission* [1998] ECR II-2937

[86] AGCM, Provvedimento n 30737 (n 37).

[87] David Tayar, 'Spreading Misleading Information on a Competitor's Product as an Abuse of a Dominant Position: a French Pharmaceutical Story?' (2014) 5(9) *Journal of European Competition Law & Practice* 631.

The last takeaway is that evidence is often about intent and sequencing. Roxtec underscores the importance of internal documents, coordinated timing across forums, and a pattern of "pressure points" used against commercial partners.

2.6 Related practice under Article 102: completing the map beyond the three anchors

2.6.1 Disparagement/misinformation as exclusionary abuse in pharma

For the regulated health market, communications can be an exclusionary act. Demand is normally mediated by trust, clinical risk-aversion, and institutional decision-making instead of ordinary consumer switching. Prescribers and pharmacists are especially sensitive to safety and efficacy signals; thus substitution regimes will often rely on professional confidence that switching is clinically equivalent. Even subtle messages to cast doubt on rival medicines will have the effect of chilling prescribing, slow substitution, and deter entry. This is especially relevant in the case where the rival is a generic or a close therapeutic substitute and the market is already defined by a number of regulatory pathways and reimbursement incentives.[88]

A good example of NCA is the French Competition Authority's 2013 Sanofi-Aventis decision. This decision resulted in a fine for Sanofi for a denigration strategy targeted to healthcare professionals that disparaged generic versions of Plavix. This sought to influence doctors and pharmacists against substitution of their own product. The communications campaign was considered as an abuse of dominance since it leveraged asymmetrical information and professional caution in order to protect the incumbent product's market position. [89]

[88] David Tayar, 'Spreading Misleading Information on a Competitor's Product as an Abuse of a Dominant Position: a French Pharmaceutical Story?' (2014) 5(9) *Journal of European Competition Law & Practice* 631.

[89] Autorité de la concurrence (France), Décision 13-D-11 du 14 mai 2013 relative à des pratiques mises en œuvre dans le secteur pharmaceutique (Sanofi-Aventis); Autorité de la concurrence, 'The Autorité de la concurrence fines Sanofi-Aventis a total of €40.6 million for disparaging the generic versions of Plavix®, one of the world's best-selling medicines' (Press release, 14 May 2013).

A good example for the EU level is the Commission's Vifor/Monofer commitments decision (22 July 2024). This decision displays identical logic in Commission practice: they accepted the legally binding commitments to address concerns about potential disparagement and misleading messaging regarding a rival iron medicine. They recognized that these communications have the ability to distort prescribing choices which will hinder competition, even without price or supply restrictions.[90]

2.6.2 Patent-procedure misuse plus disparagement as one strategy (Commission practice)

Another decision, the Teva Copaxone case, is a useful connection between AstraZeneca and Roxtec. Comparable to AstraZeneca, it treats procedural conduct directed at public and legal institutions as potentially abusive. Teva was found to have misused European Patent Office (EPO) divisional-patent procedures with the purpose of prolonging uncertainty which would lead to a delaying of generic entry. Secondly, there are also similarities to Roxtec. The decision frames the infringement as a hybrid, multi-channel strategy because the IP-procedure conduct included a systematic disparagement campaign directed at key market gatekeepers.

The Commission describes a "staggered" filing of multiple divisionals creating a web of secondary patents around Copaxone (process and dosing), enforcement actions to obtain interim injunctions, and then strategic withdrawals when revocation seemed likely—avoiding a formal invalidity precedent and forcing competitors to restart lengthy challenges. The competitive mechanism is procedural but concrete: it artificially prolonged legal uncertainty and could hinder entry and uptake of rival medicines.

On the communications side, Teva spread misleading information about a competing product's

[90] Summary of Commission Decision of 22 July 2024 relating to a proceeding under Article 102 of the Treaty on the Functioning of the European Union (Case AT.40577 – VIFOR IV iron products) (notified under document number C(2024) 5027) [2024] OJ C, C/2024/6858;

safety, efficacy, and therapeutic equivalence, despite health-authority approval, targeting doctors and national pricing/reimbursement decision-makers to slow or block market penetration. The Commission concluded the two abuses were complementary and amounted to a single and continuous infringement of Article 102.[91]

2.6.3 Leadiant (CDCA) as a boundary example of "regulatory leverage" under Article 102

Leadiant is not a classic AstraZeneca-style "procedural abuse" case since the core theory is characteristically marked as exploitative abuse (excessive pricing) rather than foreclosure. However, it still fits this chapter's map due to the fact that it shows how pharmaceutical competition can be mediated by regulatory status: once a firm secures EU-level orphan designation and a centralized marketing authorization for an ultra-rare indication, the resulting lack of close alternatives can make market power highly durable, and Article 102 scrutiny becomes acute.[92] This interaction between regulatory positioning and competition enforcement is visible in national practice. In the Netherlands, the ACM fined Leadiant for abusing dominance by charging an excessive price for CDCA-Leadiant (June 2017–December 2019), and the District Court of Rotterdam upheld the finding that the ACM correctly established an abuse of dominance.[93] In Italy, the AGCM also found an Article 102 abuse for unfairly excessive pricing of the orphan drug containing CDCA and imposed a fine, with explicit treating of the conduct as

[91] Summary of Commission Decision of 31 October 2024 relating to a proceeding under Article 102 of the Treaty on the Functioning of the European Union (Case AT.40588 – Teva Copaxone) (notified under document number C(2024) 7448 final) [2025] OJ C, C/2025/1680; European Commission, 'Commission fines Teva €462.6 million over misuse of the patent system and disparagement to delay rival multiple sclerosis medicine' (Press release, 31 October 2024) IP/24/5581.

[92] Commission Implementing Decision C(2017)2488 final (10 April 2017) granting, in exceptional circumstances, marketing authorization for 'Chenodeoxycholic acid sigma-tau – chenodeoxycholic acid' (orphan medicinal product).

[93] Rechtbank Rotterdam, ECLI:NL:RBROT:2025:1811 (13 February 2025).

with harm to the National Health Service as purchaser in a market that lacked effective competitive discipline.[94]

For the purposes of the thesis, Leadiant serves its function as a bridge case: to shows how the procedural ecosystem can create the conditions in which dominance is protected, and the reason why access-linked alternatives (including compounding pathways) become practically important when the authorized-product channel is distorted. This helps to set up the compounding analysis in Chapter 4.

2.6.4 Short consolidation: what counts as "procedural abuse" after these cases?

Taken together, the post-AstraZeneca trajectory suggests a recognizable pattern of "procedural abuse" under Article 102. It includes: deception or strategic non-transparency in submissions to public authorities (patent/SPC offices, medicines agencies); procedural sequencing that generates uncertainty or resets rivals' timelines (e.g., serial filings, withdrawals, forum-shopping); enforcement threats or litigation used primarily to delay or chill rather than to vindicate rights; and denigration/misinformation aimed at prescribers, pharmacists, payors, or regulators to deter substitution and uptake. Crucially, EU enforcement increasingly treats these elements as bundled strategies—a coordinated mix of administrative procedures, private enforcement, and communications.

Operationally, this thesis applies the following rule: EU law is most comfortable intervening where the challenged procedural acts are not assessed in isolation, but appear as part of a broader exclusionary scheme supported by evidence of a common aim and capability of foreclosure

[94] Autorità Garante della Concorrenza e del Mercato (AGCM), Provvedimento n 30156, A524 – *Leadiant Biosciences/Farmaco per la cura della xantomatosi cerebrotendinea* (17 May 2022).

(timing, internal documents, foreseeability of regulatory effects). [95] By contrast, where the alleged abuse is litigation "as such," the ITT Promedia caution remains a significant threshold.[96]

2.7 Synthesis: a practical assessment framework for "procedural abuse" under Article 102

Drawing together AstraZeneca, Servier, Roxtec and the related Commission/NCA practice, this chapter propositions a practical framework for assessing alleged abuse of legal and regulatory procedures under Article 102 TFEU. The aim is not to create a new legal test, but to operationalize the recurrent doctrinal questions into a organized checklist that can be applied consistently. This is predominantly valuable in Chapter 4 when evaluating disputes involving compounding pharmacies, safety-framed communications, and parallel legal/regulatory complaints.

Step 1 — Identify the procedure and decision-maker.

First is to specify the forum and its legal effects: court litigation (injunctions, interim measures), medicines regulator (MA status, pharmacovigilance triggers), patent/SPC authority (grant/term), or reimbursement/substitution body. The more "automatic" the consequences (e.g., exclusivity or procedural stays), the more competitively significant the step.

Step 2 — Characterize the conduct quality.

Then, the next step is to categorize what was done: misleading statement, omission/selective disclosure, procedural sequencing (serial filings/withdrawals), or litigation/threats. For litigation, flag instantly whether ITT Promedia is engaged (if it is manifestly unfounded and a plan to

[95] Christian Ahlborn, Will Leslie and Marvin Berkel, 'Legal Scalpel or Regulatory Swiss Army Knife? The New Article 102, What Market Investigations Can Tell Us about the Difference between Law and Regulation, and What That Means for Article 102's Ultimate Purpose' (2023) 14(8) *Journal of European Competition Law & Practice* 595;

[96] Case T-111/96 *ITT Promedia NV v Commission* [1998] ECR II-2937.

eliminate competition). The conduct quality often separates merits-based enforcement from manipulation.

Step 3 — Assess dominance and leverage over the procedure.

Third, there has to be an assessment if dominance is established and explain why the procedure is leverageable: high shares on a narrow pharma market, strong entry barriers, dependency of rivals on a "reference" product or dossier, switching constraints, and gatekeeper reliance (prescribers/pharmacists/payors). This step ties legal form to market power.

Step 4 — Map the foreclosure mechanism.

Fourth, the goal is to explain how competition is restricted: entry delay, prolonged uncertainty, chilling effects on supply/substitution, reputational harm, and raising rivals' costs. In regulated markets, foreclosure often occurs through altered timelines and risk, not immediate price effects.

Step 5 — Evidence and causation.

Fifth is to utilize a procedure-sensitive evidentiary set: timing around entry, internal strategy documents, inconsistencies across filings, predicted regulatory consequences, third-party reactions (doctors, payors, wholesalers), and a counterfactual entry timeline. This step will set in stone the "capability" part.

Step 6 — Objective justification and proportionality.

Sixth is to create a test of whether the conduct reasonably reflects good-faith rights vindication or compliance (safety/pharmacovigilance, accurate information, legitimate enforcement), and whether less restrictive options existed. "Lawful option" alone is not sufficient if it functions as strategic foreclosure.

Step 7 — Remedies and enforcement choice.

Seventh, and lastly, is to match remedy to the mechanism: decisions and fines where conduct is clear and deterrence is required; commitments where forward-looking transparency, non-misleading communications, or process safeguards can restore competition.

2.8 Conclusion and transition to Chapter 3 (US framework)

This chapter has shown that EU competition law can treat certain legal and regulatory tactics as an abuse of dominance under Article 102 TFEU when they function as exclusionary tools rather than as bona fide rights-vindication. Authority-facing conduct—misleading submissions to public bodies, regulatory "switching" that disrupts entry pathways, and procedural sequencing that manufactures uncertainty—can fall outside competition on the merits where foreclosure is foreseeable and supported by evidence. [97] At the same time, EU law remains cautious about condemning litigation as such: the ITT Promedia "wholly exceptional circumstances" threshold reflects the weight given to access to courts and the risk of chilling legitimate enforcement. EU enforcement is also increasingly willing to analyze bundled, multi-channel strategies—procedures plus communications/denigration—where the overall pattern is capable of postponing entry or chilling substitution.

These findings create four comparison features for Chapter 3:

1. How each system protects access to courts/petitioning while policing exclusion

[97] Richard Whish and David Bailey, *Competition Law* (11th edn, OUP 2024) ch on abuse of dominance; Case C-457/10 P *AstraZeneca AB v Commission* EU:C:2012:770.

2. The threshold for “sham litigation” (ITT Promedia vs the US standard)

3. The treatment of deception to public authorities (EU authority-facing abuse versus US doctrines such as Walker Process-type theories)

4. Remedies, including the EU’s use of commitments and behavioral constraints.

Chapter 3 turns to the US structural counterpart: the Noerr–Pennington doctrine, which more generally immunizes petitioning of courts and government from antitrust liability, subject to narrow exceptions (most importantly sham litigation and fraud-based pathways) evaluated through pharmaceutical case studies and disputes involving compounding pharmacies.

Chapter 3 – Sham litigation, petitioning immunity and pharmaceuticals in US antitrust law: Noerr–Pennington, Walker Process, FTC v Shire ViroPharma, and litigation against compounders (Eli Lilly v Empower/Strive).

3.0 Chapter Introduction

3.0.1 Chapter aim, contribution, and roadmap

Chapter 3 will provide the US doctrinal counterpart to Chapter 2's analysis of EU "procedural abuse" under Article 102 TFEU It will inspect how strategic petitioning, such as court litigation, administrative filings, and regulatory complaints, has the ability to operate as an exclusionary tool in the highly regulated and concentrated pharmaceutical market, notably including disputes that affect compounding pharmacies and patient access. US antitrust must first adhere to the Noerr–Pennington doctrine, a significant difference to the abuse-of-dominance lens that the EU uses. This difference usually has the ability to immunize genuine petitioning of government from antitrust liability. This is due to the constitutional commitment to the right "to petition the Government." [98]

The chapter will contain six major steps. First, it will set out the US antitrust baseline (Section 2 of the Sherman Act and, where applicable, Section 5 of the FTC Act) in order to gauge the exclusionary conduct in pharmaceutical markets. Second, it will explain the reasoning and the scope of the Noerr–Pennington immunity across legislatures, agencies, and courts. Third, it will develop the primary gateway to liability: the "sham" exception. This will involve the *Professional Real Estate Investors* test, seeing how repeated filings can be assessed as a

[98] U.S. Const. amend. I (Petition Clause); ***Eastern R.R. Presidents Conf. v. Noerr Motor Freight, Inc.***, 365 U.S. 127 (1961); ***United Mine Workers v. Pennington***, 381 U.S. 657 (1965)

campaign.[99] Fourth, it will introduce the *Walker Process* liability. This is where a patent is procured by fraud and then enforced, which can increase the element of anticompetitive conduct of a monopolization claim.[100] Fifth, it will apply these doctrines via two main case studies: *FTC v Shire ViroPharma* (FDA citizen petitions) and Eli Lilly's litigation against compounders (Empower/Strive). Finally, it will create a practical evaluation framework and use it to bridge to Chapter 4, which will consist of a comparative evaluation of whether EU and US rules adequately deter strategic foreclosure while preserving legitimate petitioning and public-health regulation.[101]

3.0.2 Case summaries, backgrounds, and logic behind decision-making

Noerr (Eastern Railroad Presidents Conference v. Noerr Motor Freight)

Noerr arose from a campaign by railroads against trucking companies. The truckers had argued that the railroads used a deceptive public-relations campaign in order to influence legislation and law-enforcement policy in specific ways harmful to the trucking industry. The Supreme Court, nonetheless, held that the Sherman Act did not reach a genuine effort to influence the government, even if the campaign had intentions to damage rivals and use dubious tactics. This is because they used the justification that antitrust law is not meant to police ordinary political

[99] *Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc.*, 508 U.S. 49 (1993) (defining the "sham" exception framework in the litigation context).
[100] *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965) (antitrust liability premised on enforcement of a fraudulently procured patent, subject to proof of the antitrust elements).
[101] Herbert Hovenkamp, *Federal Antitrust Policy: The Law of Competition and Its Practice* (7th ed., West Academic 2024) (treatise overview of core US antitrust doctrines, including petitioning immunity and related limits)

petitioning; instead, the Court only left open a narrow "sham" category for conduct not genuinely aimed at governmental action. [102]

Pennington (United Mine Workers v. Pennington)

Pennington involved allegations that the United Mine Workers and large coal operators had worked together to push higher labor-cost policies, including efforts directed at the Secretary of Labor and the Tennessee Valley Authority, with the intentions to disadvantage smaller coal producers. For the petitioning issue, the Supreme Court held that joint efforts to influence public officials remain immune even when they are allegedly motivated by a wish to eliminate competitors. Thus, the Court rejected jury instructions allowing lobbying to be treated as unlawful simply due to the fact that it formed a part of a broader exclusionary plan.[103]

California Motor (California Motor Transport v. Trucking Unlimited)

California Motor involved established highway carriers that were accused of systematically opposing the applications of rivals to operating rights before agencies and courts. The Supreme Court accepted that ordinary resort to agencies and courts is protected, but held that the complaint stated an antitrust claim because the alleged conduct was not genuine petitioning in the normal sense. Instead, it was \ a campaign of repetitive, meritless objections with the goal to deny competitors meaningful access to adjudicatory bodies. That is the reason why the Court treated abuse of process in adjudicatory settings as different from regular political lobbying.[104]

Omni (City of Columbia v. Omni Outdoor Advertising)

Omni arose after a dominant billboard company lobbied the city of Columbia, South Carolina,

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[102] *Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961).
[103] *United Mine Workers of America v. Pennington*, 381 U.S. 657 (1965).
[104] *California Motor Transport Co. v. Trucking Unlimited*, 404 U.S. 508 (1972).

for zoning limitations in order to make entry more difficult for a new rival. The Supreme Court held that the city was protected by Parker state-action immunity and that the private lobbying campaign was protected by Noerr. Thus the Court refused to apply the sham exception since the lobbying had genuine aim to obtain the zoning ordinances themselves, not purely at imposing process costs. In addition, it also rejected a separate "conspiracy" exception based on alleged collusion between the firm and city officials.[105]

Professional Real Estate Investors v. Columbia Pictures

PRE grew out of a copyright suit brought by Columbia against a hotel that rented videodiscs to guests to view in their rooms. Even though Columbia eventually lost the copyright case, the Supreme Court still held that the litigation was not sham petitioning since the copyright theory was not objectively baseless. This was because the law was unsettled, therefore a reasonable litigant could have expected some chance of success. PRE is important since it sets in stone the two-step sham test: first objective baselessness, and only then inquiry into subjective intent.[106]

BE&K Construction

In BE&K, an employer sued unions over their lobbying and related activity, lost or abandoned those claims, and was then found by the NLRB to have committed an unfair labor practice by filing the suit with a motive to retaliate. The Supreme Court overturned the decision, with the reasoning that a rule penalizing reasonably based but unsuccessful lawsuits burdened genuine petitioning and raised serious First Amendment concerns, which means the Board could not impose liability on that broad standard alone.[107]

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[105] *City of Columbia v. Omni Outdoor Advertising, Inc.*, 499 U.S. 365 (1991).
[106] *Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc.*, 508 U.S. 49 (1993).
[107] *BE&K Construction Co. v. National Labor Relations Board*, 536 U.S. 516 (2002).

USS-POSCO

USS-POSCO involved a large industrial project in California where unions were accused of launching multiple suits, grievances, and regulatory objections in order to pressure the project away from a merit-shop contractor. The Ninth Circuit explained that when the claim is based on a whole series of proceedings, the question is whether they were filed in accordance with a policy of proceeding without regard to the merits and for purposes of harassment. The court, nevertheless, rejected the sham theory on the facts of the case because many of the challenged proceedings had succeeded. Since about fifteen of twenty-nine were proved successful, the record did not support a claim that the unions were litigating for no reason and without regard to merit.[108]

Kottle v. Northwest Kidney Centers

Kottle involved a monopolist dialysis provider that allegedly made false statements to block a rival doctor's certificate-of-need applications for new dialysis centers. The Ninth Circuit treated the certificate-of-need process as sufficiently adjudicatory to apply the more developed sham standards used for litigation. Even so, it affirmed dismissal because the defendant had actually prevailed before the agency, only two applications were involved so there was no pattern, and the allegations of fraud and misrepresentation were too vague to overcome Noerr-Pennington immunity.[109]

Walker Process

[108] *USS-POSCO Industries v. Contra Costa County Building & Construction Trades Council, AFL-CIO*, 31 F.3d 800 (9th Cir. 1994)
[109] *Kottle v. Northwest Kidney Centers*, 146 F.3d 1056 (9th Cir. 1998).

Walker Process began as a patent infringement suit over sewage-treatment equipment, after which the accused infringer counterclaimed that the patent had been procured by fraud on the Patent Office and then used to monopolize the market. The Supreme Court held that enforcing a patent procured by intentional fraud can support a Section 2 Sherman Act claim if the typical monopolization elements are also existing. The key reason was that fraud in procurement strips the patentee of the usual antitrust shelter associated with patent enforcement, while good faith remains a complete defense.[110]

Nobelpharma

Nobelpharma involved a dental-implant patent that the alleged infringer stated had been procured through fraud and then implemented with knowledge of that fraud. The Federal Circuit affirmed the antitrust verdict for the defendant and used the case to clarify Walker Process doctrine. It also stressed that Walker Process fraud is more demanding than ordinary unequal conduct: the plaintiff must show knowing and willful fraud, but-for materiality, knowledge of the fraud when the patent is enforced, and the other elements of antitrust liability; PRE sham analysis is an alternative route to liability, not an added requirement on top of Walker Process fraud.[111]

FTC v. Shire ViroPharma

Shire concerned the FTC's claim that ViroPharma had delayed generic entry for Vancocin by filing a long series of allegedly baseless FDA submissions and related lawsuits. The Third Circuit did not dismiss because it blessed the conduct on the merits; rather, it held that the FTC had used the wrong procedural vehicle. Because Section 13(b) authorizes suit only when a

[110] *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965).
[111] *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059 (Fed. Cir. 1998).

defendant "is violating" or "is about to violate" the law, and the challenged conduct had ended years earlier, the complaint failed.[112]

Eli Lilly v. Empower / Strive

These are recent suits by Lilly against compounders marketing tirzepatide products. In the Strive case, the District of Delaware dismissed Lilly's complaint without prejudice since Lilly challenged nationally available online statements but was not able to connect those statements to Delaware closely enough to establish specific personal jurisdiction. The Empower litigation is procedurally different: Lilly's New Jersey case was voluntarily dismissed, and the dispute was refiled in Texas, where public docket materials found show threshold motion practice and discovery disputes continuing into 2026, meaning that there is not yet a comparable merit ruling to summarize from the public materials reviewed here. [113]

Allied Tube & Conduit Corp. v. Indian Head, Inc.

Allied Tube arose from a fight over whether polyvinyl chloride conduit should be encompassed in the National Electrical Code. Indian Head's product threatened steel conduit makers, and Allied Tube assisted to recruit hundreds of new members to the National Fire Protection Association solely to vote against the proposal, with the steel interests recruiting about 230 people and synchronizing the vote. The Supreme Court held that Noerr-Pennington immunity could not apply since the restraint came from the standard-setting process of a private association

[112] *Federal Trade Commission v. Shire ViroPharma, Inc.*, 917 F.3d 147 (3d Cir. 2019).
[113] *Eli Lilly and Company v. Strive Pharmacy LLC*, No. 1:25-cv-00401-SB, Memorandum Opinion (D. Del. Oct. 8, 2025); *Eli Lilly and Company v. Empower Clinic Services, LLC*, No. 2:25-cv-02183 (D.N.J. filed Apr. 1, 2025); refiled as *Eli Lilly and Company v. Empower Clinic Services, LLC*, No. 4:25-cv-03464 (S.D. Tex. filed July 25, 2025).

without official governmental authority, so this was treated as private market conduct rather than protected petitioning of government.[114]

United States v. Grinnell Corp.

Grinnell concerned the market for accredited central-station fire and burglar alarm services, where Grinnell and its affiliates held about 87% of the national market after acquisitions, market-allocation arrangements, and discriminatory pricing practices aimed at forestalling competition. The Supreme Court found monopolization under Article 2 due to the fact that monopoly power readily could be inferred from that of dominant market share, and because the power had been willfully acquired or maintained, rather than resulting just from "a superior product, business acumen, or historic accident." That case became a acknowledged statement of the two elements of monopolization.[115]

Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, LLP (Trinko).

Trinko came out of the Telecommunications Act of 1996, which required incumbent telephone networks to share access with rivals. The plaintiff alleged Verizon filled competitors' orders poorly and with discriminatory intent in order to impede entry by competing local exchange carriers. The Supreme Court rejected the claim, emphasizing that just having possession of monopoly power is not unlawful, that the Aspen Skiing doctrine sits at the outer edge of refusal-to-deal liability, and that Verizon had not voluntarily engaged in the kind of prior course of dealing that might justify imposing such a duty. The Court also noted that the existing regulatory regime had reduced the case for expanding antitrust intervention.[116]

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[114] *Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492 (1988).
[115] *United States v. Grinnell Corp.*, 384 U.S. 563 (1966).
[116] *Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398 (2004).

Atlantic Richfield Co. v. USA Petroleum Co.

Atlantic Richfield involved ARCO's effort to increase retail gasoline sales by encouraging its dealers to match the low prices of discount independents such as USA Petroleum. When USA lost sales, it sued, arguing that ARCO's vertical maximum-price-fixing scheme violated antitrust law. The Supreme Court held that USA had, in fact, not suffered antitrust injury because losses caused by a rival's nonpredatory low prices are losses from competition itself, not from the competition-reducing feature that makes a restraint unlawful. Instead, for a competitor in that position, actionable injury would require predatory pricing, and a violation does not automatically satisfy the antitrust-injury requirement. [117]

3.1 US antitrust baseline for "procedural abuse" claims in pharma

3.1.1 Section 2 Sherman Act: monopoly power, exclusionary conduct, and causation

The starting point for any US claim that a pharmaceutical company has used litigation, regulatory filings, or other anticompetitive procedures is via Section 2 of the Sherman Act. The doctrine is narrower than the EU abuse-of-dominance model. This is due to the fact that procedural tactics are not realized as a separate category in the abstract. Instead, the plaintiff has to still fit the case for the traditional monopolization framework: that there exists monopoly power in a properly defined relevant market, as well as a deliberate acquisition or maintenance of that power through exclusionary conduct rather than "a superior product, business acumen, or historic accident." [118]

[117] *Atlantic Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328 (1990).
[118] *United States v Grinnell Corp*, 384 US 563, 570–71 (1966).

This structure has two main consequences. The first is that the market definition and proof of power remain absolutely necessary, even if the narrative is one of "legal process abuse." For example, a weak lawsuit or an aggressive regulatory complaint is not enough by itself, since it is not conduct tied to the maintenance or acquisition of monopoly power in a relevant market. Secondly, the challenged conduct must be exclusionary in an antitrust sense. As is the case in EU competition law, the relevant concern is harm to the competitive process, not simply harm to an individual rival. The distinctively US feature lies in the legal structure of the claim: the Supreme Court has insisted that monopoly power is not unlawful unless accompanied by anticompetitive conduct.[119] In addition, private plaintiffs have to show that antitrust injury resulted from the competition-reducing aspect of the conduct, instead of simply harder competition or the presence of a powerful opponent.[120]

In pharmaceuticals, these requirements matter in a particularly significant way since entry to the market is often structured around regulatory chokepoints. Multiple factors, such as the FDA's ANDA framework, Paragraph IV patent certifications, 180-day generic exclusivity, and the possibility of a 30-month stay mean that litigation and regulatory filings can have immediate entry-delaying consequences. Essentially, this means that the legal process is able to be economically central to competition in drug markets. Even with all these factors, a Section 2 plaintiff still has the necessity to prove that the defendant possessed monopoly power in the relevant product market. In addition, they must also prove that the challenged resort to procedure helped preserve that power by impairing the rivals' ability to enter or compete.[121]

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[119] *Verizon Communications Inc v Law Offices of Curtis V Trinko, LLP*, 540 US 398, 407 (2004). ↩
[120] *Atlantic Richfield Co v USA Petroleum Co*, 495 US 328, 339–40 (1990)
[121] Herbert Hovenkamp, *Federal Antitrust Policy: The Law of Competition and Its Practice* (7th edn, West Academic 2024)

3.1.2 Section 5 FTC Act: "unfair methods of competition" and enforcement posture

The FTC has tried to use section 5 of the FTC act as a mechanism to challenge strategic petitioning and other types of conduct that distort the pharmaceutical market's competitive process. The statute declares that "unfair methods of competition" are unlawful and authorizes the Commission to issue an administrative complaint if it has reason enough to believe such conduct occurred. The FTC's 2022 policy statement argues that Section 5 reaches beyond the Sherman and Clayton Acts, which is why it remains attractive for claims that do not fit neatly within traditional monopolization categories.[122]

Concurrently, even the possibility of a broader substantive reach does not free the FTC from statutory limits on how it proceeds. *FTC v Shire ViroPharma* is important for this case because it shows that petitioning-based cases can fail on remedial and pleading grounds before a court fully reaches the merits. In its complaint, the FTC alleged that Shire's serial, repetitive, and meritless FDA and court filings were an unfair method of competition used to maintain monopoly power over Vancocin. But the Third Circuit held that when the Commission sues under Section 13(b), it must plausibly allege that the defendant "is violating" or "is about to violate" the law; past misconduct, standing alone, is not enough. That limitation became even sharper after *AMG Capital Management*, where the Supreme Court held that Section 13(b) authorizes prospective injunctive relief, not direct monetary relief. *Shire* is therefore a useful stress test for this chapter: it sits at the intersection of alleged sham petitioning, FTC pharmaceutical enforcement, and the statutory constraints that make such cases hard to plead and win.[123]

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[122] 15 USC § 45.
[123] *FTC v Shire ViroPharma Inc*, 917 F3d 147, 156–60 (3d Cir 2019).

3.1.3 Why petitioning is different: baseline tension with constitutional and structural protections

US antitrust law treats petitioning differently because the legal system has a strong presumption that legitimate efforts to influence the government are protected as opposed to being suspect. For example, in *Noerr*, the Supreme Court held that attempts to influence public officials ordinarily fall outside Sherman Act liability via conclusion to the constitutional value of the right to petition.[124] *California Motor* also extended this same logic to administrative agencies and courts, while still recognizing that access to those institutions can-in exceptional cases- be abused.[125]

This factor highlights the central tension that the rest of the chapter will capture. On the one hand, pharmaceutical firms can use lawsuits, citizen petitions, and regulatory complaints to delay entry and raise rivals' costs. However, on the other hand, courts are cautious of turning antitrust law into a penalty on recourse to judges and regulators. The consequence means that now before US antitrust asks whether a course of conduct is exclusionary, oftentimes it must first instead ask whether the conduct is protected petitioning. This threshold immunity helps to explain why the petitioning-based theories are narrower, more defensive, and generally harder to win in the United States versus comparable procedural-abuse theories under EU Article 102.

[124] *Eastern Railroad Presidents Conference v Noerr Motor Freight, Inc*, 365 U.S. 127, 137–38 (1961)
[125] *California Motor Transport Co v Trucking Unlimited*, 404 U.S. 508, 510–11 (1972).

3.2 Noerr–Pennington doctrine in pharma: scope of petitioning immunity

3.2.1 Core holdings and reach: lobbying, litigation, administrative petitioning

The Noerr–Pennington doctrine will establish the immunity baseline for the US part of the thesis. The core idea is that generally, antitrust liability cannot be imposed upon a firm simply if they are seeking to persuade the government to act to disadvantage rivals. A good example of this case is in *Noerr*, when the Supreme Court upheld that a campaign that was aiming to influence legislation and law enforcement did not violate the Sherman Act simply since the goal was an anticompetitive governmental outcome. Even though the conduct was not benign, it is established that antitrust laws are not ordinarily used to punish efforts to obtain public action through petitioning.[126]

With Pennington, that principle was confirmed and even broadened. The Court made it clear that the same protection is not confined to the legislative sphere. Efforts towards executive officials and agencies fall within the same immunity logic, even in cases where the purpose of the petitioner is to secure a market that creates competitive pressure on rivals. This feature is especially relevant for pharmaceutical disputes, since there are many interactions between firms and administrative decision-makers whose actions can shape entry, reimbursement, distribution, and product status.[127]

The doctrine's reach was even further extended in *California Motor Transport*. In this case, the court recognized that access to courts and adjudicative agencies is a part of the protected

[126] *Eastern Railroad Presidents Conference v Noerr Motor Freight, Inc*, 365 US 127, 136–41 (1961).
[127] *United Mine Workers of America v Pennington*, 381 US 657, 669–71 (1965).

petitioning framework. That is crucial since now litigation and administrative adjudication are inside the Noerr–Pennington doctrine, while at the same time warning that the doctrine is not absolute when the process is weaponized. As a result, the modern baseline for protected petitioning is broad, including: legislatures, executive agencies, courts, and adjudicative administrative bodies.[128]

In the pharmaceutical market, this wide baseline is important since the competition will often run via public processes instead of price or output alone. Various mechanisms, such as citizen petitions, FDA-related submissions, patent-linked entry disputes, and court challenges have the ability to affect whether rivals can enter promptly or at all. The FTC has consistently treated the alleged abuse of FDA processes as a recurring antitrust concern. This helps to explain why pharmaceutical disputes often sit at the margins of Noerr–Pennington rather than completely outside it.[129]

3.2.2 Boundary questions that matter in pharmaceuticals

Noerr–Pennington does not mean that everything surrounding a petition is automatically immunized. This doctrine protects petitioning of government, but not private market conduct. That distinction is very relevant since firms often will try to characterize mixed strategies as "petitioning" even when the relevant restraint is produced by private action. The case with *Allied Tube* involves an effort to manipulate a private standard-setting body. This did not receive Noerr protection just because governments later adopted the body's code. Immunity depended on

[128] *California Motor Transport Co v Trucking Unlimited*, 404 US 508, 510–13 (1972).
[129] Federal Trade Commission, *Staff Report: Enforcement Perspectives on the Noerr-Pennington Doctrine* (2006) 3–6.

genuine petitioning of public authority, as opposed to the strategic use of a private institution that happened to influence regulation.[130]

That distinction is very relevant in the pharmaceutical market. Since cases often have a parallel framework structure. A manufacturer may file an FDA petition or bring litigation, but at the same time also engage in private conduct that can include: market-facing communications, disparagement, distribution choices, contractual pressure. The anti antitrust perspective signifies that those elements should not be reduced into one protected entity. Even if the filing itself may be immune, the surrounding denigration or commercial coercion is considered separate for analytical purposes. This is a major reason pharma disputes are difficult: since exclusion frequently arises from a bundle of legal, regulatory, and market conduct, instead of from one isolated petition.

Furthermore, another boundary question involves the institutional setting. Case law is more protective if the conduct resembles political lobbying and more cautious if the conduct occurs in adjudicative settings. For example, in *Omni*, the Supreme Court refused to recognize a broad exception that would strip immunity from lobbying. The reasoning behind it was that simply because the campaign was self-interested, deceptive, or closely coordinated with public officials, that is not enough to justify the exemption. However, in adjudicative contexts this has long been treated more carefully because repetitive or abusive use of courts and agencies are able to burden rivals through the process itself. In the case of pharmaceutical litigation, this matters a great deal. Since an FDA citizen petition may look partly like policy advocacy, it is able to function as a

[130] *Allied Tube & Conduit Corp v Indian Head, Inc*, 486 US 492, 500–06 (1988).

targeted intervention in a rival's path to market at the same time. This classification therefore shapes the immunity analysis even before the court reaches the question of competitive harm.[131]

3.3 The sham exception: when petitioning becomes anticompetitive "process abuse"

3.3.1 Introduction

The sham exception is the main route by which US antitrust law can move past Noerr–Pennington immunity and scrutinize litigation or regulatory petitioning as exclusionary conduct. In that sense, it plays a gatekeeping role similar to the one ITT Promedia plays in the EU chapter: it marks the line between protected recourse to public institutions and strategic use of those institutions as instruments of foreclosure. The crucial point, however, is that the US threshold is deliberately narrow. Courts are reluctant to infer antitrust liability from the mere fact that a firm has sued, petitioned, objected, or complained to a regulator. The plaintiff must show not simply aggressive behavior, but abuse of process in a technically demanding sense.

3.3.2 PRE two-part test: objective baselessness and improper subjective intent

The modern framework comes from *Professional Real Estate Investors v Columbia Pictures* ("PRE"). The Supreme Court effectively updated from the older Noerr language about "sham" petitioning into a two-stage test. First, the plaintiff must show that the lawsuit or petition was objectively baseless. This means that no reasonable litigant could expect realistic success on the merits. If, and only if, that threshold is satisfied, may the court move to the second stage. The second stage involves asking whether the filing concealed an improper subjective purpose: the

[131] *City of Columbia v Omni Outdoor Advertising, Inc*, 499 US 365, 379–84 (1991).

use of governmental process itself, rather than the hoped outcome of that process, as an anticompetitive weapon.[132]

This structure is designed to be demanding. First, most of the screening work is done from the objective inquiry. For reasonably based filings, the sham theory fails even if the plaintiff can point to internal hostility, delay incentives, or an evident desire to burden a rival. Therefore, anticompetitive motive unaccompanied does not determine if a justified claim is antitrust misconduct. Later, in *BE&K Construction*, the court reinforced the same point: reasonably based but unsuccessful resort to adjudication remains protected, because a rule that penalized losing but non-frivolous claims would chill access to public tribunals.[133]

For pharmaceutical markets, that demanding threshold is relevant since the strategic value of a filing oftentimes lies less on the outcome, and more on what occurs while it is pending. A brand manufacturer may gain commercially from delay, cost, and uncertainty during the time frame when generic or compounded competition is approaching. FDA's section 505(q) guidance reflects that concern by addressing petitions that request action capable of delaying approval of pending abbreviated new drug applications (ANDAs), 505(b)(2) applications, or biosimilar applications. They authorize summary denial where a petition was submitted primarily to delay approval without raising valid scientific or regulatory issues.[134] Therefore, the sham doctrine is shown to be highly relevant to pharmaceuticals, but it does not treat every delay-oriented petition as unlawful. Under *PRE*, the claimant still has the duty to prove that the filing lacked any realistic prospect of success and in addition, that the real function was to impose the burdens of

[132] *Professional Real Estate Investors, Inc v Columbia Pictures Industries, Inc*, 508 US 49, 60–61 (1993).
[133] *BE&K Construction Co v NLRB*, 536 US 516, 531–37 (2002).
[134] FDA, *Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act* (Guidance for Industry, 2019) 9–11.

process instead of obtaining a favorable official decision. These processes can include delay, expense, distraction, or regulatory uncertainty.

That is why sham-litigation claims are hard to win in drug markets. Since pharmaceutical defendants often are able to point to at least a plausible safety, labeling, manufacturing, or compliance rationale. As long as that rationale is legally and factually sufficient to make the filing objectively reasonable, immunity remains in place. This signifies that this doctrine is not a general anti-abuse standard. It is instead a more narrow screen aimed at filings that are both meritless and strategically abusive.

3.3.3 Serial petitioning and pattern theories: when many filings matter more than one

The difficulty of the *PRE* test for individual filings helps to explain the reason why plaintiffs often will swing from a single-filing theory to a campaign theory. In *California Motor Transport*, the Supreme Court recognized that the antitrust problem may lie not in one isolated petition but in the cumulative effect of a systematic practice of filing proceedings "with or without probable cause, and regardless of the merits." The Court also placed emphasis that while one weak claim may go unnoticed, "a pattern of baseless, repetitive claims" may reveal abuse of adjudicative and administrative processes with enough severity that it has the ability to deny rivals meaningful access to those institutions.[135]

That logic has a clear relevance in the pharmaceutical market, where competitive disputes can generate chains of filings rather than one decisive lawsuit. For example, a firm might first decide to file a citizen petition, then add supplements or comments, then related court actions, and lastly

[135] *California Motor Transport Co v Trucking Unlimited*, 404 US 508, 512–16 (1972).

even further interventions or objections as the approval approaches. In these settings, some courts have distinguished between applying *PRE* to a single filing and evaluating the overall pattern under a *California Motor* theory. The leading case for this is *USS-POSCO*. This explains that when a plaintiff challenges a whole series of proceedings, the question is not whether any single filing had merit, but whether the filings were brought in without regard to the merits and for the goal of injuring a market rival. Success rate, repetition, timing, and internal evidence all become relevant, as they help show whether the defendant was genuinely trying to persuade the tribunal or using the tribunals as a burdensome tactic.[136]

For drafting purposes, that distinction should be made explicit. A claimant should say whether the alleged abuse lies in one objectively baseless petition or in a broader campaign of repetitive filings. Those are related but distinct theories, therefore the evidence needed for each is different. This means that courts are often unwilling to let the party challenging the filings under antitrust law reframe one or two plausibly grounded proceedings as a broader "campaign" in order to avoid the stricter sham-litigation requirements.

3.3.4 Misrepresentation in adjudicative contexts: fraud and loss of immunity

A narrower route beyond immunity concerns material misrepresentation in adjudicative settings. This doctrine is less settled than *PRE*, but lower courts have treated it as an important qualification to Noerr–Pennington. The basic intuition is institutional. Falsehoods in political advocacy are generally tolerated as part of open contestation, whereas adjudicative bodies depend more directly on accurate factual and legal submissions. In *Kottle v Northwest Kidney*

[136] *USS-POSCO Industries v Contra Costa County Building & Construction Trades Council*, 31 F3d 800, 810–11 (9th Cir 1994).

Centers, the Ninth Circuit captured this distinction by treating knowing fraud or intentional misrepresentations before an adjudicative body as a possible basis for finding that the proceeding had been stripped of legitimacy.[137]

This route should be framed carefully. Not every weak argument, overstatement, or self-serving characterization is enough. The point is not that aggressive advocacy loses immunity; it is that deliberate and material deception may corrupt the decisional process so thoroughly that the petition can no longer claim Noerr protection. That makes the doctrine narrower than a general complaint about bad-faith lobbying, but still highly relevant in regulated industries, including pharmaceuticals, where public authorities often make entry-sensitive decisions on the basis of submissions from interested firms.

The importance of this idea in the present thesis is that it leads directly to *Walker Process*. There, the concern is not merely the filing of an aggressive suit, but the enforcement of a patent allegedly obtained through knowing fraud on the Patent Office. *Walker Process* thus represents the most developed US example of fraud-based loss of immunity in an IP setting and provides the next doctrinal step in the chapter.[138]

3.4 Walker Process: fraudulently procured patents as an antitrust problem

3.4.1 Introduction

The Walker Process creates a separate doctrinal pathway in order to challenge patent-based exclusion under US antitrust law. It does not focus primarily on whether the lawsuit itself was objectively baseless like the sham-litigation route discussed in the previous section. It instead

[137] *Kottle v Northwest Kidney Centers*, 146 F3d 1056, 1060–63 (9th Cir 1998).
[138] *Walker Process Equipment, Inc v Food Machinery & Chemical Corp*, 382 US 172, 174–77 (1965).

targets a more narrow and specific form of misconduct: the enforcement of a patent that was obtained through knowing and willful fraud on the Patent Office. Here the patent is treated not simply as a background legal right, but as a deception that has the ability to exclude rivals from the market. This is the reason why the Walker Process is important in important patent sectors such as pharmaceuticals, since the existence and scope of patent rights can determine whether entry is possible at all.[139]

3.4.2 Elements and proof: what must be shown (and why it is demanding)

In *Walker Process Equipment v Food Machinery*, The Supreme Court held that the enforcement of a patent procured by fraud on the Patent Office may violate Section 2 of the Sherman Act, given that the normal elements of a claim of monopolization also are present. Thus, this claim has several cumulative components. First, knowledge of and willful fraud in procurement has to ensue. This can be an action such as material misrepresentation or omission made to the PTO with the intention of the office issuing a patent that would not have been granted otherwise. Secondly, the patent must then be asserted and/or enforced against rivals. This action is typically done via infringement litigation or related threats. Third, the antitrust plaintiff still has the burden to prove the rest of the Section 2 case. This includes elements such as monopoly power in a relevant market, anticompetitive conduct, causation, and injury. By itself, fraud on the PTO does not itself complete the antitrust claim. However, it strips the patent's ordinary immunity away and therefore allows the enforcement conduct to be examined with standard monopolization principles.

[139] *Walker Process Equipment, Inc v Food Machinery & Chemical Corp*, 382 US 172, 177–78 (1965).

The Federal Circuit's en banc discussion in *Nobelpharma* helps to show how demanding this route is in reality. The court made it clear that Walker Process fraud is not able to simply be established by showing that a patent is weak, invalid, or even unenforceable on the grounds of regular patent-law. A much more serious requirement is needed: independent and clear evidence of deceptive intent, combined with a clear showing of materiality and reliance. This means that the patent would not have been issued if it were not for misrepresentation or omission. The court also stressed that inequitable conduct and Walker Process fraud are two different things. Inequitable conduct may rest on lesser misconduct and equitable balance. This is a clear variance to the Walker Process liability, which requires a higher threshold of intent and materiality and therefore carries a much narrower scope. *Nobelpharma* also helps clarify the relationship between this doctrine and the PRE sham test. The two theories are alternative routes instead of cumulative ones. For example, if Walker Process fraud and then remaining antitrust elements are able to be proved, the plaintiff does not need to show that the ensuing infringement suit was sham under PRE. Overall, this doctrine is powerful but very narrow and exacting. The aim is deliberate corruption of the patent-granting process, not at more ordinary hard-fought validity disputes.[140]

This high threshold for evidence is very significant for pharmaceutical cases. Since the drug patents are often extremely complex, combined with being surrounded by multiple continuation, formulation, method-of-use, and device claims, and even litigation in settings where uncertainty is normal. Therefore, courts have the duty to carefully distinguish between an aggressive style of patenting and actual fraud. As an example, a claimant alleging Walker Process liability cannot rely on the fact that the patentee advanced a weak theory of patentability or enforced a patent

[140] *Nobelpharma AB v Implant Innovations, Inc*, 141 F3d 1059, 1068–71 (Fed Cir 1998).

that was later invalidated. Instead, they must show a knowing and/or willful deception of the PTO that led to materially inducing the patent and then used as part of an exclusionary strategy. This narrowness explains why Walker Process claims are much less common and more difficult to sustain than a more general complaint about over-patenting or strategic patent assertion.

3.4.3 Why Walker Process matters for pharmaceuticals

Even though some of the disputes examined later in the chapter are framed via other mechanisms rather than straightforward patent infringement, the Walker Process still has relevance to this thesis. In the pharmaceutical market competition is structured by patents and exclusivities from the very beginning. In the Supreme Court case *FTC v Actavis*, using the Hatch-Waxman framework, it created special procedures to identify and resolve patent disputes between brand-name and generic firms. These include features such as Paragraph IV challenges, a possible 30-month stay of FDA approval if suit is filed promptly, and 180-day exclusivity for certain first filers. Those features signify that patent procedures are not just a fringe to competition in drug markets; instead, they are a feature of the architecture which determines when lower-cost entry can occur.[141]

The Walker Process remains important conceptually even when the lawsuit is not a patent suit. Pharmaceutical competition oftentimes is shaped by dense patent portfolios and forms of extended exclusivity which easily can deter or complicate generic or biosimilar entry long before a court decides a claim in court. Recent writings describe this more broad pattern as one in which brand manufacturers accumulate overlapping patents and related legal protections in order to prolong effective exclusivity even much longer than the legal patent term. This shows how the

[141] *FTC v Actavis, Inc*, 570 US 136, 142–46 (2013).

Walker Process performs an important limiting function within US antitrust law: it offers a route for condemning authority-facing deception in the patenting process, but only under a much narrower standard than the EU's more general concern with procedural abuse. This doctrine therefore sits at the intersection of patent law and antitrust as a very specified response to fraudulent patent procurement, not as a general prohibition on strategic patent-based exclusion.[142]

3.5 Case study: FTC v Shire ViroPharma — sham petitioning through FDA processes

3.5.1 Regulatory and market setting: citizen petitions as an entry choke point

The FDA citizen petition mechanism allows anybody to ask the regulatory agency to "issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action."[143] Essentially this means that in a formal setting it is a public-law procedure for raising scientific, regulatory, or safety concerns. In the competitive and practical setting, however, it is able to become highly consequential for pharmaceutical entry since incumbent firms have a structured way to intervene in the approval environment for rival products. As discussed earlier in Chapter 1, the entry of a generic version of a medication is not achievable simply by lowering price or increasing output; instead it depends on regulatory clearance. Therefore, a petition addressed to the FDA acts as a sort of a gatekeeper point in the competitive process, especially in cases where the petition challenges standards in which bioequivalence or approvability will be assessed.

[142] M Houston Brown Jr, 'Pharmaceutical Patent Protection Beyond the Twenty-Year Statutory Term' (2023) 108 *Cornell Law Review* 993, 994–1000.
[143] 21 CFR § 10.30.

This gatekeeping act helps to explain the reason citizen petitions have long attracted antitrust attention. Congress responded to concerns about delay by enacting section 505(q). This section requires the FDA to consider petition issues on a separate basis from application reviews, permits the delay of approval only if it is deemed necessary to protect the public health, and authorizes denial of petitions submitted with the main focus to delay approval without raising valid scientific or regulatory issues.[144] The design of the statute itself even shows the potential of competitive risk: even in cases where a petition is ultimately denied, it has the potential to generate uncertainty and consume time at the moment when a generic or follow-on product is nearing approval. For the purpose of this thesis, *Shire* becomes a particularly clear and clean "procedural abuse" fact pattern. The alleged conduct was not a covert market exclusion but instead a petition directed at a regulator whose decisions directly control the timing of entry.

3.5.2 Litigation posture and holdings: what the case did and did not decide

The FTC's 2017 complaint framed the case exactly in these terms discussed. Proceeding under section 5 of the FTC Act and invoking section 13(b) for federal-court relief, the Commission alleged that ViroPharma had used the FDA process to maintain monopoly power over Vancocin capsules by inundating the agency and the courts with repetitive, serial, and meritless filings after learning that generic manufacturers were approaching entry. According to the complaint, the campaign comprised forty-six filings between 2006 and 2012—forty-three submissions to the FDA and three lawsuits against the FDA—all with the intention delaying approval of generic Vancocin. The FTC alleged that the filings lacked the clinical support ViroPharma knew that would be necessary to pursue the filing. Therefore, by the time the FDA would have finally

[144] 21 USC § 355(q).

rejected the company's position as unsupported and without merit in 2012, the generic entry had already been delayed at significant cost to purchasers.[145]

The Third Circuit however did not make the decision of whether or not those allegations were sufficient on merit alone to establish sham petitioning. Instead the case was resolved on a threshold issue tied to a chosen FTC enforcement route. They accepted that the complaint's factual allegations were true for purposes of the motion to dismiss, upholding that section 13(b) authorizes a suit only when the defendant "is violating" or "is about to violate" the law. Since the petitioning campaign had ended a few years before the complaint was even filed, and Shire had already divested itself of Vancocin, the conclusion was that the FTC had not plausibly alleged ongoing or imminent misconduct. This led to a consequence of dismissal. The dismissal did not amount to a finding that the alleged filings were lawful. Rather, the court held that the statutory route chosen by the FTC did not extend to conduct that had ceased years earlier in the absence of concrete allegations of ongoing or likely recurrent misconduct.[146]

Therefore*, Shire's* unresolved resolutions are as central as what it decides. In the end, the courts did not determine whether continuous, constant FDA filings alleged would satisfy the *California Motor* or *PRE* sham framework on a developed factual record. Nor did they determine whether section 5 had the ability to reach such conduct if pursued via different procedural pathways, such as a timelier administrative proceeding or a suit brought during the campaign. The practical lesson drawn is that *Shire* is best understood not as a merits endorsement of the conduct, but instead as a decision about timing, pleading, and institutional authority. In that sense, it illustrates

[145] Complaint for Injunctive and Other Equitable Relief, *FTC v Shire ViroPharma Inc*, No 1:17-cv-00131 (D Del, 7 February 2017).
[146] *FTC v Shire ViroPharma Inc*, 917 F3d 147, 151–60 (3d Cir 2019).

the difference between identifying a plausible exclusion story and successfully converting that story into an actionable federal antitrust case.[147]

3.5.3 Antitrust learning outcomes for the thesis

Several outcomes from *Shire* are able to be implemented in Chapter 4. First, petitioning immunity sets a very high condemnation threshold in pharmaceutical cases: even a complaint alleging dozens of unsupported filings will not produce liability unless the claimant both defeats Noerr–Pennington and proceeds through a procedurally valid enforcement route.[4] Second, the forum is very relevant to the outcome of the process. Ordinary market conduct petitioning is not inspected in the same way as petitioning to the FDA since the agency has a scientific gatekeeping role that changes both the evidentiary inquiry and the institutional caution with which courts approach antitrust review.[4] Third, even if the campaign evidence may be powerful, the courts still are obliged to demand precision. A claimant has to unify serial filings to baselessness, intent, and legally relevant timing, not simply relying on repetition alone.[4] Fourth, the enforcement pathway and remedy choice can be outcome-determinative. In *Shire*, the decisive issue was not just whether there were conveyed anticompetitive allegations, but whether section 13(b) permitted the FTC to challenge a completed petitioning campaign even years after the event had finished.

In a more broad sense, the case of *Shire* exposes a possible gap in protection that matters for the thesis's focus on access-sensitive pharmaceutical markets. Writings on sham citizen petitions have long argued that the anticompetitive value of the strategy often lies in interim delay, cost,

[147] Lynn C Tyler, 'FTC v. Shire ViroPharma: Start with a Bang, Finish with a Whimper' (Food and Drug Law Institute, 2020)

and uncertainty rather than in an ultimate success before the agency. If that is correct, then a legal system that strongly protects petitioning, insists on narrow sham exceptions, and imposes additional remedial constraints may under-deter exclusionary use of the regulatory process, especially where the target is an entrant that depends on timely regulatory clearance. That concern is easiest to see with ANDA filers, but the same structural logic helps explain why later disputes involving alternative supply channels, including compounding pharmacies, may raise comparable competition concerns even when the formal legal claims are framed differently.[148]

3.6 Case study: litigation against compounders — Eli Lilly v Empower/Strive (GLP-1 compounding disputes)

3.6.1 Context recap: compounding as a competitive constraint in shortage/access conditions

As discussed in the first chapter, the US compounding framework has a clear distinction between the more traditional patient-specific compounding under section 503A, and outsourcing-facility compounding under section 503B. Section 503A is built with identified patients and valid prescriptions, excluding products that are "essentially a copy" of a commercially available drug unless there are patient-specific clinical differences. Section 503B instead regulates outsourcing facilities and similarly restricts compounded products that are essentially copies of approved drugs, while still conserving additional room should the approved drug appear on the FDA shortage list.[149]

[148] Matthew Avery, William Newsom and Brian Hahn, 'The Antitrust Implications of Filing "Sham" Citizen Petitions with the FDA' (2013) 65 *Hastings Law Journal* 113.
[149] 21 USC § 353a. 21 USC § 353b.

This framework is very important in competitive terms because compounding is able to function as a residual supply channel in the event when FDA-approved products are unsuitable, unavailable, or difficult to obtain. In the *Strive* litigation we will discuss this section, even the court's summary of Lilly's allegations recognized that compounded GLP-1 products may serve patients with unique needs and can also act as a workaround when a brand-name drug is expensive or in short supply.[150]The competition case for this section is therefore not whether all compounding is lawful, but rather if litigation and regulatory pressure can chill lawful or arguably lawful compounding activity. This results in a narrowing of access to an alternative supply channel in markets that are already marked by shortages and high demand.

3.6.2 Claims architecture: why Lanham Act / consumer-protection framing matters for Noerr analysis

The recent Lilly suits against compounders are notable because they are not framed in the conventional language of patent infringement. Instead, they decided to build the complaints using other mechanisms. These included false advertising, deceptive marketing, trademark misuse, and related state-law unfair competition theories. For the Empower complaint, Lilly alleged that Empower marketed oral tirzepatide and tirzepatide/niacinamide injections as safe, effective, and "personalized,". However, they alleged that those products had not been clinically tested in those forms and were mass-produced rather than individually created and tailored. Lilly also mentioned that Empower made statements that suggested regulatory compliance and

[150] *Eli Lilly and Company v Strive Pharmacy LLC*, No 1:25-cv-00401 (D Del, memorandum opinion, 8 October 2025).

superior safety or quality. [151] The *Strive* opinion follows a similar mechanism: Lilly challenged Strive advertising that said their compounded tirzepatide was "customized," "specifically designed" for "one-of-a-kind needs," "safer and better for you" than products from "Big Pharma," and above regulatory standards.

The decision Eli Lilly made for their cause of action matters since now the focus is not centered on patent validity and instead on the truthfulness of promotional claims and the relationship between compounding, regulation, and consumer deception. Under the Lanham Act this has legal significance since the act reaches commercial advertising or promotion that misrepresents the nature, characteristics, or qualities of goods or services.[152]It is also significant strategically, because a plaintiff now can frame cases as one of protecting consumers and brand integrity instead of trying to exclude rivals through patent rights. Since the pharmaceutical sector is heavily regulated, that framing has very impactful potential, since safety, approval status, and clinical support are all potential matters on which courts can hesitate to second-guess a challenger too quickly.

For Noerr purposes, these cases still involved protected court petitioning in form, but the sham inquiry looks different from the classic patent case. The issue is not whether the brand's patent position is valid, rather, it is whether the false-advertising or consumer-protection theory had an objectively reasonable basis. If the compounder's promotional claims do imply FDA approval, established clinical testing, or individualized tailoring that did not exist, then the suit is unlikely to be called objectively baseless. If, however, the claims mainly repackage lawful compounding

[151] Complaint, *Eli Lilly and Company v Empower Clinic Services, LLC d/b/a Empower Pharmacy et al* (D NJ, filed 1 April 2025). ↩
[152] 15 USC § 1125(a)(1)(B)

as “deception” in order to suppress a rival supply channel, the antitrust analysis becomes more legitimate.

3.6.3 Antitrust lens: how (and how not) to argue sham litigation here

For Chapter 4, the analytical pathway will be framed with very specific parts. The first question is whether the litigation is plausibly understood as good-faith enforcement of consumer-protection, false-advertising, or trademark interests. Where a complaint points to concrete statements about approval status, clinical testing, personalization, or comparative safety, a court may find at least a colorable basis for suit. Under *PRE*, that is usually enough to block sham liability at the first stage, because a reasonably grounded claim remains protected even if the plaintiff also had competitive motives.[153]

The antitrust claimant’s harder argument is therefore a campaign theory: that litigation, public warnings, and regulatory complaints were used together to suppress compounders and telehealth-linked distribution channels during a period of intense demand. To make that argument plausible, the claimant would need more than allegations of aggressive enforcement. It would need evidence of real merits weakness, internal documents showing delay or exclusion as the objective, timing linked to shortages or entry pressure, repetitive filings across forums, and perhaps settlement or remedial demands that look more like market suppression than correction of deception. Even then, this remains a hard case. Safety and quality concerns give brand manufacturers an obvious objective-justification narrative, and courts are likely to be cautious before characterizing such litigation as sham. For that reason, these disputes are best treated not as easy examples of abusive petitioning, but as borderline cases that test whether US antitrust

[153] *Professional Real Estate Investors, Inc v Columbia Pictures Industries, Inc*, 508 US 49, 60–61 (1993).

leaves a protection gap where legal process is used to constrain an alternative access channel without clearly crossing the PRE threshold.

3.7 Synthesis: a practical assessment framework for sham litigation/petitioning in US antitrust

Chapter 3 yields a seven-step framework that can be reused in Chapter 4. First, identify the petitioning venue: court, FDA, PTO, state board, or another agency. That matters because the immunity analysis depends in part on the institutional setting and on whether the conduct is directed at a public decision-maker.

Second, confirm Noerr–Pennington coverage by distinguishing genuine petitioning from adjacent private market conduct. A filing, complaint, or request for agency action may be protected, while commercial coercion, disparagement, or other market-facing conduct accompanying the petition may remain outside the immunity baseline.

Third, select the correct exception pathway. If the theory concerns one lawsuit or petition, the main route is the *PRE* sham-litigation test. If the conduct consists of repetitive filings across one or more fora, the better framework may be a *California Motor* campaign or serial-petitioning theory. If the conduct concerns a patent allegedly procured through deception and later asserted against rivals, the relevant route is *Walker Process*.

Fourth, apply the legal threshold that belongs to that route. Under *PRE*, the claimant must show objective baselessness first and only then improper subjective intent. Under *Walker Process*, the claimant must establish knowing and willful fraud on the PTO, materiality, and subsequent enforcement of the patent.

Fifth, complete the ordinary monopolization analysis. Even if petitioning immunity is overcome, liability does not follow automatically. The claimant must still prove a relevant market, monopoly power or dangerous probability of monopoly power, a plausible foreclosure mechanism, causation, and antitrust injury.

Sixth, test objective justifications and policy constraints. In pharmaceutical disputes, safety, labeling, compliance, and public-health narratives often provide facially legitimate reasons for petitioning, and courts are cautious not to let antitrust law chill resort to courts and regulators merely because the dispute occurs in a competitive setting.

Seventh, ask whether the chosen enforcement pathway and remedy are realistically available. This is not a secondary issue. *FTC v Shire ViroPharma* shows that even a plausible exclusion story could fail if the statutory route invoked does not reach completed conduct or if the claimant cannot allege ongoing or imminent misconduct with sufficient specificity. The practical lesson is that US law addresses sham litigation and abusive petitioning through a layered sequence rather than a single open-ended abuse standard: immunity first, exception second, monopolization proof third, and enforceability last. That sequence is what most sharply distinguishes the US model from the more direct procedural-abuse analysis established under EU competition law.

3.8 Conclusion and transition to Chapter 4

The central lesson of this chapter is that US antitrust law treats petitioning as presumptively protected conduct, not as an ordinary form of exclusionary behavior. Antitrust liability therefore arises only in narrow circumstances: the claimant must first move past Noerr–Pennington

immunity, usually through the sham exception or, in patent cases, through *Walker Process*, and must then still prove the ordinary monopolization elements, including market power, foreclosure, causation, and harm to the competitive process. The result is a system that is structurally cautious about condemning litigation, regulatory complaints, and other resort to public processes, even where those procedures may have strong exclusionary effects in pharmaceutical markets.

This provides the main comparison point for Chapter 4. Whereas the EU framework developed in Chapter 2 is more willing to scrutinize "procedural abuse" by dominant firms, US law begins from an immunity baseline and only exceptionally allows competition review. The contrast is especially sharp at the level of gatekeeper tests: ITT Promedia and related EU authority-deception cases ask whether recourse to procedures forms part of an abusive exclusionary strategy, while US doctrine insists on narrower routes such as *PRE* and *Walker Process*. The systems also differ in evidentiary burden, remedial design, and institutional posture.

Chapter 4 builds on that contrast in applied form. It asks whether these doctrines are properly calibrated in markets where litigation and regulatory complaints may affect compounding pharmacies, telehealth-linked supply channels, and patient access to medicines. The key question is not only when intervention is justified, but also when legal systems risk over-protecting petitioning at the expense of competition and access.

Chapter 4 – Comparative and applied analysis: impact of strategic litigation and regulatory complaints on compounding pharmacies and patient access; evaluation of the EU and US frameworks.

4.0 Introduction

This chapter will provide a comparative and applied analysis of the way that strategic litigation and regulatory complaints have influence over the regulation of compounding pharmacies and, as a consequence, the patient access to compounded medicines within the European Union and the United States. Using the regulatory frameworks examined in Chapters 2 and 3, this chapter will evaluate how legal and administrative enforcement mechanisms function in practice, especially in the cases where pharmaceutical manufacturers have a goal to challenge or curb the activities of compounding pharmacies. While regulatory regimes have a official aim to balance pharmaceutical innovation, patient safety, and market competition, the increasing use of litigation and regulatory complaints by originator pharmaceutical companies has raised concerns about whether these mechanisms are being used as strategic tools to limit competition, as opposed to purely enforce compliance within the regulatory framework.

The analysis on this chapter will focus on the specific mechanisms in which strategic legal actions interact with existing regulatory frameworks that govern pharmaceutical compounding. These legal actions can consist of actions like regulatory complaints, intellectual property enforcement, and administrative challenges. In both the European Union and the United States, compounding pharmacies hold a legally complex position within pharmaceutical regulation. Since they are permitted to prepare individualized medicines for patients, they must work within specific boundaries that are created to prevent them from essentially functioning as de facto

pharmaceutical manufacturers. When pharmaceutical companies argue that certain compounding practices exceed these limits, disputes arise, particularly in situations where medicines are in high demand, or when shortages occur of commercially available drugs.

This chapter will also compare the way the EU and US regulatory systems address these disputes, and assess the broader implications for patient access to medicines. A particular focus is given to if litigation and regulatory complaints have the practical effect of constraining the availability of compounded medicines that may otherwise fill therapeutic gaps or address drug shortages. Via this comparative analysis, the chapter will evaluate the extent on which current regulatory frameworks adequately balance patient access, regulatory oversight, and the commercial interests of pharmaceutical manufacturers. Ultimately, the chapter's main goal is to identify structural differences between the EU and US approaches and to assess whether these differences produce divergent outcomes for compounding pharmacies and the patients who rely on them.

4.1 Comparative lens and evaluation criteria

4.1.1 What exactly is being compared?

The comparison adopted in this chapter is viewed from a functional rather than a purely terminological standpoint. It does not ask, from the beginning, whether EU competition law generally is stricter than US antitrust law. Instead, it asks how each system responds to the same general areas of conduct: litigation before courts, complaints to medicines regulators, authority-facing misrepresentations, and hybrid campaigns (in which IP-regulatory, commercial, and

procedural tools are combined to obstruct rival supply). [154] The context in relation to the market is held in a constant manner. For both systems, the applicable disputes emerge in pharmaceutical markets marked by dense regulation, safety supervision, episodes of shortage, high entry barriers, and limited substitutability between products. [155]

On the EU side, the reference point is Article 102 TFEU as applied to exclusionary strategy and abuse of regulatory procedures, most clearly in the *AstraZeneca case*. On the US side, the reference point is Section 2 of the Sherman Act and, in appropriate areas, Section 5 of the FTC Act. However, these rules operate additionally through the filters of: Noerr-Pennington immunity, the narrow sham-petitioning exceptions, and, in patent-procurement settings, *Walker Process* fraud. Therefore, for the chapter purposes, the comparison is not between labels in and of itself—"abuse of dominance" and "monopolization"—but instead, between two legal architectures. This is in order to distinguish legitimate recourse to public processes from the strategically exclusionary uses of those processes.

4.1.2 Why compounding pharmacies are the stress test

Compounding pharmacies deliver the clearest stress test for this comparison since they are at the cusp of the boundary between pharmacy practice and market-facing drug supply. In the EU market, Directive 2001/83/EC excludes magistral and officinal formulas from the harmonized marketing-authorization regime. This results in a significant part of the practical regulation of

[154] Consolidated Version of the Treaty on the Functioning of the European Union [2012] OJ C326/47, art 102; Sherman Antitrust Act 1890, 15 USC § 2; Federal Trade Commission Act 1914, 15 USC § 45.
[155] OECD, *Pharmaceutical Innovation and Access to Medicines* (OECD Publishing 2018); US Food and Drug Administration, 'Compounding and the FDA: Questions and Answers'.

compounding being left to Member State medicine and pharmacy law.[156] In contrast, federal law in the United States explicitly created 2 compounding routes: section 503A for traditional patient-specific compounding and section 503B for outsourcing facilities, which may compound on a larger scale but are subject to registration, current good manufacturing practice requirements, and additional FDA oversight. [157]

This intermediate position matters for analysis of the competition since compounding does not automatically have an equivalent to ordinary generic entry. A compounded medicine is not in all cases a direct market substitute for an approved product. Therefore for the purposes of the thesis, it should avoid assuming that every conflict between an originator and a compounder is simply a normal rivalry between horizontally competing sellers.[158] Nevertheless, where there is a shortage, a dosage-form or strength gap, a clinically significant difference for a particular patient, or no viable commercial supply, compounders are able to become a real competitive constraint and oftentimes even the only workable lawful channel through which treatment can reach the patient. [159] Legal or regulatory strategies directed at compounders therefore can result in consequences that extend beyond the position of one rival undertaking. They are able to chill lawful alternative supply, affect hospital and prescriber behavior, and reduce practical patient access to medicines. [160]

4.1.3 Evaluation criteria used in this chapter

[156] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [2001] OJ L311/67
[157] 21 USC §§ 353a–353b;
[158] US Food and Drug Administration, 'Compounding and the FDA: Questions and Answers';
[159] Shweta Kumar, 'Compounding Inequities Through Drug IP and Unfair Competition' (2024)
[160] Ashlee N Mattingly, 'The Role of Outsourcing Facilities in Overcoming Drug Shortages' (2021)

The chapter accordingly evaluates the EU and US frameworks against five criteria. First, the legal reach: can the framework capture exclusionary conduct when it is expressed through formally lawful petitions, complaints, IP assertions, or safety objections? Second, evidentiary administrability: can courts or agencies distinguish ordinary regulatory advocacy from strategic abuse without demanding proof that is unrealistic in practice? Third, sensitivity to hybrid conduct: can the framework assess campaigns made up of many individually plausible steps rather than a single obviously baseless lawsuit? Fourth, the analysis asks how well each system protects legitimate interests. Pharmaceutical undertakings must remain free to enforce patents, raise genuine safety concerns, and petition public authorities in good faith; overbroad liability would risk chilling conduct that medicines regulation sometimes depends upon. Fifth, and most importantly for this thesis, the chapter asks how far each framework responds to patient-access effects. In pharmaceutical markets, false negatives are not costless: under-enforcement may permit dominant firms to use litigation costs, regulatory bottlenecks, or complaint-based pressure to suppress lawful alternative supply, especially during shortages or where individualized treatment is clinically necessary. At the same time, false positives matter too, because a standard that is too loose may weaken legitimate pharmacovigilance, public-health reporting, and innovation incentives. [161]

For that reason, the question pursued in the following sections is not which system is abstractly harsher. The better-calibrated framework is the one broad enough to reach strategically exclusionary uses of legal and regulatory process, yet disciplined enough to preserve genuine petitioning, bona fide safety enforcement, and legitimate IP protection. That is the benchmark

[161] OECD, *Pharmaceutical Innovation and Access to Medicines* (n 3);

applied in Sections 4.2 to 4.6, and it provides the bridge from comparative analysis in this chapter to the policy recommendations developed in Chapter 5.[13]

4.2 Comparative threshold question: when does strategic use of procedure become abuse or monopolization?

4.2.1 EU threshold: dominance, *ITT Promedia*, and broader strategy logic

EU law is generally more cautious about treating litigation as an abusive action. The initial point is that recourse to courts and public procedures cannot simply be condemned, especially in the cases where undertakings are asserting legal rights or seeking regulatory clarification. For that reason, *ITT Promedia* sets a demanding threshold where alleged abuse exists, specifically for court proceedings: only in wholly exceptional circumstances can litigation amount to an abuse of dominance, namely where the action is manifestly unfounded and forms part of a plan to eliminate competition. [162] Yet the noteworthiness of *ITT Promedia* for the purposes of this thesis is not that it closes the door to intervention, but instead, it identifies the specific problem presented by pure sham litigation and distinguishes it from other more broad forms of procedural abuse.

That distinction is essential in the case of European competition law. For example, in *AstraZeneca*, the EU courts did not focus on litigation baselessness in the sense of *ITT Promedia*. Instead, they focused on the misleading representations to public authorities, as well

[162] Case T-111/96 *ITT Promedia NV v Commission* EU:T:1998:183.

as the strategic use of regulatory procedures to delay or hinder generic entry. [163] The primary legal concern was therefore not simply that AstraZeneca had enacted procedures, but instead that a dominant undertaking, subject to a special responsibility not to impair undistorted competition, had instrumentalized regulatory mechanisms in a manner capable of producing foreclosure. The same general strategic logic also appears in *Servier* and in national practice such as *Roxtec*. This helps clarify that the issue is oftentimes not a single filing viewed in isolation, but more an exclusionary plan composed of multiple steps—IP assertions, administrative maneuvers, threats, litigation, and communications. This plan is then determined by the courts on the cumulative effect to raise rivals' costs, create uncertainty, or delay access to the market.[164]

For Chapter 4, the reusable EU building blocks are definitely clear. The threshold inquiry begins with dominance and special responsibility. Then, it asks whether the conduct, individually or cumulatively, had the capability of foreclosing equally efficient rivals or constraining market access; whether the undertaking has the objective justification to invoke these actions, such as genuine safety or compliance concerns; and what is the specific evidence that supports the idea of an exclusionary mechanism. For these cases there are a few decisive features such as timing, internal documents, sequencing, and inconsistency between public justifications and private strategy. [165] Therefore, the EU threshold is relatively open-textured: stand-alone litigation claims remain difficult under *ITT Promedia*, but Article 102 is more willing to intervene where legal or

[163] Case T-321/05 *AstraZeneca AB and AstraZeneca plc v Commission* EU:T:2010:266., Case C-457/10 P *AstraZeneca AB and AstraZeneca plc v Commission* EU:C:2012:770.
[164] *Commission v Servier and Others* and *Servier and Others v Commission* (Cases C-176/19 P and C-201/19 P and related appeals, 27 June 2024).
[165] Pinar Akman, 'The Concept of Abuse in EU Competition Law' (Hart 2012).

regulatory steps form part of a broader exclusionary strategy rather than simply ordinary competition on the merits. [166]

4.2.2 US threshold: petitioning immunity, sham exception, and *Walker Process*

The US threshold starts under a different premise. Under Noerr-Pennington, genuine petitioning of legislatures, agencies, and courts is strongly protected from antitrust liability, even in the cases where the petitioner's aim is to preserve or extend market power. [167][168] This baseline immunity is of great importance in the pharmaceutical industry, since firms engage routinely with the FDA, courts, patent offices, and state authorities. Therefore, the first question is not whether the conduct appears to be strategically exclusionary in an overall sense, but whether it is protected petitioning. If, and only if, the conduct falls outside that immunity, or within a recognized exception, the monopolization inquiry realistically is able to begin.

That strict baseline is the reason why the *PRE* test is so demanding. A claimant must first show objective baselessness: no reasonable litigant could realistically expect success on the merits. [169] Only if that hurdle is crossed, the court can examine subjective intent and then ask whether the filing was brought to use the process itself—delay, cost, uncertainty, or chilling effect—instead for the purposes of obtaining a favorable legal outcome.[12] This structure makes these cases especially difficult, since a filing may be aggressive, strategically timed, and aimed at harming a rival, but if it is not objectively baseless, immunity generally remains intact. However, there is an exception to this case. *California Motor* leaves room for campaign or serial-petitioning theories,

[166] Renato Nazzini, 'Abuse of Process and Abuse of Rights in EU Competition Law' in Ariel Ezrachi (ed), *Research Handbook on European Competition Law* (Edward Elgar 2012).
[167] *Eastern Railroad Presidents Conference v Noerr Motor Freight Inc* 365 US 127 (1961).
[168] *United Mine Workers of America v Pennington* 381 US 657 (1965).
[169] *Professional Real Estate Investors, Inc v Columbia Pictures Industries, Inc* 508 US 49 (1993).

particularly if there are repetitive filings used to harass rivals and to deny meaningful access to decision-makers. However, US courts often remain cautious for this case because of the perceived risk of chilling protected petitioning. [170]

The Walker Process provides a different but narrow pathway where the exclusion relies on the enforcement of a patent procured by knowing and willful fraud on the Patent Office. [171] Even here, however, the plaintiff cannot escape the ordinary requirements of Section 2 of the Sherman Act. Fraud on the patent office is essentially the only gateway to overcome this issue. The claimant still has the duty to prove monopoly power, exclusionary conduct, causation, and antitrust injury. [172]In practice, that makes *Walker Process* an important conceptual parallel to *AstraZeneca*, but with a much narrower operational tool.

FTC v Shire ViroPharma shows an additional US concept: institutional route and remedial posture may be outcome-determinative even before a court fully resolves the sham theory on the merits. The FTC alleged that several(serial in this case) meritless citizen-petition filings were designed to delay generic entry, yet the Third Circuit affirmed dismissal of the case because the Commission had proceeded under section 13(b) of the FTC Act and failed to show that Shire "is" or "is about to" violate the law. [173][174] This resulted in signifying that the US threshold is not only substantively narrow, but in addition, procedurally layered. Here, the immunity, exception doctrine, and enforcement vehicle can each screen out a claim before a court even has the ability to reach the broader competitive significance of the conduct.

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[170] *California Motor Transport Co v Trucking Unlimited* 404 US 508 (1972).
[171] *Walker Process Equipment, Inc v Food Machinery & Chemical Corp* 382 US 172 (1965).
[172] *Nobelpharma AB v Implant Innovations, Inc* 141 F 3d 1059 (Fed Cir 1998).
[173] *FTC v Shire ViroPharma Inc* 917 F 3d 147 (3d Cir 2019).
[174] Federal Trade Commission Act 1914, 15 USC §§ 45, 53(b).

4.2.3 Same facts, different outcomes? Comparative implications

Several comparative propositions follow. First, misleading authority-facing conduct is more readily actionable in the EU than in the United States. An EU authority can ask whether a dominant firm used regulatory procedure in a misleading or strategically distortive way capable of foreclosure, whereas US law more often begins from immunity and requires the claimant to fit the case within a narrow exception such as sham petitioning or *Walker Process*.

Second, mixed-merits conduct is treated differently. In the EU, a campaign may still be abusive even if some individual acts are not plainly unlawful, provided the overall pattern reveals a strategy outside competition on the merits. In the US, by contrast, one non-baseless petition may preserve immunity for that filing, making it harder to aggregate a hybrid campaign into a single exclusionary theory.

Third, internal strategy evidence plays a stronger gatekeeping role in the EU. Timing, sequencing, and internal documents can help show that individually lawful steps were coordinated toward foreclosure. In the US, those materials matter too, but ordinarily only after the plaintiff has already crossed the objective-baselessness barrier or another immunity exception.

Fourth, safety and regulatory narratives are structurally more protective in the US. A plausible safety rationale may defeat baselessness and preserve immunity even where exclusionary intent is strong. In EU law, however, the same narrative is examined as a possible objective justification with a review subject to proportionality: the pursuit of a legitimate aim does not justify actual or potential anticompetitive conduct unless the measure is appropriate and

necessary for achieving that aim.[175] Thus, in instances when the conduct is excessive, misleading, or goes beyond what is required to address the alleged safety concern, the justification may fail, particularly if the evidence suggests that the safety rationale was strategically instrumental.

Fifth, the same hybrid campaign directed at compounding pharmacies—regulatory complaints, warning letters, litigation, and public safety messaging—may therefore be easier to characterize in the EU as part of a broader exclusionary strategy, while in the US it may be filtered out earlier by petitioning immunity or by the plaintiff's inability to satisfy the demanding thresholds of *PRE*, *Walker Process*, or the chosen enforcement route. That structural divergence is the bridge to Sections 4.3 and 4.4, where the abstract threshold difference is tested against complaints to regulators and litigation directed at compounders.

4.3 Regulatory complaints as competitive instruments

4.3.1 Why regulatory complaints matter for compounding markets

In the compounding markets complaints to regulators are not merely procedural side actions. A complaint to the FDA, a medicines agency, a state board of pharmacy or medicine, or a reimbursement authority can trigger many factors. Investigations, warning activities, extra scrutinies, or at least uncertainties about legality and supply continuity. That is very relevant since compounding already operates in a very sensitive space in the legal sense: compounded

[175] European Commission, *Guidance on the Commission's enforcement priorities in applying Article 82 [now 102] EC to abusive exclusionary conduct by dominant undertakings* [2009] OJ C 45/7, paras 28–30.

drugs are not FDA-approved, state boards retain important supervisory functions over traditional pharmacies, and telehealth-linked channels can be vulnerable to signs that their practices may attract regulatory attention. [176] In settings where there are shortages or sensitive accesses, even a temporary chilling can reduce the output of the pharmacy via various means. The pharmacy itself may slow dispensing, a platform may stop onboarding patients, a prescriber might become reluctant to prescribe, or a supplier can decide that the compliance risk is no longer worth carrying. In the space where the compounded supply is filling a gap left by shortage, dosage needs, or formulation needs, those chilling reactions may strengthen the incumbent's control over the therapeutic channel even before any authority has actually had a chance to find a potential violation. [177]

Due to that reason, complaints to authorities have to be treated as a potential competitive lever. Their importance lies not only in whether the complaint succeeds on the merits, but in the foreseeable market effects it has the ability to trigger for the duration the complaint is pending. In the context for the compounding market, regulatory uncertainty itself can be exclusionary because lawful alternative supply depends heavily on perceived legitimacy, trusted compliance, and continued willingness by intermediaries to participate. [178]

4.3.2 EU approach: misleading or strategic authority-facing conduct

The clearest EU model that applies for this case is *AstraZeneca*. The importance of *AstraZeneca* for this thesis is not just confined to its pharmaceutical facts, but to its broader principle: a

[176] U.S. Food and Drug Administration, 'Compounding and the FDA: Questions and Answers'.
[177] U.S. Food and Drug Administration, 'Compounding when Drugs are on FDA's Drug Shortages List'.
[178] Shweta Kumar, 'Compounding Inequities Through Drug IP and Unfair Competition' (2024) 102 *Washington University Law Review* 371.

dominant undertaking may abuse Article 102 by making misleading representations to public authorities or by strategically using regulatory procedures in a way capable of restricting market access. [179] This signifies that EU law does not begin from a rule of petitioning immunity. The central question is whether the conduct, when viewed in its legal and economic context, falls outside competition on the merits and has the capability of foreclosure. This results in the authority-facing conduct being analytically easier to integrate into a wider strategy theory as opposed to the United States. A complaint, dossier, warning, or representation to a regulator can be examined not only to see if it is a formal truth or falsity, but additionally, for its role in a broader exclusionary design.

Later Article 102 practice reinforces the point specified. The Commission's Teva/Copaxone decision shows a more recent willingness to treat misleading safety- and equivalence-related messaging, communicated to pricing and reimbursement authorities, health insurance funds, and healthcare professionals, as exclusionary disparagement in cases where it was objectively misleading, capable of hindering uptake, and not objectively justified. [180] That logic is very relevant to complaints involving compounders. For these cases, the important evidence would include misleading statements or omissions about whether the compounding is lawful, conflation of lawful compounding with counterfeiting or mass manufacture, timing linked to shortage transitions or rising alternative supply, foreseeability that the authority or surrounding market actors would react cautiously, and the capability of the complaint to chill access even absent a formal prohibition. A useful evidence can be a reliance on authority, but it should not be the only relevant one. In a market where the access is sensitive, it may simply be enough that a complaint

[179] Case C-457/10 P *AstraZeneca AB and AstraZeneca plc v Commission* EU:C:2012:770.
[180] European Commission, Summary of Decision in Case AT.40588 *Teva* (exclusionary disparagement), OJ C/2025/1680.

predictably causes boards, reimbursement bodies, prescribers, platforms, or suppliers to step back from a lawful channel. The EU framework is therefore comparatively more open to treating misleading complaints as a component of a cumulative foreclosure strategy, while still giving room for an objective justification where the safety or compliance concerns are genuine, precise, and proportionate.

4.3.3 US approach: petitioning agencies and boards

The US framework starts from the complete opposite direction. Complaints to agencies and boards are presumptively protected petitioning under the Noerr-Pennington doctrine, even in the cases where they are filed by firms with obvious and clear commercial motives, and even when they may affect rival entry, timing, or credibility. [181] The *California Motor* case shows that this protection is not absolute: a pattern of repetitive, abusive filings or misrepresentations in adjudicative settings may fall outside immunity. [182] But still, the doctrinal path is narrow, and the *Professional Real Estate Investors* case makes it clear why. To lose immunity as sham petitioning, the filing must first be objectively baseless. Only after this is proven, then does subjective intent matter. [183]That standard is particularly difficult to satisfy in compounding disputes, where safety, approval status, "essentially a copy" restrictions, telehealth-linked prescribing, and shortage-related compliance are all legally and factually contested.

This means that in practice, antitrust claims against regulatory complaints are especially hard to win. The same set of facts that make compounding important for society in shortage settings also create the legal terrain complicated enough to give many complaints at least an arguable basis.

[181] *Eastern Railroad Presidents Conference v Noerr Motor Freight Inc* 365 US 127 (1961).
[182] *California Motor Transport Co v Trucking Unlimited* 404 US 508 (1972).
[183] *Professional Real Estate Investors, Inc v Columbia Pictures Industries, Inc* 508 US 49 (1993).

Even the FDA's own guidance underscores both sides of the issue: compounded drugs can meet important patient needs, including during shortages, but they are not FDA-approved and may raise real safety, quality, and promotional concerns, including in online and telehealth channels. With that background, it supplies incumbents with a strong objective-basis narrative. The result of this means that even a strategically timed complaint oftentimes is able to remain protected unless the challenger can show something closer to serial abuse, knowing falsity, or repeated filings after the underlying theory has already been rejected.

The clearest reminder that the US route is narrow is via *FTC v Shire ViroPharma*, not only substantively but institutionally as well. The FTC alleged that Shire used serial, repetitive, and unsupported FDA filings and related litigation to delay generic approval. Even with all these allegations, the case failed because of the limits of the Commission's chosen Section 13(b) route rather than because a court fully adjudicated the sham theory on the merits. [184] That is relevant here because complaints to the FDA or boards may be easier to narrate as exclusionary instead of converting it into a viable antitrust case. In the United States, forum choice oftentimes shapes the fate of the claim before the full competitive significance of the complaint is ever tested.

4.3.4 Comparative takeaways for patient access

Four comparative propositions follow. First, EU law is more open to policing misleading complaints as part of a broader exclusionary strategy. It does not start by immunizing the use of public procedures, and it is therefore more willing to ask whether authority-facing conduct departed from competition on the merits and was capable of foreclosure.

[184] *FTC v Shire ViroPharma Inc* 917 F 3d 147 (3d Cir 2019).

Second, US law is more protective of complaints to agencies and boards unless objective baselessness, adjudicative misrepresentation, or a similar exception can be shown. That means the same complaint campaign may be legally delicate in the EU but largely insulated in the United States, especially where safety or compliance arguments provide some plausible foundation.

Third, access harm is often easier to describe than to translate into legally cognizable competition harm. The analysis should therefore insist on a clear causal chain: complaint, then market reaction, then reduced patient access. Without that chain, patient harm risks remaining rhetorical background rather than part of the competition analysis itself.

Fourth, forum choice forms not only doctrine but evidence and remedy. The authority or court that hears the complaint determines what can be discovered, how quickly relief may be obtained, and whether the response is likely to preserve lawful compounding before access loss becomes irreversible. That institutional point will matter directly in Sections 4.4 and 4.6.

4.4 Applied analysis: litigation targeting compounders and telehealth-linked channels

4.4.1 Factual pattern to test

The most practical applied pattern for this thesis starts with an access-sensitive disruption in supply. Either demand for a branded medicine rises sharply, or official shortage conditions make ordinary distribution systems unreliable, leading to compounders becoming an alternative channel through which patients can continue treatment. In the United States, that channel may involve either traditional 503A pharmacies and 503B outsourcing facilities, as well as possibly

being linked to telehealth-driven prescribing and patient-acquisition models. The FDA itself recognizes that compounded drugs may be needed where an approved product is not medically appropriate for a patient or where a product on the shortage list cannot be reliably obtained through ordinary channels. [185] However, the shortage will eventually ease, or, if the brand manufacturer concludes that compounding has moved from individualized preparation to scaled commercial substitution, the dispute shifts. The manufacturer may bring the Lanham Act or unfair-competition litigation, send cease-and-desist letters, complain to regulators, and publicly emphasize that compounded products are not FDA-approved, may differ in formulation, and may expose patients to safety or deception risks. [186]

The GLP-1 disputes provide the clearest current reference point, but the analysis should remain general enough to travel to other such instances. The core issue is not whether or not every such campaign is abusive. Some complaints will be justified, especially in cases where a compounder or telehealth intermediary implies that a product is falsely FDA-approved, equivalent to the branded drug, or supported by the brand manufacturer's clinical evidence. The real question to answer is more narrow: when does legitimate enforcement of safety, labeling, and approval-status rules become a strategy for foreclosing lawful compounding channels precisely when those channels matter most for continuity of care, affordability, or treatment customization? This is the core competition question this section tests.[187]

4.4.2 EU assessment of a compounder-targeting campaign

[185] U.S. Food and Drug Administration, 'Compounding and the FDA: Questions and Answers'.
[186]
[187] Shweta Kumar, 'Compounding Inequities Through Drug IP and Unfair Competition' (2024) 102 *Washington University Law Review* 371.

The key analytic move under EU law is to look at the campaign as a possible whole act, as opposed to a series of disconnected legal acts. If assuming dominance is established, Article 102 will not require the authority or court to ask only if one lawsuit, complaint, or warning letter was unlawful independently. The more clarifying question is whether litigation, authority-facing complaints, and external communications combined were part of a cumulative strategy with the capability of foreclosing rivals or possibly chilling alternative supply. [188] That perspective is relevant due to the fact that the campaign's exclusionary force may lie less in any single filing, rather the interaction between multiple steps: legal pressure on compounders, reputational signaling to prescribers and patients, and induced caution by suppliers, digital intermediaries, or reimbursement actors. In a market where patients depend on alternative channels because branded supply has been unstable or unaffordable, the cumulative pressure from these combined acts can therefore function as a barrier to access.

AstraZeneca remains the clearest doctrinal anchor for this approach. Its significance is not limited to misleading submissions to regulators in the narrow historical context of supplementary protection certificates and marketing authorizations. In the broader sense, it stands for the proposition that a dominant pharmaceutical undertaking may abuse Article 102 when it instrumentalizes legal or regulatory procedures in specific ways that do not go along with competition on the merits and are capable of blocking entry. [189] When this is applied for the test campaign, that signifies a dominant manufacturer's campaign has the potential to raise EU concerns if systematically it blurs the boundary between unlawful counterfeiting and lawful compounding, or also if it presents safety and approval-status arguments in a method that is

[188] Consolidated Version of the Treaty on the Functioning of the European Union, art 102.
[189] Case C-457/10 P *AstraZeneca AB v European Commission* EU:C:2012:770.

devised to induce over-deterrence. This analogy becomes even more powerful in cases where communications are framed not just to correct specific misleading claims, but with the intention of creating a general impression that all compounded alternatives are unlawful, clinically suspect, or commercially untouchable. Recent EU pharmaceutical enforcement also displays more willingness to treat misleading safety or equivalence messaging as exclusionary when directed at the actors who determine market uptake.[190]

In such a campaign the foreclosure channels have multiple and concrete mechanisms. Litigation is able to delay or discourage expansion by compounders. Complaints and warning letters can trigger supplier or platform withdrawal. Safety-focused messaging can make prescribers and insurers more hesitant, even where the legality of compounding depends on individualized factors rather than a blanket prohibition. Reputational injury may even outlast the lawsuit itself, especially in health markets where trust and regulatory legitimacy are central. Patient confusion can further reduce access, especially if patients cannot tell the difference between an unlawful copy, a lawful compounded alternative, and a product that is simply not FDA- or EMA-approved. This is due to the fact that compounding sits outside the ordinary premarket approval model. Under Article 102, these are not just social-policy side effects, they form a key part of the foreclosure analysis itself. When more access-sensitive the background conditions such as shortage, limited substitutes, continuity-of-care needs, individualized dosing, or formulation needs, there exists the possibility of more a serious exclusionary significance of a campaign that chills lawful compounding beyond what is necessary to vindicate genuine safety or compliance concerns.

[190] European Commission, notice concerning the Teva/Copaxone decision, OJ C/2025/1680, para 3.3 (exclusionary disparagement).

4.4.3 US assessment of the same pattern

The United States starts out with a more segmented and protective framework. The first step would be to separate immunized petitioning from non-immunized commercial conduct, not to treat the campaign as a single unit. Court filings, FDA complaints, and some other requests for government action are assessed through the Noerr-Pennington/sham-litigation structure. In contrast, patient-facing advertising, website claims, representations to telehealth partners, and some forms of market messaging could possibly fall outside petitioning immunity and therefore be tested under the Lanham Act, consumer-protection, or antitrust theories as ordinary commercial conduct. That distinction matters with great importance in GLP-1 disputes because the overall pressure exerted on compounders may come from the interaction between both categories. A brand manufacturer potentially can have strong immunity arguments for its lawsuits or agency complaints while at the same time deciding on deploying aggressive non-immunized messaging about sameness, legality, or safety in ways that shape the behaviors of patients, prescribers, and intermediaries. [191]

In the component of litigation, the *Professional Real Estate Investors* case makes condemnation a difficult task to achieve. The antitrust challenger first must show that the suit was objectively baseless even before a court will examine if it was filed to use the process itself as a weapon of delay, cost, or intimidation. [192]For the context of compounding, this threshold is a genuinely demanding one. Claims about whether a compounded product is "essentially a copy," if the shortage leeway has ended, whether a dosage change or added ingredient is actually meaningful clinically, whether a telehealth-linked prescribing model is truly individualized or not, and

[191] Frier Levitt, 'Intellectual Property Challenges for 503A Pharmacy Compounding' (19 April 2024).
[192] *Professional Real Estate Investors, Inc v Columbia Pictures Industries, Inc* 508 US 49 (1993).

whether marketing language wrongly implies FDA approval or therapeutic equivalence all are legally and factually contestable. The guidance of the FDA makes it clear that both compounded drugs can serve legitimate patient needs as well as possibly presenting real safety, effectiveness, and quality concerns due to the reason they are not FDA-approved. [193] This mixed reality of regulations enables brand manufacturers to create a plausible objective-justification narrative in many cases. Even in certain instances where the commercial motive is obvious, a Lanham Act or unfair-competition action can still be too plausible to qualify as sham litigation.

That does not mean US antitrust law has nothing to say about this issue. A legitimate and serious challenge would need to have evidence that goes beyond ordinary hard-fought enforcement. Such actions such included can be repeated filings after regulators or courts have already rejected the core theory; internal documents displaying that the real aim was to end the compounded supply rather than correct specific false claims; timing that tracks closely to shortage transitions or access-sensitive moments; settlement demands with the aim for market exit rather than truthful advertising corrections; and broad communications seeking to make third parties treat all compounded supply as presumptively unlawful. If these same actors repeatedly invoke courts, agencies, and public messaging in order to increase cost and uncertainty, then a serial-campaign theory becomes more plausible even if difficult to sustain. Even though this is the case, *FTC v Shire ViroPharma* shows how fragile these claims remain in reality. Even an FTC theory that is built with serial, repetitive, and unsupported FDA-related filings failed due to the Commission proceeding under section 13(b) and thus could not show that the defendant "is" or "is about to" violate the law. [194] This case therefore serves as warning that enforcement route, remedial

[193] U.S. Food and Drug Administration, 'FDA clarifies policies for compounders as national GLP-1 supply begins to stabilize' (updated 2025).
[194] *Federal Trade Commission v Shire ViroPharma Inc* 917 F 3d 147 (3d Cir 2019).

posture, and timing can be outcome-determinative before a court reaches the full merits of the alleged exclusion strategy.

For purposes of the test case, the hard-case problem should be stated in an open manner. In pharmaceutical markets, safety narratives are not always grounds for false justification. They may in fact, reflect legitimate concerns about sterility, sourcing, dosage integrity, patient confusion, or unauthorized therapeutic claims. However, those same concerns can also be strategically useful for the firm to utilize in an anticompetitive manner. The US framework tends to protect them unless the challenger can show something close to sham, fraud, or clearly false commercial speech. That makes hybrid campaigns against compounders particularly hard to attack under Section 2, since each individual element of the campaign could retain at least some arguable legal basis even if the overall effect is clearly to reduce alternative supply during an access-sensitive period.

4.4.4 Applied takeaways for the thesis

Four propositions follow.

First, hybrid campaigns against compounders are harder than classic sham-litigation cases because they mix petitioning, commercial messaging, and genuine regulatory-compliance arguments. The real competitive harm may come from the accumulation of these steps rather than from any one plainly baseless suit.

Second, safety narratives must be taken seriously but not treated as self-validating. In this area, the same argument can be both partially true and strategically overextended. The correct task is

therefore not to dismiss safety concerns, but to test whether the campaign was targeted and proportionate or whether it was framed broadly enough to chill lawful compounding as such.

Third, the same campaign is more likely to be actionable under Article 102 than under US antitrust. EU law is more open to asking whether litigation, complaints, and communications together amount to a foreclosure strategy by a dominant undertaking. US law begins from a narrower gate: if each filing is at least arguable, antitrust liability becomes much harder to establish even where the wider campaign is commercially coercive.

Fourth, access-sensitive facts should not remain as background context. Shortage conditions, lack of substitutes, patient dependency, customization needs, and affordability constraints should be integrated into the foreclosure analysis itself. Where a manufacturer's campaign suppresses lawful alternative supply precisely when patients depend on it, the competition problem becomes more acute, not less. That proposition should carry forward into the final comparative judgment of the thesis.

4.5 Patient access and competitive effects: how should this chapter measure harm?

4.5.1 Access harms to identify and prove

This chapter will distinguish three layers of harm in the competitive process. The first one is the harm to a rival compounder. These include litigation cost, reputational damage, delayed expansion, or lost sales. That may be important evidentially, but it is not yet the central competition-law injury. The second is the harm to the competitive process: a tactic that reduces the availability, credibility, or scale of a lawful alternative supply channel that otherwise would

constrain the incumbent or fill a shortage. The third one is downstream patient-access harm: delayed treatment, loss of customized formulations, weaker price pressure, insurer or telehealth withdrawal, geographic access loss, or interruption of care. The FDA's guidance makes it clear that compounded drugs can serve important patient needs and that they may become especially important in cases when approved products are unavailable or not medically appropriate. [195]

Due to that reason, the chapter requires an explicit causal chain in 3 phases. legal or regulatory tactic, then market effect, then patient outcome. A lawsuit or complaint matters simply not since it burdens a rival, but due to the fact that it may induce wholesalers, platforms, payment processors, telehealth partners, or prescribers to disengage from a lawful compounding channel. This reaction in the market can shrink output, reduce geographic reach, or eliminate dosage and formulation options. Then, patients experience the real downstream harm: a cheaper source disappears, a customized preparation is no longer available, or continuity of treatment is broken. In shortage settings this chain is important since outsourcing facilities and other compounders function as mechanisms for resilience in the market, rather than simply acting as fringe sellers. [196]

4.5.2 Countervailing considerations: safety, quality, and regulatory integrity

A patient-access framework must not fall into an assumption that all compounding deserves protection. Some litigation and complaints genuinely protect patients from unlawful or unsafe conduct. FDA again and again emphasizes that compounded drugs are not FDA-approved, and thus risks relating to sterility, potency, labeling, or product quality arise. Likewise, EU medicine

[195] U.S. Food and Drug Administration, 'Compounding and the FDA: Questions and Answers'.
[196] Ashlee N Mattingly, 'The role of outsourcing facilities in overcoming drug shortages' (2021) 61 *Journal of the American Pharmacists Association* e110.

law treats magistral and officinal preparations as a distinct regulatory category, not as centrally authorized products. This underscores that compounding is tolerated for specific therapeutic purposes, not exempted from quality discipline. [197] Competition law should not become a way to defend poor-quality supply simply due to the fact that it costs less or it is more locally available.

The more intuitive approach is to ask whether or not the safety narrative is specific, proportionate, and tied to identifiable non-compliance, or whether it is framed in such a broad way that the result chills lawful compounding. Here, the EU and US vocabularies differentiate but the underlying question is similar. In the United States, a credible safety or deception claim may conserve protected petitioning and subdue sham-liability arguments since *PRE* requires objective baselessness before the motive becomes legally relevant. [198] In the EU, in contrast, safety arguments are not screened through petitioning immunity in the same way. The argument is weighed as possible objective justification, and can fail if the conduct is misleading, disproportionate, or part of a broader exclusionary strategy. *AstraZeneca* still remains the clearest illustration of that logic. [199]

4.5.3 Which framework is better calibrated in shortage and access settings?

The answer to this question should be qualified rather than an absolute one. If the market power is uncertain, the legality of the underlying compounding is doubtful, or safety concerns are concrete and immediate, the US framework has specific real virtues. Strong protection for petitioning reduces the risk that antitrust law will punish firms merely for going to court or

[197] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, art 3.
[198] *Professional Real Estate Investors, Inc v Columbia Pictures Industries, Inc* 508 US 49 (1993).
[199] Case C-457/10 P *AstraZeneca AB and AstraZeneca plc v Commission* EU:C:2012:770.

raising legitimate regulatory concerns in a technically complex sector. That caution matters because compounding disputes often involve mixed facts: some individualized compounding may be lawful and necessary, while some scaled activity may look much closer to commercial substitution. In those settings, the demanding US threshold helps avoid over-deterrence and preserves room for genuine compliance-driven complaints.

Even so, in shortage and access-sensitive settings the EU framework is generally better calibrated to the thesis's main concern in the normative sense. Where dominance is clear, the underlying compounding is lawful, and the evidence suggests a coordinated effort to shut down alternative supply, Article 102 can evaluate the cumulative strategy and its capability of foreclosure without first requiring proof that each individual filing was objectively baseless. That is important because the practical harm for these cases often arrives from hybrid campaigns. They involve components such as complaints, lawsuits, warning letters, public messaging, and induced caution by market intermediaries. By themselves, components may each be arguable on their own but in combination, the damage might be clearer. From an access perspective, the EU structure therefore has greater capability of recognizing that shortage severity, lack of substitutes, affordability barriers, continuity-of-care needs, and customization requirements are not background policy concerns; they are part of the competitive effect in and of itself. [200] On the most central facts for this thesis—dominant branded firms, strong strategy evidence, lawful compounding, and real patient dependence on alternative channels—the EU framework is modestly better suited to intervene before access harm hardens into enduring foreclosure.

[200] OECD, *Pharmaceutical Innovation and Access to Medicines* (OECD Publishing 2018).

This conclusion is also strengthened by the Leadiant case. Leadiant is doctrinally an excessive-pricing case not a procedural-abuse case, but still is able to demonstrate the same wider point: in access-sensitive pharmaceutical markets, EU competition law is prepared to examine whether a dominant firm's conduct forms part of an overall strategy that restricts alternative supply beyond what is necessary to pursue any legitimate commercial or regulatory objective. This is due to the fact that the Italian authority treated Leadiant as concerning a solitary, multilayered approach that affected both price and access, including the foreclosure of competing supply channels and obstructive conduct in negotiations with AIFA in a market for a life-saving medicine. Leadiant therefore supports the broader claim of this thesis that, in the EU, proportionality and patient-access effects must not be treated as external policy concerns. Instead they have to be viewed upon as portion of the valuation of whether dominant-firm conduct has developed to become abusive.[201]

4.6 Remedies, institutions, and enforcement feasibility

4.6.1 EU routes and remedies

Once a problematic campaign has been identified, EU law is able to provide the more adaptable remedial toolkit. Regulation 1/2003 allows the Commission to adopt infringement decisions that require the conduct to end, impose proportionate behavioral or structural remedies, order interim measures in urgent cases, and make commitments binding. Additionally, the same regulation

[201] Autorità Garante della Concorrenza e del Mercato (AGCM), Provvedimento n 30156, A524 – *Leadiant Biosciences/Farmaco per la cura della xantomatosi cerebrotendinea* (17 May 2022).

also gives national competition authorities the capacity to require an infringement to cease, order interim measures, accept commitments, and impose penalties under national law. [202] In the compounder-targeting setting, that institutional design has relevance because litigation, authority complaints, and market-facing disparagement can be addressed as one Article 102 matter rather than artificially split into isolated legal episodes.

The decisive EU advantage in shortage or continuity-of-care settings is the speed of the processes. If there is access to lawful compounded supply that is currently being chilled in real time, a fine imposed months or even years later does little for patients whose treatment has already been interrupted. Interim measures from Article 8 are precisely built for this type of urgency, and a 2024 report by the Commission on interim measures stresses that they look to preserve competition at the same time that an antitrust investigation is still ongoing. [203]For this context, the most useful remedies oftentimes would be behavioral- not punitive: temporary suspension of overbroad complaints, correction of misleading statements about the legal status of lawful compounding, transparency obligations clarifying exactly which products or claims are challenged, and non-retaliation or standstill obligations toward suppliers, platforms, or intermediaries while the legality question is being resolved. Even with these behavioral remedies, the design must still be precise. The Commission's 2025 ex post study discovered that purely behavioral remedies were less likely than other remedies to be both fully implemented

[202] Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty.
[203] European Commission, 'The Report on the legal framework for and the use of interim measures by national competition authorities', on the ECN+ Directive page (5 September 2024).

and effective, which suggests that any correction, transparency, or non-disparagement package would still need monitoring, reporting, and a tightly defined scope. [204]

4.6.2 US routes and constraints

The US position is more fragmented as compared to the EU position. A compounder, outsourcing facility, or intermediary, in principle, can bring a Sherman Act section 2 counterclaim or separate private antitrust suit, including for injunctive relief. However, private plaintiffs still have to satisfy the ordinary requirements of private enforcement, including antitrust injury, and then overcome Noerr-Pennington immunity and the demanding *PRE* sham-litigation threshold. This means that private enforcement is available, but it is difficult structurally: the target of the brand manufacturer's Lanham Act or unfair-competition suit may be best placed to gather evidence of motive, timing, and strategic intent. Yet, it must still translate that record into a fully pleaded monopolization case rather than merely showing aggressive brand enforcement.

FTC enforcement in theory appears broader than it often is in practice. The FTC's 2022 Section 5 policy statement states that Section 5 reaches beyond the Sherman and Clayton Acts, but the agency's own enforcement overview still reflects a two branched design: Section 5(b) remains the traditional administrative cease-and-desist route, while Section 13(b) is the direct-to-court injunction route and, for competition matters, has been used primarily for preliminary merger relief.[205] For petitioning-heavy campaigns against compounders, that institutional structure is just

[204] European Commission, 'Ex-post economic evaluations' (2025 study on the effectiveness of EU antitrust remedies).
[205] Federal Trade Commission, *Policy Statement Regarding the Scope of Unfair Methods of Competition Under Section 5 of the Federal Trade Commission Act* (10 November 2022).

as important as doctrine. Oftentimes, administrative proceedings will be too slow to preserve patient access during a live shortage. Court proceedings under Section 13(b) are generally faster, but *FTC v Shire ViroPharma* shows that they have the ability to fail before the sham-petitioning theory is ever adjudicated if the Commission cannot plead that the respondent "is violating" or "is about to violate" the law, rather than merely having engaged in strategic petitioning in the recent past. [206]

The practical consequence of these reasons is that the US system is constrained at three levels at once. First, immunity doctrine screens out much of the petitioning conduct. Also, private plaintiffs face antitrust-injury and proof burdens even after immunity is overcome. In addition, the agency forum choice can narrow the remedy before the merits are reached. Section 5 still has the ability to be useful where the campaign includes ongoing, non-immunized commercial misrepresentations to patients, telehealth partners, or prescribers. But in the circumstances where the exclusionary pressure is driven mainly by lawsuits and regulatory complaints, the realistic enforcement path is much narrower than the abstract breadth of "unfair methods of competition" might suggest.

4.6.3 What remedy package would actually help compounders and patients?

The remedy package that would actually help compounders and patients therefore goes beyond fines and damages. In access-sensitive markets, the most useful interventions are faster and more information-correcting: rapid filters for repetitive or misleading complaints, temporary standstill obligations preventing overbroad withdrawal demands to suppliers or digital platforms, correction or withdrawal duties for statements that conflate lawful compounding with unlawful

[206] *FTC v Shire ViroPharma Inc* 917 F 3d 147 (3d Cir 2019).

copying, and disclosure obligations specifying exactly which formulations, claims, or marketing practices are alleged to be unlawful. Those measures are more directly responsive to the way foreclosure happens in these markets, namely through chilled dealing, reputational contamination, and patient confusion before any final adjudication occurs.

Just as importantly, remedies should preserve only lawful compounding. The point is not to immunize unsafe or non-compliant conduct, but to stop dominant firms from using procedural and informational pressure to suppress legitimate alternative supply. That makes coordination between competition authorities and medicines regulators especially important. The best remedy package is therefore conditional and targeted: preserve access while legality is tested, correct misinformation quickly, separate genuine safety review from commercial foreclosure strategy, and intervene early enough that lawful supply is not extinguished before the case ends. That conclusion provides the bridge to Chapter 5, where the thesis turns from comparative diagnosis to institutional design.

4.7 Synthesis: a practical comparative assessment framework for future compounder disputes

This chapter's main reusable output is a real-world framework for future disputes involving litigation or regulatory complaints against compounders. It is intended to be functional rather than purely formal. The core question is not simply whether a branded firm sued, complained to a regulator, or issued a public warning. The better question is whether the overall conduct restricted lawful alternative supply in a way that mattered for patient access.

Step 1: Define the product, channel, and access setting. The analysis should start by identifying the approved product, the compounded alternative, and the conditions under which compounding

is occurring. Shortage, customization, dosage differences, formulation needs, and continuity-of-care concerns are all relevant at the beginning for the reason that they determine whether compounding is functioning as a marginal substitute or as a clinically important access channel.

Step 2: Map the conduct bundle. The subsequent step is to define the campaign as a whole: litigation, agency complaints, pharmacy-board complaints, cease-and-desist letters, threats to suppliers or platforms, denigration, and public messaging about safety, approval status, or deception. Hybrid strategies should be studied as bundles instead of being artificially separated into isolated acts.

Step 3: Choose the doctrinal entry point by system. In the EU, the entry point is Article 102 and the question whether the conduct forms part of a broader exclusionary strategy, with *ITT Promedia* supplying the narrower threshold for litigation as such and *AstraZeneca* illustrating how misleading regulatory conduct itself may become abusive. In the United States, the first gate is usually Noerr-Pennington and *Professional Real Estate Investors*, with serial petitioning, adjudicative misrepresentation, *Walker Process*, and sometimes Section 5 operating as narrower channels around immunity.

Step 4: Test market power and dependency. The framework should then ask whether the branded undertaking is dominant or has monopoly power, and if compounders, telehealth-linked channels, prescribers, or patients are dependent on alternative supply because substitutes are weak, delayed, or practically unavailable.

Step 5: Evaluate conduct quality. Not all aggressive enforcement is abusive. The analysis should ask whether the conduct was misleading, manifestly unfounded, repetitive, disproportionate, or strategically sequenced. Timing, internal documents, settlement posture, and inconsistency

between public justification and private strategy may be especially probative where each individual act is arguable on its own but more troubling in combination.

Step 6: Map foreclosure and patient-access effects. The chapter should require a clear causal chain: tactic, market effect, patient outcome. Relevant effects include delayed expansion, supplier or platform withdrawal, insurer hesitation, chilled prescribing, shortage persistence, loss of customized formulations, weaker price pressure, and reduced geographic availability. Harm to a rival is relevant, but the central question is whether lawful supply and patient access were materially degraded.

Step 7: Check objective justification and the strength of the safety case. Safety and compliance concerns must be taken seriously. The decision-maker should ask whether there are specific and evidenced concerns about sterility, sourcing, labeling, or deceptive promotion, or whether safety language is being used in a broader and more pretextual way to suppress lawful compounding beyond what is necessary.

Step 8: Match remedy and forum to the practical problem. Finally, the framework should ask what interventions would actually preserve access. If the harm is urgent, interim or injunctive relief matters more than later fines or damages. If the problem lies in reputational contamination or third-party withdrawal, correction, transparency, standstill, or carefully targeted behavioral obligations may be more useful than ex post monetary sanctions alone.

This framework is deliberately modest. It does not assume that branded complaints are unlawful, nor that compounders should be insulated from quality control. Its value is that it forces the analysis to hold together product setting, conduct bundle, legal doctrine, market structure, safety evidence, and patient effects in one sequence. That makes it reusable not only for the GLP-1

disputes discussed in this thesis, but for future cases in which lawful compounding becomes an access channel and is then challenged through litigation, regulatory process, or coordinated commercial pressure.

4.8 Conclusion and transition to Chapter 5

Chapter 4 yields a qualified but clear comparative conclusion. EU law is institutionally and doctrinally more flexible in addressing hybrid campaigns that combine litigation, regulatory complaints, and market-facing pressure. Once dominance is established, Article 102 allows courts and authorities to evaluate cumulative conduct, misleading use of procedures, and capability of foreclosure without requiring proof that every individual step was wholly baseless. By contrast, US law begins from a stronger presumption in favor of petitioning. Noerr-Pennington and *PRE* make antitrust condemnation difficult where litigation or agency engagement has at least some objective basis, and *Shire ViroPharma* shows that forum choice and remedial posture may narrow enforcement even before the merits of a sham theory are reached.

This does not mean the EU model is always preferable. The US framework better protects bona fide resort to courts and agencies and reduces the risk that antitrust law will chill genuine safety or compliance complaints in a technically complex sector. Yet in the disputes most central to this thesis—where lawful compounding operates during shortage, customization, or other access-sensitive conditions—the EU framework is generally better calibrated to intervene before exclusionary strategy hardens into sustained access harm. FDA's own compounding materials confirm both sides of that tension: compounded drugs can serve important patient needs, but they

also raise real quality and safety concerns. Chapter 5 therefore proceeds from a double premise: neither system fully closes the protection gap on its own, and more precise guidance, stronger coordination between competition authorities and medicines regulators, faster intervention, and access-sensitive remedies are needed if law is to protect both lawful compounding and patient welfare.

Chapter 5 – Conclusions and policy recommendations

5.0 Chapter aim, contribution, and roadmap

The goal of Chapter 5 is to translate the doctrinal and comparative analysis that was developed in Chapters 1–4 into material policy conclusions. Its contribution is not simply to review and summarize the case law, but additionally, to identify the cases where existing EU and US competition/antitrust frameworks leave open practical gaps in instances when pharmaceutical firms use litigation in regulatory or IP procedures ways that affect compounding pharmacies and, ultimately, patient access to medicines. To build on Chapter 1's account of the regulatory vulnerability of compounding, Chapters 2 and 3's analysis of Article 102 TFEU, Section 2 Sherman Act, and Section 5 FTC Act, and Chapter 4's comparative assessment, this chapter will ask the question of what each system should do differently if competition law is to respond more effectively to exclusionary conduct in regulated pharmaceutical markets. This will be determined through five main steps. First, the step is to diagnose the main enforcement and policy gaps revealed by the thesis. Then, it describes recommendations for EU law and enforcement, followed by recommendations for US antitrust law and agency practice. A comparative section then extracts the broader lessons on institutional design, evidentiary thresholds, and coordination with medicines regulators. The chapter closes by giving a direct answer to the primary research question and restating the balance that should be struck between patent protection, lawful regulation, and patient access through compounding.

5.1 Diagnosing the remaining gaps after Chapters 1–4

5.1.1 Introduction

The first 4 chapters suggest that the main issue is not the absence of legal tools, rather a recurring mismatch between the way competition law identifies exclusion and the way pharmaceutical regulation structures market access. EU and US law are able to already condemn specific forms of abusive conduct, particularly in the instances when a dominant or monopolistic firm deploys legal, regulatory, or communications strategies as part of a more broad exclusionary scheme. Still, the prior chapters also display the fact that the conduct most harmful to compounding pharmacies is often procedurally complex, facially lawful, and capable of inflicting damage before any final merits decision is reached. Due to that reason, the recommendations that follow do not require a large-scale redesign of Article 102 TFEU, Sherman Act § 2, or FTC Act § 5. Instead they call for specific reforms: clearer thresholds, better evidentiary guidance, and closer coordination with medicines regulators in the specific settings where compounding and patient access are most exposed.

5.1.2 Competition law and medicines regulation do not line up neatly

A core issue is that competition law and medicines regulation are based upon different institutional logic. Competition law is typically meant to intervene ex post with the goal to assess market power, exclusion, and competitive effects. In contrast, medicine regulations continuously govern authorization, compounding exemptions, shortages, dispensing, and safety. [207] The issue lies that in the pharmaceutical markets, the same conduct may appear as ordinary regulatory

[207] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [2001] OJ L311/67, art 3;
Food, Drug, and Cosmetic Act 1938 and Drug Quality and Security Act 2013, including the Compounding Quality Act, 21 USC §§ 353a–353b.

participation, IP enforcement, or an exclusionary strategy depending on the surrounding facts and incentives. A refusal to supply, a warning letter, a complaint to a medicinal authority, or a challenge to a compounder's practices may be framed as lawful rights-enforcement while simultaneously having a dual purpose to function to delay or chill rivalry. Compounding disputes sit at this exact boundary because frequently, the argument turns to narrow regulatory carve-outs and claims about whether a pharmacy is addressing genuine patient need or unlawfully substituting for an authorized medicine. A simple binary between "competition" and "regulation" is therefore inadequate to compare.

5.1.3 Why compounding pharmacies remain structurally vulnerable

The nature of compounding pharmacies remains structurally fragile even in the space where the law recognizes awful compounding. Their legal exceptions are narrow, the scale and litigation budgets are often limited, and commonly have to depend on upstream suppliers, wholesalers, PBMs, prescribers, and professional trust to survive. [208] This combination makes them very vulnerable to strategies that raise rivals' costs before any authority decides the merits. Repeated complaints, denigrating communications, IP threats, or pressure on supply and reimbursement channels may unsettle trading partners, deter prescribers, and consume the resources of compounders long before a court or regulator reaches a final view. The access stakes are unusually high because compounding often matters most where ordinary pharmaceutical supply performs poorly: shortages, pediatric dosing, orphan uses, and other settings in which authorized medicines are unavailable, unsuitable, or not supplied on reasonable terms.

[208] Kumar, 'Compounding Inequities Through Drug IP and Unfair Competition' (*Washington University Law Review*, forthcoming);

5.2 Recommendations for the EU

5.2.1 Clarify Article 102 enforcement against authority-facing deception and regulatory manipulation

Reform for the EU should not begin with a new category of pharmaceutical abuse, instead clarify the way Article 102 applies to authority-facing deception and regulatory manipulation. The doctrinal tools needed to distinguish competition on the merits from procedural misuse already is contained in Article 102. [209] AstraZeneca is still the central authority: the main importance was not that the undertaking used patent and marketing-authorization procedures, but that it did so with misleading representations and through regulatory maneuvering that has the effect of making generic entry and parallel trade more difficult. [210] Servier supports the supporting point that pharmaceutical exclusion often has strategic and accumulative elements, therefore authorities should examine how each separate procedural step fits in an overall plan to delay rivalry as opposed to isolating each act from its commercial setting. [211]On the basis of that information, the Commission and national competition authorities should articulate and develop a clear practical framework that asks four core questions: what representation or procedural move was made; why it was misleading or manipulative in context; what precise foreclosure mechanism it activated; and how the evidence links that mechanism to downstream market exclusion. Timing, internal documents, foreseeable effects, and the relationship between

[209] Consolidated Version of the Treaty on the Functioning of the European Union [2012] OJ C 326/47, art 102.
[210] Commission Decision of 15 June 2005 relating to a proceeding under art 82 EC and art 54 EEA (Case COMP/A.37.507/F3 – *AstraZeneca*) [2006] OJ L 332/24;
[211] Commission Decision of 9 July 2014 relating to a proceeding under arts 101 and 102 TFEU (Case AT.39612 – *Perindopril (Servier)*) [2016] OJ C 393/7;

regulatory delay and market closure should all have relevance for these questions. [212] This keeps Article 102 narrow enough to respect legitimate regulatory participation. It would not penalize aggressive but truthful use of public procedures, instead, the smaller class of cases in which deception or manipulative procedural design substitutes for product-based rivalry would be targeted.

5.2.2 Keep a high threshold for pure litigation, but scrutinize hybrid campaigns against compounders

However, at the same time, EU law should still be able preserve a high threshold for pure litigation claims. ITT Promedia is correct in order to protect recourse to courts except in exceptional circumstances, since the purpose of competition law should not be to turn ordinary IP, regulatory, or unfair-competition suits into abuse whenever a dominant undertaking litigates hard or ultimately loses. [213] The particularness in pharmaceutical markets, however, is the fact that exclusionary pressure oftentimes emerges via hybrid campaigns, not stand-alone proceedings. Roxtec, even though it sits outside the pharmaceutical sector, is very analytically useful, displaying how litigation, trademark-related maneuvers, and denigratory communications may operate as mutually reinforcing parts of a single foreclosure strategy. [214] For compounding pharmacies, the identical logic should apply. Since they operate in a narrow room they have to follow, their reputational position with prescribers and regulators is fragile, causing even undetermined allegations about legality or safety to chill demand, trigger additional compliance costs, or push hospitals and pharmacists toward withdrawal before a court has concluded the

[212] Richard Whish and David Bailey, *Competition Law* (OUP);
[213] Case T-111/96 *ITT Promedia NV v Commission* EU:T:1998:183, paras 55–60.
[214] Autorità Garante della Concorrenza e del Mercato, Case A538 – *Sistemi sigillanti multidiametro per cavi e tubi (Roxtec)*, decision published in *Bollettino* n 31/2023.

case.[215] EU authorities should question whether letters, complaints, warnings, professional communications, and court actions were sequenced in a strategic way with the goal to raise rivals' costs or to deter lawful compounding. The threshold should still remain with discipline: that not every safety warning, complaint, or infringement action is abusive. But in the cases where the conduct is misleading, disproportionate, and designed to exploit regulatory fragility rather than to vindicate a genuine right, Article 102 has to be capable of responding well.

5.2.3 Coordinate Article 102 enforcement with medicines regulators and make lawful compounding visible in access policy

The third main point is that Article 102 enforcement in this field should be coordinated in a closer manner than with medicines regulators. The reason, already visible from Chapter 1, is that lawful compounding in the EU occupies a narrow and access-sensitive legal space. Directive 2001/83/EC excludes magistral and officinal preparations from the ordinary marketing-authorization regime, but only within the spaces of tightly bounded conditions that are worked out through laws of the national pharmacy and medicines. [216] That makes safety, authorization, and substitution arguments unusually easy to weaponize for disputes of competition. When a dominant undertaking decides to make a claim that a compounded alternative is "unapproved", unsafe, or an illegitimate substitute, competition authorities should obtain technical input from the competent medicines authority before treating those assertions as self-proving. The role of regulators should involve a more clear communication in instances when compounding is lawful and necessary, safety concerns are genuinely evidence-based, and when hospitals or prescribers

[215] Shweta Kumar, 'Compounding Inequities Through Drug IP and Unfair Competition' (2024) 102 *Washington University Law Review* (forthcoming).
[216] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [2001] OJ L 311/67, arts 3(1)–(2), 5.

receive statements that are misleading in context. Remedies should therefore be access-sensitive as well as deterrent. Therefore, Article 102 enforcement should consider corrective communications, withdrawal of misleading professional guidance, non-discrimination obligations in dealings with pharmacies or hospitals, and commitments that reduce avoidable regulatory uncertainty. That would not reduce competition law into simply another form of medicines regulation; it would instead ensure that lawful compounding stays visible as part of the medicines system's safety valve, especially in the areas where patient access is already fragile. Leadiant briefly confirms this point. Although normally deliberated as an excessive-pricing case, it can confirm as well how regulatory positioning and control over access pathways are able to affect compound preparation and patient access. This is strengthening the need to have closer coordination between competition authorities and medicines regulators.[217]

5.2.4 The EU pharmaceutical reform supports, but does not replace, competition-law coordination

In addition, that recommendation should now be read against the background of the ongoing overhaul of EU pharmaceutical legislation. The current reform package moves in the same general direction as this thesis in one important respect: it is increasingly focused on patient access, shortages, and security of supply, and the negotiating texts have treated the magistral and officinal formula exemptions as matters requiring clarification rather than disappearance. [218] At the same time, the reform does not remove the core problem addressed here. The Commission

[217] Autorità Garante della Concorrenza e del Mercato (AGCM), Provvedimento n 30156, A524 – *Leadiant Biosciences/Farmaco per la cura della xantomatosi cerebrotendinea* (17 May 2022).
[218] Council of the European Union, 'Pharma package: Council agrees its position on new rules for a fairer and more competitive EU pharmaceutical sector' (4 June 2025); Council of the European Union, 'Pharma package: Council and Parliament reach a deal on new rules for a fairer and more competitive EU pharmaceutical sector' (11 December 2025, updated 6 March 2026).

proposal retained the exclusion of magistral and officinal preparations from the ordinary marketing-authorisation regime, and their practical boundaries remain heavily dependent on national pharmacy and medicines law. [219] Nor does the package itself provide a competition-law response to strategically sequenced litigation, denigration, or regulatory/IP pressure directed at compounders. The same is true of the proposed Critical Medicines Act, which complements the reform by strengthening shortage management and supply resilience, but not by addressing procedure-based exclusion. [220] Accordingly, the ongoing overhaul partly supports this proposal's access-sensitive orientation, but it does not eliminate the need for structured coordination between competition authorities and medicines regulators where the legality, safety, or substitutability of compounded medicines is contested.

5.3 Recommendations for the US

5.3.1 Narrowly but more realistically police sham litigation and regulatory abuse

US antitrust law should respond more in a more realistic way to pharmaceutical procedural abuse, but it needs to make sure to not dilute genuine petitioning immunity. A good approach would be to not to weaken Noerr–Pennington, but instead recognize that pharmaceutical exclusion often will operate with a sequence of legal and regulatory steps instead of one obviously baseless lawsuit. As a summary, Noerr and Pennington protect genuine petitioning; PRE sets a demanding test for a single sham suit; California Motor Transport shows that a pattern of repetitive, baseless resort to adjudicative processes may fall outside immunity; and

[219] Proposal for a Directive on the Union code relating to medicinal products for human use, COM(2023) 192 final, art 2(5)(a)-(b)
[220] European Commission, 'Commission proposes new rules to ensure stable supply of critical medicines' (11 March 2025).

Walker Process confirms that the enforcement of a patent procured by fraud can, with the other elements of monopolization, trigger antitrust liability. The inference for cases in the pharmaceutical sector is that courts and agencies not ask only whether one complaint, citizen petition, or warning letter was objectively weak. They should also ask whether a strategically sequenced campaign of lawsuits, regulatory filings, public safety allegations, and professional complaints had capability of delaying entry or raising rivals' costs. FTC v Shire ViroPharma is relevant here: the Third Circuit rejected the FTC's chosen procedural route under section 13(b), but did not hold that serial FDA-facing petitioning is categorically immune from antitrust scrutiny. [221] For compounding pharmacies, this pattern analysis has relevancy due to the fact that reputational and regulatory pressure may chill market participation much before any merits ruling is reached.

5.3.2 Use Section 5 FTC Act more confidently where conduct falls short of Section 2 monopolization

The second recommendation is to use Section 5 FTC Act more confidently where conduct distorts the competitive process but does not fit neatly within classic Section 2 monopolization doctrine. That does not mean turning Section 5 into a free-floating fairness rule. It means using the statute for what it was designed to do: address unfair methods of competition that threaten competitive conditions even when proof of monopolization, dangerous probability, or a conventional refusal-to-deal theory is difficult. The FTC's 2022 policy statement expressly says that Section 5 reaches beyond the Sherman and Clayton Acts and targets methods of competition

[221] *FTC v Shire ViroPharma Inc* 917 F3d 147 (3d Cir 2019).

that avoid rivalry on the merits while tending to reduce competition. [222] In pharmaceuticals, the agency has already moved in this direction by treating improper Orange Book (*Approved Drug Products with Therapeutic Equivalence Evaluations*) listings as a potential Section 5 problem and by coordinating with FDA to challenge listings that may trigger automatic regulatory delay and deter lower-cost entry. [223] The same logic should be extended to procedural campaigns directed at smaller access-sensitive actors. Compounding pharmacies may face cumulative pressure from legal threats, regulatory ambiguity, and allegations about safety or authorization even when no single act cleanly satisfies Section 2. Section 5 is therefore the better tool for identifying and prioritizing pharmaceutical procedural abuse as an unfair method of competition, provided that enforcement remains tied to competitive distortion rather than mere commercial aggressiveness

5.3.3 Better integrate antitrust analysis with FDA/regulatory context and the legal status of compounding

Finally, antitrust analysis in this area should be integrated more closely with the FDA framework governing compounding. Under the FDCA as amended by the Drug Quality and Security Act, section 503A governs traditional patient-specific pharmacy compounding, and section 503B governs outsourcing facilities subject to stronger federal oversight. The FDA is also explicit to recognize the fact that compounded drugs are not FDA-approved, but they still may serve important patient needs, and in specific circumstances, may be prepared when approved drugs

[222]Federal Trade Commission, *Policy Statement Regarding the Scope of Unfair Methods of Competition Under Section 5 of the Federal Trade Commission Act* (10 November 2022).
[223] Federal Trade Commission, *Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book* (14 September 2023); Federal Trade Commission, *FTC Challenges More Than 100 Patents as Improperly Listed in the FDA's Orange Book* (7 November 2023).

are medically inappropriate for a patient or appear on a shortage list. [224] This mixed framework is exactly the reason why antitrust enforcers and courts have to resist treating labels such as "unapproved", "unsafe", or "non-personalized" as self-proving justifications for exclusionary conduct. Yes, those descriptions may be legally relevant, but they can additionally be deployed strategically in ways to obscure the real line between lawful compounding, non-compliant compounding, and ordinary commercial rivalry. The recent Eli Lilly litigation against Strive and Empower illustrates this point well. Lilly alleged that the pharmacies falsely marketed compounded tirzepatide products as personalized, clinically tested, or superior to "Big Pharma" offerings. One question is whether those claims are lawful, but it also shows how advertising law, compounding law, safety discourse, and competitive steering have a possible result of being entangled in a single dispute. [225] This is an important reason why the US antitrust policy should distinguish more carefully between genuine patient-protection interventions and strategic use of regulatory ambiguity, while still recognizing compounding as a limited but important safety valve when approved supply is inadequate or unsuitable.

5.4 Comparative lessons and cross-cutting proposals

5.4.1 The EU is stronger on procedural abuse; the US is stronger on protecting petitioning rights

The comparisons developed in Chapters 2–4 suggest that institutionally, the EU framework has more willingness to treat misleading regulatory conduct, denigration, and bundled procedural strategies as exclusionary abuse where they are used by a dominant firm to obstruct market

[224] FDA, *Compounding and the FDA: Questions and Answers*;
[225] *Eli Lilly and Company v Strive Pharmacy LLC*, No 1:25-cv-00401 (D Del, filed 1 April 2025); *Eli Lilly and Company v Empower Clinic Services, LLC*, No 2:25-cv-02183 (D NJ, filed 1 April 2025).

access. This framework is displayed through the three main cases we discussed in Chapter 2. AstraZeneca, together with the broader strategy analysis reflected in Servier and the more practice-oriented reasoning of Roxtec, show a readiness to examine the exclusionary logic of an overall campaign instead of isolating each procedural step from its context in the market. In contrast, US antitrust law gives stronger presumptive protection to litigation and petitioning through the Noerr–Pennington doctrine and its narrow exceptions. Even though the Walker Process and sham-litigation doctrine leave room for intervention, the threshold for resonating a firm conducting abusive action remains high. The case FTC v Shire ViroPharma helps to illustrate the realistic difficulty of challenging serial regulatory petitioning in pharmaceutical markets. Overall, the conclusion is that neither model is wholly sufficient on its own. The EU has a risk for uncertainty if the boundary between legitimate enforcement and abusive process is not clearly articulated, while the US has a risk to under enforce if the strategic recourse to legal and regulatory procedures inflicts exclusionary harm before any final adjudication. These tensions are especially visible in disputes involving compounders, where the conduct often lies in an area in between lawful rights enforcement and exclusionary market strategy.

5.4.2 The real policy challenge is institutional coordination, not doctrinal reinvention

The central lesson of the comparison is not that either system requires sweeping doctrinal reinvention. Rather, the more important gap is institutional sense. For both jurisdictions, competition/antitrust law and medicine regulation do not always communicate in an efficient manner when legal procedures are used strategically in access-sensitive pharmaceutical markets.

[226] This signifies that both systems need better ways to distinguish genuine safety, authorization, and legality concerns from claims deployed to raise rivals' costs or chill lawful competition. That is particularly of value in relation to compounding, since the legality and clinical role of compounded medicine depends on a detailed regulatory framework rather than on abstract assumptions about what counts as an "approved" or "safe" product. [227] The cross-cutting proposal of this thesis is therefore a modest yet important one: competition authorities, courts, and medicines regulators should coordinate more closely when assessing procedural strategies that affect pharmacy compounding and patient access. Compounding pharmacies should be treated as relevant market actors in this inquiry, not as marginal anomalies, because in both the EU and the US they may function as limited but important safety valves where authorized supply is unavailable, unsuitable, or strategically disrupted.

5.5 Final answer to the research question

The answer to the main research question is therefore qualified but clear. EU and US competition/antitrust rules do address sham litigation and abuse of regulatory or IP procedures by pharmaceutical firms, but neither framework is fully adequate where such conduct affects compounding pharmacies and patient access to medicines. The EU system is comparatively better equipped to reach misleading regulatory conduct and strategically bundled procedural behavior under Article 102, especially after AstraZeneca and the strategy-based reasoning reflected in Servier and, at national level, Roxtec. The US framework is more constrained.

[226] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [2001] OJ L 311/67, arts 3 and 5; Federal Food, Drug, and Cosmetic Act 1938, 21 USC §§ 353a–353b.

[227] Drug Quality and Security Act, Pub L No 113-54, 127 Stat 587 (2013)

Sherman Act § 2, FTC Act § 5, and Walker Process can in principle reach exclusionary conduct, but Noerr–Pennington and the narrow sham exception make intervention difficult unless petitioning is objectively baseless or clearly fraudulent; FTC v Shire ViroPharma illustrates both the antitrust concern and the practical limits of enforcement.

Both systems also understate the structural vulnerability of compounding pharmacies. Because compounders operate within narrow legal carve-outs and access-sensitive settings, procedural pressure may reduce competition and patient access in shortage, personalized-treatment, and continuity-of-care contexts before any final ruling is reached. Recent Eli Lilly suits against Strive and Empower show how safety claims, legality arguments, and competitive steering can become entangled in practice. In conclusion, the preferable response is not to weaken legitimate patent, litigation, or regulatory rights, but instead articulate clearer standards for procedure-based exclusion and stronger coordination with medicine regulators so that lawful rights-enforcement is distinguished from strategic conduct that suppress lawful compounding and undermine patient access.

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