Parallel Trade in Pharmaceutical Products within the European Economic Area

- A legal and economic inquiry

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Abstract

Herein follows an examination of the current legal status of parallel trade in pharmaceutical products within the EEA. It adopts a de lege ferenda perspective to the current legal regime and concludes that the overall consequences of parallel trade in pharmaceuticals are undesirable under current market conditions with regard to European integration, consumer welfare and investment in innovation. This conclusion follows an analysis based on basic economic theory and economic studies targeting parallel trade. The most pertinent reason behind this outcome is the presence of national pricing regulations for pharmaceuticals, which results in vast price discrepancies between Member States. These price disparities are not shown to constitute any problems in themselves, because the prices often reflect inter alia the relative purchasing power of the Member State and thus seem legitimate. The situation does however prove to result in problems in context of the principle of free movement of goods, namely because the situation provides for unlimited arbitrage opportunities resulting in distorted resource allocations. Basic and very conceptual policy recommendations are presented to suggest exempting certain medicinal products from the substantive rules that make parallel trade possible within the Internal Market.
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## Abbreviations

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<th>Description</th>
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<tbody>
<tr>
<td>CJEU</td>
<td>Court of Justice of the European Union</td>
</tr>
<tr>
<td>ECJ</td>
<td>European Court of Justice</td>
</tr>
<tr>
<td>EEA</td>
<td>European Economic Area</td>
</tr>
<tr>
<td>EFPIA</td>
<td>European Federation of Pharmaceutical Industries and Associations</td>
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<tr>
<td>EFTA</td>
<td>European Free Trade Association</td>
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<tr>
<td>EU</td>
<td>European Union</td>
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<tr>
<td>FTMD</td>
<td>First Trade Mark Directive</td>
</tr>
<tr>
<td>GDP</td>
<td>Gross Domestic Product</td>
</tr>
<tr>
<td>R&amp;D</td>
<td>Research and Development</td>
</tr>
<tr>
<td>TFEU</td>
<td>Treaty on the Functioning of the European Union</td>
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<tr>
<td>TMD</td>
<td>Trade Mark Directive</td>
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1 Introduction

1.1 Background and introduction to the main issues

Parallel trade in pharmaceuticals has been subject to keen debate for decades. Significant price discrepancies between different geographic markets for pharmaceutical products open the doors for arbitrage opportunities for parallel import businesses. These price disparities are due to national pricing policies and regulations rather than market pricing by means of effective competition.

Representatives of the parallel traders claim that parallel importation reduces prices and increases availability of drugs for the consumers and patients while converging prices between different geographic markets and thereby harmonizing the markets for pharmaceutical products.

Representatives of the pharmaceutical industry, on the other hand, claim that parallel trade (or “gray market trade”) is nothing more than free riding, or piggy-backing, on pharmaceutical companies’ profits and thereby condemning innovation by reducing the ability and willingness to invest in research and development (“R&D”), while at the same time distorting the supply chain of drugs in low-price countries, which makes availability of certain drugs uncertain for patients.

Meanwhile, patients and society as a whole have an interest in low prices for medicinal products because they jointly pay the healthcare bills, and pharmaceutical products constitute a measurable portion of total healthcare costs.¹ At the same time, patients, society, the healthcare sector and the pharmaceutical industry all benefit from innovative and safe healthcare and a rapid and qualitative development of pharmaceutical products. These interests – low prices vs. high levels of innovation – are somewhat inconsistent, because most R&D in the pharmaceutical sector is financed by – and hence most

¹ Based on a non-weighed average from 20 EU and EFTA countries, in the year 2012,
commercial risk is borne by – private research companies.\(^2\) This is problematic, because commercial research activities are high risk operations so to attract investments to finance R&D enterprises, investors and other stakeholders must be able to yield profits if the research activities are successful. Otherwise, incentives to invest in research will be starved, because there are decades of accumulated development costs behind every new drug that reaches the market, and these costs must be recouped by profit.\(^3\)

While the stakeholders are arguing to improve their positions on the market, the legal debate is paralyzed by the issues of balancing the different interests at stake.

### 1.2 Scope and objectives of this paper

This paper will provide a legal and economic inquiry on parallel trade with pharmaceutical products within the European Economic Area (“EEA”). The purpose is to determine to what extent it would be realistically possible for a proprietor to oppose parallel trade in its products under current EU internal market law and intellectual property law – specifically trade mark law. To fulfill this objective, the current legal situation will be presented by providing an overview of relevant legislation, highlighting doctrine and analyzing relevant case law.

The aim of this work is also to provide a de lege ferenda perspective to the issues, by analyzing the identified problems using economic theory with the

\(^2\) Altogether, in the EU the private sector finances slightly less than two thirds of total R&D expenditure and the public sector slightly more than one third; European Commission, *Innovation Union Competitiveness Report 2011*, page 73 ff. The figures are similar to the data from the United States, where in 2007, the private sector financed 58% of R&D, the federal government 33% and the rest was financed by private donations and foundations; Dorsey, E. Ray et al., *Funding of US Biomedical Research, 2003-2008*, The Journal of the American Medical Association, Vol. 303, No. 2, pp. 137-143.

\(^3\) In 2012, the average time to develop a new drug was 12 years, and the average cost was EUR 1,172 billion. Furthermore, only about one in 10,000 substances that are synthesized in laboratories will pass all the development stages to finally reach the market. The European Federation of Pharmaceutical Industries and Associations, *The Pharmaceutical Industry in Figures – Key Data*, 2013.
The main question as regards the *de lege ferenda* issue can be defined as follows:

- Does parallel trade in pharmaceuticals result in benefits that actually accrue to patients and society, or is it merely a practice that exploits the legal principle of exhaustion of intellectual property rights to the ultimate benefit of short-term opportunists?

1.3 Delimitations

The scope of this paper will cover Internal Market aspects and intellectual property, with emphasis on trade mark rights, and will thus not consider competition law or situations of limiting parallel trade by refusal to supply products, or other actions involving illegal abuse of a dominant position. It will be necessary to mention the impacts of EU competition law to some extent, especially the demarcation between intellectual property rights and free competition, however it would be unworkable to include all market aspects and a pure analysis under Article 101 or 102 of the Treaty on the Functioning of the European Union (“TFEU”) will therefore fall outside the scope of this paper.

1.4 Method and materials

Traditional legal research methods will be applied in this paper, with the purpose of identifying, interpreting and systemizing the current legal status of parallel trade in pharmaceuticals. In the legal method relating to EU law, case law from the CJEU is of great importance, especially the jurisprudence of the
ECJ. This is because the treaty articles are concise and lack detailed information on how to interpret the law. For this reason, the ECJ has an essential function in interpreting, developing and thus establishing EU law, within the framework of the treaties. Other materials used include legal acts and regulations and literature.

The derived view of the current legal regime will serve as a foundation for an economic analysis. Modern economic case studies, as presented in academic articles, are used to examine the likely effects of pharmaceutical parallel trade, under the market conditions rendered under the current legal situation. The approach of the paper is, however, not a strict law and economics analysis under a neoclassic theoretical framework.

Because the economic and policy conclusions in this paper are mainly based on economic studies, there are a few important aspects to keep in mind. When a problem is to be analyzed under economic theory, the problem must first be divided into small pieces. These pieces are then transformed into assumptions which function as the basis and frame for the economic models. The result of an economic analysis is never better than the pieces and assumptions that are put into the models that constitute the analysis (nor better than the quality of the models, of course). Sometimes, sections of high leverage in the models can give the assumptions put into it more importance than intended. It might even be possible to twist and turn the results in favor of a predetermined or bias opinion. It is therefore critical to examine all of the presumptions made in an economic study before relying on it blindly. This is especially important when, as in this paper, the studies referred to are not described in detail, but instead only recited in summary.

In this paper, the materials used to outline the economic overview in Section 5 were chosen based on the level of establishment and repute of the study, and of course the suitability of the models in context of the objectives of the paper. Furthermore, the attempt has been to thoroughly highlight any compatibility problems between the analysis set forth herein and the referred studies. One should always keep in mind though the influence of the assumptions and other
circumstances in economic analyses, such as the importance given to differences in perspectives by the individual analysts. Therefore, in regard to issues of specific interest to the reader, relating to economic aspects, it is always best to investigate the relevant background material in question to avoid confusion or misleading.

A few lines of text should also be devoted to pointing out some potential issues regarding sources of data. In particular, for statistical data specific to the pharmaceutical industry, one of the main sources is the European Federation of Pharmaceutical Industries and Associations. It should be clearly noted that the members of this federation are mainly research entities and commercial pharmaceutical companies. Even though the reports and data from the EFPIA are widely trusted as objective and accurate, readers should keep this factor in mind and maintain a critical point of view. Despite the, perhaps, rather subjective status of the EFPIA, its data is nevertheless referred to in this paper because some data is simply so specific to its nature that it has only been collected and processed by the EFPIA (often with raw data obtained from its members) and as a result, does not exist elsewhere in a verified format.

1.5 Outline and structure

This paper sets out in Section 2 with a presentation of the legal and commercial nature of parallel trade, and some of the related problems and issues, such as some ethical dilemmas. The purpose of this section is to outline a foundation for understanding the nature of parallel trade.

The legal status and prerequisites for parallel trade are then identified and examined in further depth in Sections 3 and 4. Section 3 outlines the legal situation in relation to the Internal Market, especially as regards the general policy of free movement of goods. Section 4 covers the pertinent questions related to intellectual property – particularly trade mark rights and how exhaustion of intellectual property rights occurs. Section 4 also covers a chapter on legal ways of opposing parallel trade under the de lege lata. It shows some ways a proprietor could prevent parallel trade and a general
inquiry on the exceptions to the identified legal situation. This section also includes details on how parallel trade in pharmaceuticals is generally conducted by means of repackaging and relabeling.

In Section 5 follows a presentation and analysis of some economic aspects to parallel trade in general and parallel trade in pharmaceuticals specifically. The aim is to investigate how the markets function, with the purpose of laying forth a basis for informed conclusions on de lege ferenda in Sections 6 and 7.

In Section 6 follows an analysis, where some important issues identified in the paper are put under the magnifying glass, and the interests of the different stakeholders are benchmarked. The analysis is followed by a few short concluding remarks in Section 7, including very simple and conceptual policy recommendations.

1.6 Definitions

The Commission is the European Commission – the executive body of the European Union.

Innovation can, simplified, be defined as a process that brings together new original ideas that can be applied on the market and that have an impact on society. In this paper, it includes both development and commercialization of such new solutions.

The Internal Market is the internal market of the European Union. It is synonymous with the Single Market.

Member States refers to the Member States of the European Union. Where applicable, it also includes the members of the European Economic Area.

A parallel import is a product imported into a market by means of parallel trade.

5 At the time of writing this paper, there are 28 Member States in the EU.
Parallel trade and parallel importation are used synonymously to describe the action of importing a genuine good that is protected by intellectual property, from one market to another, without the authorization of the proprietor.

Pharmaceutical products, pharmaceuticals and drugs are used synonymously in this paper to describe a chemical compound intended for use as a medicinal drug to treat, prevent or diagnose diseases or injuries.

In this paper, a proprietor of a certain right could be either the owner or a licensee of that right.
2 Parallel trade

2.1 Parallel trade in general – the nature of parallel trade

2.1.1 The commercial nature of parallel trade

Any goods or products can of course be subject to parallel trade, not just pharmaceutical products. Parallel trade exists where there are significant price disparities in different markets for a specific product. A parallel import is a product placed into circulation in one market and then imported by an intermediary into a second market, without the consent of the proprietor. If the price difference of a certain product (between two markets) is sufficient to make a profit after transaction costs, parallel trade will occur if legally accepted and if the regulatory barriers for trade are low enough.

The idea is obviously simple – buy a product in a market where the price is low, in hope to sell the product in another market where the price is higher, and thereby make a profit. This behavior is generally considered beneficial for consumers. The phenomenon of parallel trade fosters trade in general by converging prices between different geographic markets while increasing the turnover of goods (parallel trade increases the number of transactions and thus also ensures high liquidity in the affected markets).

2.1.2 The legal nature of parallel trade

It is important to point out that when discussing parallel trade within the scope of this paper, it is not a matter of trade with counterfeit products. Parallel trade consists of arbitrage business transactions with genuine products, however without the permission of the intellectual property proprietor and outside the proprietor’s normal distribution network.

The legal nature of parallel trade relates closely to the issue of exhaustion of intellectual property rights. The core questions that arise are in what situations
and circumstances most or all intellectual property rights related to a good are exhausted on first sale? Also, accordingly, which rights might actually survive exhaustion to resurface post-sale; allowing the proprietor some control even after the good has been put on the market?\(^6\)

### 2.2 The special case of pharmaceuticals

#### 2.2.1 General about protection of pharmaceuticals

Pharmaceutical products can be protected by different kinds of intellectual property, or be unprotected. A patent protection is tied to the chemical properties of the drug. Any particular pharmaceutical can be protected by trade mark or sold under a generic name referring to the chemical structure of the drug.\(^7\) It is not uncommon for pharmaceuticals to have overlapping patent protection and trade mark protection.

#### 2.2.2 Outline of market conditions

In the markets for pharmaceutical products, prices vary vastly between different geographic markets. In the EU, the price difference for specific drugs between Member States is as significant as 300\%.\(^8\) The basis for these enormous and stable price discrepancies is the fact that prices are not set as a result of normal market forces. Instead, prices are set on a national basis by national governments in local pricing policies and price regulations. The national pricing models account for the relative buying power of the population based on the nation’s Gross Domestic Product (“GDP”), as well as other factors, such as the nation’s social security policy.\(^9\)

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\(^6\) The principle of exhaustion of (trade mark) rights is described in detail in Section 4.4 and the questions on post-sale control of trade mark rights is addressed further in Section 4.5.

\(^7\) Such drugs are generally referred to as "generics".


The circumstances described above result in a segregated market which is highly lucrative to parallel trade. The entire market value for pharmaceuticals in Europe amounted to € 160,6 billion in 2011, while parallel trade was estimated at € 5 billion.  

2.2.3 Policy issues & ethical aspects

Health care (including access to pharmaceutical products) is generally considered to be a ‘merit good’, meaning that it is desirable that everyone should have access to it, even those who cannot afford it and lack the ability to pay. This view must be considered uncontroversial – the absolute majority of people in the world ought to agree that society (public as well as private entities) should strive at enabling every single individual on this planet to receive the health care that they need – monetary wealth should not be a requirement for quality health care.

This issue enters the discussion on parallel trade mainly in two intersecting aspects; pricing and supply.

When products are necessary to the lives and well-being of hundreds of thousands of people, some parallel trade related ethical dilemmas become obvious. An example is pharmaceuticals developed to treat HIV infections. In general, patients in industrial countries can access this treatment and can afford to pay the price. Patients in developing countries generally cannot. To get the necessary treatment through to patients in developing countries, pharmaceutical companies, non-profit organizations and governmental aid programs supply the necessary drugs at substantially lower prices in developing countries than the authorized prices in industrial nations. However, the price differentials that result from this setup generate parallel trade. Subsequently the drugs, that are more or less donated for the benefit of patients

10 The European Federation of Pharmaceutical Industries and Associations, The Pharmaceutical Industry in Figures – Key Data, 2013 (hereinafter “EFPIA”), value at ex-factory prices.
who cannot afford the treatment, never reach the intended recipients. Instead, they are exported out of the developing countries and subsequently re-imported into the industrial nations where the parallel traders undercut the authorized prices in those countries.\textsuperscript{12}

\textsuperscript{12} Regarding the HIV example, see Hays, Thomas, \textit{Parallel Importation Under European Union Law}, 1\textsuperscript{st} ed., Sweet & Maxwell Limited, London, 2004, page 12 (hereinafter "Hays").

The purpose of the example is is not to invoke a witch-hunt, but merely to highlight an issue.
3 The Internal Market - Free Movement of Goods

3.1 Introduction to the chapter

This chapter presents an introduction to the aim and functioning of the Internal Market in general and the principle of free movement of goods in particular. The purpose of the chapter is to provide the reader with an understanding of the relevant provisions and how they relate to the more substantive EU law on the topic of parallel trade – especially intellectual property law. An understanding of the purpose and functioning of the Internal Market is essential in keeping an informed opinion on *de lege ferenda* issues relating to parallel trade.

3.2 Background to the Internal Market

The EU is a very special and unique political construction with a complex organizational structure. This structure is engineered to unite the Member States in a social and economic framework. It is worth reminding that many of the EU Member States are powerful nations and all Member States have very diverse cultures, traditions and economies. The EU unites its members into a body far more powerful than any single Member State could make on its own. However, because of the diversity in nature between Member States, this integration process is of course not always without difficulty.

With successful integration however, the diversity between nations is a great basis for the wealth of the EU. This is because a successful Internal Market provides for free trade and hence specialization for companies and nations. Specialization leads to comparative advantages, which in turn leads to economies of scale, which in a setting of effective competition leads to maximization of consumer welfare and an efficient use of resources.\(^\text{13}\)

The Internal Market is the heart and the engine of EU integration. It is the driving force in uniting both the economic markets and the people of Europe.

3.3 The Four Freedoms

The aim of the Internal Market is to create one single geographic market within the EU for what is commonly referred to as the “four freedoms” – goods, services (Articles 56 to 62 TFEU), capital (Articles 63 to 66 TFEU) and persons. The free movement of persons category includes free movement of workers (Articles 45 to 48 TFEU) and freedom of establishment (Articles 49 to 55 TFEU). Pharmaceutical products are goods, therefore free movement of goods is the ‘freedom’ that will stay in focus in this section henceforth.

3.4 Free Movement of Goods

3.4.1 General

The free movement of goods has its basis in Article 28 of the TFEU, providing for the foundation of the customs union. Article 28(1) TFEU reads:

“The union shall comprise a customs union which shall cover all trade in goods and which shall involve the prohibition between Member States of customs duties on imports and exports and of all charges having equivalent effect, and the adoption of a common customs tariff in their relations with third countries.”

Thus, any goods originating from a Member State shall be subject to free movement within the Internal Market. Any goods originating from a third country (outside the EU) shall enjoy free movement within the Internal Market once they have been imported to the EU and any common customs tariffs have been paid.

14 Barnard, page 27.
15 Ibid.
3.4.2 Definition of “goods” for the purpose of free movement

We first need to establish a uniform definition of the term “goods” for the purpose free movement. The TFEU uses both the term “goods” (e.g. Article 28(1) TFEU) and “products” (e.g. Article 28(2) TFEU). However there does not seem to be any difference of meaning between the terms. The German version of the TFEU provides support for this assumption, as it uses the word “waren” for both goods and products.\(^{16}\)

There is no definition of “goods” in the TFEU. It was however defined by the ECJ in the *Commission v Italy*\(^ {17}\) case as:

“[…] products which can be valued in money and which are capable, as such, of forming the subject of commercial transactions”.\(^ {18}\)

Furthermore, goods:

“[…] in the common connotation of the term, possess tangible physical characteristics”.\(^ {19}\)

For example, all of the following diverse categories have been deemed included in the definition of goods: paintings, petroleum products, animals, waste and electricity.\(^ {20}\)

3.4.3 Targets of the provisions on free movement

Articles 34 to 36 of the TFEU clearly target actions of Member States, such as quantitative restrictions or measures having equivalent effect. Also, since these


\(^{18}\) Id., page 428.

\(^{19}\) Case C-97/98 *Peter Jägerskiöld v Torolf Gustafsson*, [1999] ECR I-7319, opinion of the Advocate General, para 20.

\(^{20}\) Barnard, page 27.
articles have direct effect, individuals may rely on them in national courts, at least against actions by Member States.  

3.4.4 Prohibition of quantitative restrictions and measures having equivalent effect

Article 34 of the TFEU states:

"Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States."

This provision, along with Article 35 TFEU, which concerns exports, prevents the Member States from measures involving quantitative restrictions or measures having equivalent effect. Quantitative restrictions are defined as measures restraining imports or exports in total or in part. Measures included are therefore quotas, limiting the quantity of goods coming into a Member State, or total bans, meaning a total limit of importation of certain goods.  

Articles 34 and 35 TFEU have direct effect, meaning that individuals can rely on the provisions and the rights conferred by the articles should be protected by national courts.  

Measures having equivalent effects to quantitative restrictions include measures by Member States that restrict the sale, use or possession of products. The distinction between quantitative restrictions and measures having equivalent effect is somewhat blurred and in essence, they have the same meaning and concept. The difference is that 'measures having equivalent effect' has a considerably wider scope than quantitative restrictions.  

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21 Woods, Lorna, Free Movement of Goods and Services within the European Community, 1st ed., Ashgate Publishing Limited, Aldershot, 2004, page 29 (hereinafter "Woods"). It is somewhat unclear in the literature whether or not these rules can be invoked against actions by individuals, even if this is most likely not possible. This is however not interesting to investigate further within the scope of this paper.

22 Barnard, page 64 f.

23 Oliver, page 81.

24 Id., page 83 f.
purpose of this paper it is not relevant to present a detailed description of measures having equivalent effect.\textsuperscript{25}

\textbf{3.4.5 Derogations from the provisions on quantitative restrictions}

Quantitative restrictions are considered to be the most damaging measures to free movement of goods, and can therefore only be justified by reference to one of the exceptions explicitly presented in Article 36 TFEU. Article 36 thus provides grounds for derogation from Articles 34 and 35. The TFEU allows national measures by the Member States to take precedence over the principle and provisions concerning free movement of goods, however only where the measures in question meet one of the grounds stipulated in Article 36. Any such measures must also be proportionate, and may not be discriminatory or constitute a disguised restriction on trade.\textsuperscript{26}

One of these derogations is the protection of ‘industrial and commercial property’, which includes \textit{inter alia} intellectual property.\textsuperscript{27}

In addition to the (exhaustive) list of derogations in Article 36, the CJEU has developed a list (non-exhaustive) of mandatory requirements. The purpose of this list is to supplement Article 36 by justifying certain measures having equivalent effect to quantitative restrictions. Both the derogations in Article 36 and the list of mandatory requirements are only available for application in the absence of harmonizing legislation.

The mandatory requirements were established in \textit{Cassis de Dijon},\textsuperscript{28} where the ECJ developed a non-exhaustive list of ‘good reasons’ to justify conduct by the Member States that are contrary to Articles 34 and 35 TFEU. These good reasons must not be related to the origin of the goods, and they must serve objectives which the ECJ considers to be legitimate.\textsuperscript{29}

\textsuperscript{25} For further reading, see Oliver, chapters 6-7 and Barnard, chapters 5-8.
\textsuperscript{26} Barnard, page 65 f.
\textsuperscript{27} See Woods, page 139.
\textsuperscript{28} Case 120/78 \textit{Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein}, [1979] ECR 649 (hereinafter “\textit{Cassis de Dijon”).
\textsuperscript{29} Barnard, page 115.
In short, the circumstances and the conclusions of *Cassis de Dijon* were the following. Cassis de Dijon was a French liquor product which the German authorities refused to allow for sale in the German market, because the alcoholic strength of the product was not sufficient to qualify as liquor in Germany.

The ECJ said that Member States may regulate matters which have not been harmonized, in this case in relation to the production and marketing of alcoholic products, and that in some cases, obstacles to the free movement of goods resulting from any discrepancy between national laws must be accepted. This is the case when such provisions are necessary in order to satisfy mandatory requirements, especially in relation to the effectiveness of tax supervision, defense of consumers’ interests and protection of public health.\(^{30}\)

Thus, in matters where there is no harmonization legislation, Member States may regulate product requirements even if such regulation has a negative effect on free movement of goods, if the national rules or conduct can be justified by showing one of the mandatory requirements, and if it is proportionate.\(^{31}\)

### 3.5 National Pricing Regulations vs. Article 34 TFEU

Since the Member States are entitled to control their health expenditure budgets, the mere existence of a national pricing regulation does *not* constitute a quantitative restriction or a measure having equivalent effect. Furthermore, the ECJ has in general not been very strict in applying Articles 34 and 35 TFEU to pricing regulations.\(^{32}\)

For example, for Article 34 to be applicable in cases of pricing regulations, it is necessary to show that the pricing regulation at question discriminates against imports. For example, such could be the case if costs incurred outside a Member States are not allowed to be included in the price calculations or

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\(^{30}\) Case 120/78 *Cassis de Dijon*, para 8.
\(^{31}\) Barnard, page 111.
\(^{32}\) Hancher & Sauter, page 113 f.
reimbursement systems. More examples of pricing regulations that may be contrary to Article 34 is price freezing or profit regulations.\textsuperscript{33} The general legality of national pricing regulations for pharmaceuticals was upheld by the ECJ in, for example, \textit{Commission v Belgium}, where the Commission had failed to show discrimination.\textsuperscript{34}

\textbf{3.6 Intellectual Property in the context of Free Movement}

It is inevitable that the goal of free movement of goods sometimes clashes with the national, statutory rights to intellectual property and its exercise. Intellectual property rights pertain from the laws of the Member States separately, and as the proprietors seek to enforce their rights, there are sometimes conflicts with the principles of free movement of goods. Such is often the case in issues relating to parallel trade.\textsuperscript{35}

The intention of the Trade Mark Directive ("TMD")\textsuperscript{36} is to ensure the free movement of goods, by harmonizing the trade mark laws between the Member States. The TMD and Articles 34 to 36 of the TFEU are to be interpreted consistently with each other as regards the intention to ensure free movement of goods within the Internal Market.\textsuperscript{37} Even though most of the disparities between national trade mark laws have been eliminated through the TMD, it is problematic in the context of free movement of goods that trade mark rights are created and enforced on a national level. Creating a balance between trade mark rights and the provisions of free movement of goods has not been an easy task for the ECJ.

The case law dealing with this balance, namely the compatibility of Articles 34 to 36 of the TFEU with the exercise and enforcement of intellectual property

\textsuperscript{33} Ibid.
\textsuperscript{34} Case C-249/88 \textit{Commission of the European Communities v Kingdom of Belgium}, [1991] ECR I-1275.
\textsuperscript{37} Hays, page 277 f.
rights can in short be summarized in a main rule with a set of exceptions. The main rule is that Member States are free to legislate in the field of intellectual property unless (and until) the specific field is harmonized. The first exception is that Member States may not use its legislation to discriminate on grounds of nationality or place of manufacture. The second exception is that no Member State may prevent goods in transit from moving through its territory (unless the transit entails intellectual property rights within the territory). The last exception is that of exhaustion. That is – a Member State may not legislate to allow proprietors of intellectual property rights to prevent the importation, exportation or sale of a product pertaining to which the intellectual property rights have been exhausted.38

3.7 Concluding remarks

The principles and provisions on free movement of goods constitute a framework under which the substantive EU law on parallel trade and intellectual property exhaustion exist. This framework is more than just principles and provisions – it is the essential core of the EU integration. An analysis should thus keep these provisions and their essence in mind when examining de lege lata and de lege ferenda for any issues relating thereto.

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38 Regarding the compatibility of Articles 34 to 36 with intellectual property rights, see Oliver page 234.
4 Intellectual Property Rights

4.1 Introductory remarks

The substantial legal status of parallel trade is mainly determined by the way intellectual property rights are exhausted. This section will explain what is meant by “exhaustion” of intellectual property rights, how and when it occurs, how it affects an intellectual property right and to what extent proprietors can possibly deter parallel trade by preventing or limiting third parties from exploiting an exhausted right.

With reference to Section 1.2, this paper will focus on exhaustion of trademark rights.

4.2 General about Intellectual Property – Trade mark rights

Intellectual property rights are certain exclusive rights to intangible assets. These intangible assets are often the results of creative, mental human activity in the fields of industry, science, art and literature. The power to use and prevent others from using these exclusive rights are statutory privileges; created and enforced under the protection of laws.39

Trade marks are signs used in the course of trade to identify the source of goods or services. These signs must be distinctive, meaning that they must be able to identify and distinguish the goods or services to which it relates, from other goods or services.40

The specific subject matter of intellectual property rights describes the scope of the right, as recognized by the Court of Justice of the European Union (“CJEU”).41 For trade marks, the specific subject matter is the essential

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39 Kur & Dreier, page 2.
40 Id., page 3.
41 Oliver, page 314.
function of the trade mark, but also including related legitimate interests and 'other functions'. 'Related legitimate interests' includes preventing damage to the trade mark or its proprietor, and 'other functions' includes guaranteeing the quality of the goods or services relating to the trade mark. It also includes the right to prevent interference from a third person, such as actions affecting the original condition of the trade mark protected product.

The specific subject matter for trade marks was defined in *Centrafarm v Winthrop* as:

"[...] the guarantee that the owner of the trade mark has the exclusive right to use that trade mark, for the purpose of putting products protected by the trade mark into circulation for the first time, and is therefore intended to protect him against competitors wishing to take advantage of the status and reputation of the trade mark by selling products illegally bearing that trade mark." 

### 4.3 Intellectual Property Rights vs. Competition Law

As underlined in Section 1.3 above, this paper will not cover situations where a proprietor prevents parallel trade by conducting methods of unlawful competition, e.g. by infringing Art. 101 or Art. 102 TFEU. However, as the legal status of parallel trade is sometimes determined in the intersection between intellectual property law and competition law, it is necessary to include herein a few words on the relationship between these two fields of law.

There is a clear conflict of interest from a legal point of view: how should intellectual property rights – statutory privileges to exercise exclusive rights without interference from third parties – be balanced against the public interest of efficient markets characterized by effective competition? The answer is not obvious and the circumstances are rarely simple.

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42 Ibid.
44 Case 16/74 Centrpharm BV and Adriaan de Peijper v Winthrop BV, [1974] ECR 1183, para 8 (hereinafter "Centrafarm v Winthrop").
In the EU, competition law and internal market law take a central role. The high profile of competition law is intended to ensure effective markets, which has been one of the main goals of the European Union throughout the treaties – both pre Lisbon and in the TFEU.\textsuperscript{45} Because intellectual property rights are national statutory privileges, granted and protected under national law, the general paradigm is that intellectual property rights are subordinate to EU competition law where there is a conflict. The basis for the current form of relationship, or reconciliation, between intellectual property rights and EU competition law was established by the ECJ in the \textit{Consten and Grundig} case.\textsuperscript{46} In Consten & Grundig, a trade mark right was used to stop parallel trade related to the trade mark. The exercise of the trade mark right was stopped by the Commission, whose decision was later upheld by the ECJ. The ECJ concluded that the exercise of intellectual property rights may not be used to frustrate the competition rules; otherwise the competition provisions would be meaningless.\textsuperscript{47} Thus, the EU competition rules will not interfere with ‘normal exercise’ of intellectual property rights, but only where such exercise becomes abusive.\textsuperscript{48}

In summary, even in a case where a proprietor of intellectual property seemingly has the option to exercise his rights in a beneficial manner, the intended action might be considered unlawful as a result of competition law regulations. With this situation in mind, we will now leave competition law aside and move on to exhaustion of trade mark rights.

\section*{4.4 Exhaustion of trade mark rights within the EEA}

\section*{4.4.1 General about exhaustion of intellectual property rights}


\textsuperscript{47} Joined Cases 56/64 and 58/64 Consten & Grundig page 346.

\textsuperscript{48} Anderman & Schmidt page 18.
Exhaustion of intellectual property rights is a traditional and widely known and accepted concept. In fact, the principle can be found in most national laws on intellectual property, not just in EU law.49

The basic idea of exhaustion is rather simple – once a product has been placed on the market for the first time, that particular product can be traded freely, "second hand", in that market.

The legal basis for the exhaustion doctrine within the EU is found in Article 7(1) of the TMD, which states:

"The trade mark shall not entitle the proprietor to prohibit its use in relation to goods which have been put on the market in the Community under that trade mark by the proprietor or with his consent."

The EU exhaustion doctrine found in Article 7(1) of the TMD50 was first established in 1971 by the ECJ in the Deutsche Grammophon Case.51 The exhaustion principle was later confirmed in Centrapharm v Sterling Drug52 (for patents) and Centrapharm v Winthrop53 and Centrapharm v American Home Products54 (for trademarks).

4.4.2 How and when exhaustion occurs

4.4.2.1 Acts conferring exhaustion

The first essential question in the issue of determining when exhaustion occurs – what is the meaning of the wording " [...] put on the market [...]" in Article 7(1) of the TMD? In other words, at which point and by what actions is a good

49 Oliver, page 334.
53 Case 16/74 Centrafarm v Winthrop.
deemed to have been put on the market? Is it when a good is manufactured? When it is put on the shelf in a warehouse? When offered for sale to customers? When it is sold, and if so – by sale to the ultimate customer, or is a sale to a wholesaler or distributor enough? Is importation alone enough to confer exhaustion? This issue was addressed and clarified by the ECJ in Peak Holding.55

The circumstances in Peak Holding were as follows. Peak Holding AB was the proprietor of several trade marks, *inter alia* the trade mark "Peak Performance". The Peak Performance trade mark was granted to the company Peak Performance Production AB, a company producing and selling clothing under the Peak Performance trade mark. Peak Performance Production AB sold a consignment of outdated clothes, which had first been offered for sale in a store in Denmark, to a French company, COPAD International, under the condition that the clothes may not be re-sold in any European countries except Russia and Slovenia (other than 5% of the consignment which could be resold in France).

Axolin-Elinor AB, a Swedish company in the business of running outlet stores, bought the consignment of clothes and offered them for sale in Sweden.

Peak Performance Holding AB sued Axolin-Elinor AB, alleging trade mark infringement. Axolin-Elinor AB disputed infringement and claimed that the trade mark rights related to the products had been exhausted. The question arose whether the goods had been put on the market by importing them into the EEA with the intention of selling them or by offering the goods for sale in the proprietor’s own shops.

The ECJ held that goods are deemed to have been put on the market when the right to dispose of the goods is transferred to third parties, allowing the proprietor to realize the economic value of the goods bearing the trade mark.56

55 Case C-16/03 Peak Holding AB v Axolin-Elinor AB, [2004] ECR I-11313 (hereinafter “Peak Holding”).

56 Id., para 41 and 42.
The Peak Holding case clarified that exhaustion will only occur when goods are actually sold outside the distribution network of the proprietor, thus realizing the economic value of the trade mark. Importation or offering the goods for sale, as such, is thus not enough to confer exhaustion.  

4.4.2.2 The definition of "goods" for the purpose of exhaustion

The next essential question in determining how exhaustion is conferred, is what actually constitutes "goods" for the purpose of Article 7(1) of the TMD. Does the term "goods" include all identical units of goods bearing a trade mark, or just individual units? In other words, when a good is put on the market, is the trade mark rights related to the good exhausted for all goods identical to the sold good, or only that specific unit? This question was *inter alia* addressed in Sebago.  

In short, the circumstances in Sebago were the following. Sebago Inc. marketed and owned trade marks related to certain shoes. The shoes were manufactured under license by a contract manufacturer in El Salvador. The shoes were sold both within and outside the EEA. In Benelux, Sebago sold shoes through an exclusive retail agreement with Ancienne Maison Dubois & Fils SA. A Belgian retailer, G-B Unic SA, bought a consignment of shoes from outside the EEA through a parallel importer, who had bought the shoes from the manufacturer in El Salvador.  

Sebago and Ancienne Maison Dubois sued G-B Unic, alleging trade mark infringement because Sebago had not consented to the shoes being imported into the EEA from El Salvador. G-B Unic responded *inter alia* that there was no infringement because similar goods bearing the same trade marks were sold within the EEA, and thus the trade mark rights had been exhausted.

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57 Kur & Dreier, page 224.  
Question arose *inter alia* whether exhaustion is conferred for all similar goods bearing the same trade mark as soon as some goods have been sold with the proprietor’s consent, or if only the trade mark rights for the specific units, or each defined batch, sold are exhausted.

In regard to this question, the ECJ stated:

“The text of Article 7(1) of the Directive does not give a direct answer to that question. Nevertheless, the rights conferred by the trade mark are exhausted only in respect of the individual items of the product which have been put on the market with the proprietor’s consent in the territory there defined. The proprietor may continue to prohibit the use of the mark in pursuance of the right conferred on him by the Directive in regard to individual items of that product which have been put on the market in that territory without his consent.”

The ECJ enforced this statement by concluding that the interpretation that exhaustion only concerns specific goods which have been first put on the market with the consent of the proprietor, is confirmed by Article 7(2) of the TMD by its reference to “further commercialisation” of goods.

The conclusion of this case seems logical and rightful – only trade mark rights related to actual individual and identifiable items put on the market should be exhausted. Otherwise the nature of the EEA-wide regional exhaustion principle would lose its importance, as in reality, as soon as trade mark rights were exhausted in the EEA, similar goods bearing the same trade mark could have easily been imported from outside the EEA.

However, the outcome of Sebago might give rise to problems in practice, because it might sometimes be difficult or even impossible to prove the identity of, and consent to the first sale of, all individual items at dispute at a certain time.

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59 Case C-173/98 *Sebago* para 19.
60 Id. para 20.
61 This was noted by the Advocate General in C-173/98 *Sebago Inc. and Ancienne Maison Dubois & Fils SA v G-B Unic SA*, [1999] ECR I-4103, opinion of the Advocate General. The (potential) issues are also pointed out in Hays, page 300.
4.4.2.3 Consent

The issue of ‘consent’ refers to when, in what circumstances, a trade mark proprietor should be regarded as having marketed a product (or ‘consented to the product being put on the market’). For a trade mark proprietor, it is of course also very important to know who may consent to the products being put on the market, and whether consent must be expressed or whether it may also be implied.

These questions arise particularly in cases where goods are imported into the EEA from other countries. Parallel importation is the result of the intellectual property proprietor losing control over their protected products. When goods are sold outside the EEA, the goods are generally re-sold subsequently in the distribution chain, and hence the proprietor loses control of the goods. The question of consent often arises in respect of such goods – has the proprietor consented, express or implied, to the goods being imported into the EEA? If so, then the intellectual property rights are to be deemed exhausted within the EEA, otherwise they are still in full force.

In Zino Davidoff and Levi Strauss, the ECJ found that it had to establish a uniform interpretation of the concept of ‘consent’ for the purpose of Article 7(1) of the FTMD. The substantive questions raised were, inter alia, whether consent may be implied, or whether it must be expressed explicitly, and if consent may be implied, may it be inferred from the mere silence of the proprietor?

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62 Oliver, page 337.
63 Hays, page 313 f.
The ECJ found that:

“[...] the consent of a trade mark proprietor to the marketing within the European Economic Area of products bearing that mark which have previously been placed on the market outside the European Economic Area by that proprietor or with his consent may be implied, where it follows from facts and circumstances prior to, simultaneous with or subsequent to the placing of the goods on the market outside the European Economic Area which, in the view of the national court, unequivocally demonstrate that the proprietor has renounced his right to oppose placing of the goods on the market within the European Economic Area.”

Thus, consent may in fact be implied. However, implied consent cannot be inferred just because the trade mark proprietor has not communicated his opposition to marketing within the EEA to all subsequent purchasers of the goods. Neither can implied consent be inferred from the fact that the goods carry no warning of such opposition, or from the fact that the proprietor has transferred ownership of the goods without a contractual prohibition to import the goods to the EEA.

It can be concluded that the main rule is that consent must be expressed explicitly, however it may be implied “where it follows from facts and circumstances prior to, simultaneous with or subsequent to the placing of the goods on the market”, if it has been unequivocally demonstrated that the proprietor has renounced his right to put the goods on the market within the EEA. Yet another case from 2010 reinforces this principle.

The remaining question is who may consent to the products being put on the market. According to Article 7(1) of the TMD, consent may be given:

“[...] by the proprietor or with his consent.”

66 Id., page 8760.
67 Ibid.
68 Case C-127/09 Coty Prestige Lancaster Group Gmbh v Simex Trading AG, [2010] ECR I-0000. Surprisingly, in this case one of the questions referred to the ECJ concerned the issue of placing goods on the market, and the ECJ had to remind of the accepted principle established in Sebago, namely that trade mark rights are only exhausted with respect to individual items.
However, on a closer look, it is not entirely obvious who is covered by that wording. Does it include all subsidiaries in a group of companies? Does it include licensees? Even agents? The question was raised in the *Ideal Standard* case.\(^6^9\) The ECJ stated:

“[...] the owner of the right in the importing State must, directly or indirectly, be able to determine the products to which the trade mark may be affixed in the exporting State and to control their quality. That power is lost if, by assignment, control over the trade mark is surrendered to a third party having no economic link with the assignor.”\(^7^0\)

Thus, for the “owner of the right” to be able to consent to goods being put on the market, it must be able to determine which goods may be affixed with the trade mark in the exporting country, and to be able to control their quality. Consent constitutes the decisive power, and for this power, an economic link is the necessary prerequisite.\(^7^1\)

### 4.4.3 Territorial frame for exhaustion

#### 4.4.3.1 General

The next issue to be addressed on the subject of exhaustion is a question of territorial reach – when a trademark right has been deemed ”exhausted”, how far geographically does this phenomenon reach? In other words, when a product is placed on a market for the first time and exhaustion is conferred, in what specific nations does this exhaustion take effect, and where is the product still under full protection of the trademark rights?

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\(^7^0\) Case C-9/93 *Ideal Standard*, para 43.

\(^7^1\) The meaning of ”consent” was addressed by the ECJ again, in an intra-EEA context, in Case Case C-324/08 *Makro Zelfbedieningsgroothandel CV v. Diesel SpA.*, [2009] ECR 1-10019. The ECJ reinforced the principles first set out in *Ideal Standard* and *Zino Davidoff and Levi Strauss*. 
There are three identified categories of territorial reach of exhaustion in the world – global exhaustion, national exhaustion and regional exhaustion. Naturally, for a proprietor the difference is tremendous between national exhaustion and global exhaustion in how to strategically plan for market introduction of its protected goods, and for predicting the effects of market introduction. The categories of exhaustion are described further below.

### 4.4.3.2 Global exhaustion

If goods are placed on the market in a nation which applies global exhaustion, the trade mark rights related to the goods are exhausted globally; in every nation in the world where the goods are protected by trade mark rights. This doctrine assumes that the entire world is one geographic market, and that trade mark rights are exhausted world-wide once goods are put on the market with the consent of the trade mark proprietor, in any nation in the world.

### 4.4.3.3 National exhaustion

If a nation applies the principle of national exhaustion, when trade mark protected goods are put on the market within a certain nation, the trade mark rights related to those goods are exhausted only in the specific nation where the sale took place. In all other jurisdictions where the goods are protected by trade mark rights, the goods are not considered to have been put on the market, and hence the first sale exclusivity is still in force.

This approach seems rather logical from a legal point of view; intellectual property rights are national statutory rights, created and protected under national laws. Therefore it seems right that a commercial action taken in one nation should only have automatic legal effect in that particular nation or jurisdiction.

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72 Sometimes referred to as "international exhaustion".
74 Sometimes referred to as "territorial exhaustion" or "jurisdictionally specific exhaustion".
However, a disadvantage of the principle of national exhaustion is that it obviously disrupts world trade by allowing intellectual property rights proprietors to isolate markets and thereby promote market segregation.\textsuperscript{75}

4.4.3.4 Regional exhaustion

Regional exhaustion means that a trade mark right is exhausted in an entire specific region, if the product related to the trademark is put on the market anywhere within that region.

Regional exhaustion is the category applied in the EU. This follows directly from the exhaustion regulation in Article 7(1) of the TMD.

The obligation for member states to adopt the principle of regional exhaustion, and the reach of Article 7(1) of the FTMD, was set by the ECJ in the Silhouette case.\textsuperscript{76}

The circumstances in Silhouette were, in short, the following. Silhouette International Schmied GmbH & Co. KG was an Austrian developer and manufacturer of high quality spectacle frames. Silhouette sold a consignment of spectacles to Union Trading, a trading company in Bulgaria,\textsuperscript{77} but under the condition that the goods may not be re-imported into the EU or the EEA. Hartlauer Handelsgesellschaft mbH was an Austrian trading company who sold items, \textit{inter alia} spectacles, through its low price stores in Austria. Hartlauer imported spectacles marked with the Silhouette trade mark from Union Trading in Bulgaria back into Austria, without the consent of Silhouette.

Silhouette sued Hartlauer in Austria for trade mark infringement under the claim that the trade mark rights for the spectacles sold in Bulgaria had not been exhausted (because the first sale took place outside the EEA). It should be noted that, at least before the implementation of the FTMD, Austria applied

\textsuperscript{75} Hays, page 8.


\textsuperscript{77} Bulgaria was, at this time, not a member of the EU or the EES.
global exhaustion of trade mark rights. The Austrian Oberster Gerichtshof asked the ECJ *inter alia* whether national rules providing for global exhaustion of trade mark rights were contrary to Article 7(1) of the FTMD.\(^\text{78}\)

The ECJ ruled in favor of Silhouette, and concluded that Member States may only apply regional exhaustion, thus the trade mark rights relating to the re-imported spectacles had not been exhausted (and thus Silhouette still had a fully active right of first sale for the spectacles within the EEA). The ECJ concluded, to ensure that the purpose of the FTMD is achieved (namely to safeguard the functioning of the internal market) that;

> [...] A situation in which some Member States could provide for international exhaustion while others provided for Community exhaustion only would inevitably give rise to barriers to the free movement of goods and the freedom to provide services.\(^\text{79}\)

The ECJ also highlighted that the FTMD embodied a complete harmonization of trade mark rights between the Member States.\(^\text{80}\)

The Silhouette case provides an important clarification in how to interpret the territorial reach of Article 7(1) of the FTMD (and, of course, also the TMD), namely that Member States may only apply regional exhaustion, and that any other territorial application of the exhaustion doctrine is contrary to EU law. The principle of regional exhaustion is thus not just a *minimum* standard, but the *exclusive* standard to be applied within the EEA.\(^\text{81}\)

### 4.5 Opposing parallel trade

#### 4.5.1 Introduction to the chapter

\(^{78}\) Regarding the question(s) asked to the ECJ by the Austrian Oberster Gerichtshof, see *Silhouette* para 14.

\(^{79}\) Case C-355/96 *Silhouette*, para 27.

\(^{80}\) Id., para 25.

This sub-section outlines the situations where a trade mark proprietor may oppose further commercialization of products bearing the trade mark, that is – situations where a proprietor may oppose parallel trade under *de lege lata*.

### 4.5.2 Exceptions to the exhaustion doctrine

In some specific cases, a trade mark proprietor may oppose further commercialization even after a good has been put on the market with the proprietor’s consent. Such is the case when the condition of a good has changed or been impaired after it has been put on the market. This follows directly from Article 7(2) of the TMD, which states:

> “Paragraph 1 shall not apply where there exist legitimate reasons for the proprietor to oppose further commercialisation of the goods, especially where the condition of the goods is changed or impaired after they have been put on the market.”

But what constitutes “legitimate reasons” to limit the application of the trade mark exhaustion principle under Article 7(2)? Legitimate reasons include situations where:

- the condition of the trade mark protected goods have been changed or impaired,
- the trade mark protected goods have been repackaged in a way that could damage the reputation of a trade mark or confuse consumers regarding the origin of the goods,
- the trade mark has been changed by the parallel importer to gain a commercial advantage, or
- the trade mark protected goods have been marketed in a way that could damage the reputation of the trade mark.\(^\text{82}\)

In the following, this section will focus on these ‘legitimate reasons’ by examining the case of repackaging, including effect on the quality of the goods and altering of the trade mark, and the case of damage to a trade mark’s prestige.

\(^{82}\) Regarding these conditions, see Barnard pages 192-193.
4.5.3 Repackaging and relabeling

4.5.3.1 Introduction – different perspectives

Repackaging is the action of replacing the packaging – the container – in which the products were originally sold. It is considered a rather intrusive measure, and indeed normally the proprietor of a trade mark has the exclusive right to affix this brand to products.

From a proprietor’s point of view, repackaging might threaten the main purposes that the packaging served in the first place; marketing and protection. It may be important how the trade mark is presented, not just on the product, but on the packaging as well. As regards protection; goods are not just packaged to group products together, but to protect them during transportation, storage, etc.83 When products are taken out of their containers and put into new ones with the purpose of further commercialization, it is natural for an intellectual property proprietor to feel that there has been an infringement.

From a parallel trader’s point of view, however, this action may feel appropriate. The parallel trader has purchased the goods and gained the right to dispose of them in any quantity she likes. Furthermore, repackaging might be necessary to meet regulatory requirements of the Member State to which the goods are to be imported.84

Allowing repackaging would facilitate free trade and market integration, while at the same time it could raise questions about the quality or origin of a trade mark. The ECJ seems to partially accept arguments from both sides simultaneously, while leaning towards the central objective of market integration through free movement of goods.85

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83 Hays, page 94.
84 Id., page 95.
85 Ibid. See also Barnard, page 193.
4.5.3.2 Prerequisites for legal repackaging

4.5.3.2.1 General

Repackaging of goods is only acceptable if the repackaging does not damage either of the trade marks applied to the products or the quality of the goods. In the jurisprudence of the ECJ, five cumulative criteria have been established, for repackaging to be considered legal:

- it is established that the use of the trade mark right by the owner, having regard to the marketing system which he has adopted, will contribute to the artificial partitioning of the markets between Member States;
- it is shown that the repackaging cannot adversely affect the original condition of the product;
- the new packaging clearly states who repackaged the product and the name of the manufacturer;
- the presentation of the repackaged product is not such as to be liable to damage the reputation of the trade mark and of its owner; thus, the packaging must not be defective, of poor quality, or untidy; and
- the importer gives notice to the trade mark owner before the repackaged product is put on sale, and, on demand, supplies him with a specimen of the repackaged product.

Unless all these criteria are met, the proprietor may oppose further commercialization of the goods. The criteria are described in further detail in the following.

4.5.3.2.2 Artificial partitioning of the Internal Market

A proprietor’s opposition to further commercialization of a trade mark protected good that has been repackaged must not lead to an artificial

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86 Essentially, the same criteria must be observed in cases of relabeling; Kur & Dreier, page 227.
87 The cases where these criteria were developed are C-102/77 Hoffmann-La Roche, as refined in Joined cases C-427/93, C-429/93 and C-436/93 Bristol-Myers Squibb v Paranova A/S and C. H. Boehringer Sohn, Boehringer Ingelheim KG and Boehringer Ingelheim A/S v Paranova A/S and Bayer Aktiengesellschaft and Bayer Danmark A/S v Paranova A/S, [1996] ECR I-3457 (hereinafter “Bristol-Myers Squibb”). The criteria were then reaffirmed in Case C-348/04 Boehringer Ingelheim KG and Others v Swingward Ltd and Dowelhurst Ltd, [2007] ECR I-3391 (hereinafter “Boehringer Ingelheim vs. Dowelhurst”).
88 The wording of the cumulative criteria is quoted from Kur & Dreier, page 227.
partitioning of the Internal Market. In other words, if a product cannot be marketed in a certain Member State without first being repackaged, repackaging should be allowed; otherwise the parallel trader would not be able to access that specific market.

The term ‘artificial partitioning’ thus targets the objective necessity of the repackaging; if a parallel trader could gain access to a market without repackaging, it is not objectively necessary. In *Bristol-Myers Squibb*, the ECJ held that repackaging would be necessary where national rules or practices prevents the use of the original packaging, where the original packaging does not fulfill requirements by insurance rules, or where established medical prescription practices recommends certain sizes of the packaging (for example, a certain number of pills in each box). However, if relabeling would suffice for the parallel trader to gain access to the targeted market, repackaging can be opposed. If the outer packaging would give the impression that the goods are of poor quality, or if it would invoke mistrust among consumers in the target market, it is objectively justified to repackage the goods even if labeling could be enough to comply with local regulations. It is up to the national courts to decide when repackaging is justified, and when relabeling would be sufficient.

If the repackaging was conducted merely to obtain commercial advantages, even if it was not objectively necessary, the proprietor can oppose the repackaging.

Furthermore, it does not matter whether the proprietor had any intention of partitioning the market or not by opposing the repackaging. The criterion is thus objective and not subjective.

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89 Joined cases C-427/93, C-429/93 and C-436/93 *Bristol-Myers Squibb*, paras 53 and 54.
90 Id., para 55.
92 Case C-379/97 *Pharmacia & Upjohn SA v Paranova A/S*, [1999] ECR I-6927, para 44. See also C-348/04 *Boehringer Ingelheim vs. Dowelhurst*.
93 Joined cases C-427/93, C-429/93 and C-436/93 *Bristol-Myers Squibb*, para 57.
4.5.3.2.3  Effect on the original condition of the product

A proprietor may oppose further commercialization of a good, if the original condition of the good is impaired as a result of the repackaging. Allowed altering of the original condition of the good would compromise the essential function of the trade mark.

In *Bristol-Myers Squibb*, the ECJ held that it is up to the national courts to determine if the original condition of a good has been impaired, and that this assessment should be made in particular by comparing the repackaged product with the product marketed by the proprietor.94 The ECJ further exemplified conditions under which the original condition should not be considered to have been affected; merely by replacing one set of external packaging with another, by attacking a new label to flasks or inhalers, the addition of new user instructions or other information in the local language of the targeted market, or the addition of an extra article from another source than the trade mark proprietor (that however must comply with the method of use of the original product).95

4.5.3.2.4  Notification attached to the new packaging

The new packaging must clearly state who repackaged the good, and the name of the manufacturer.96 The ECJ clarified in *Pfizer vs. Eurim-Pharm* that the consumer must not be mislead as regards the manufacturer of the product.97 In *Bristol-Myers Squibb*, the ECJ confirmed this, and added that the notification on the packaging has to be printed in a way that it can be understood by persons with normal eyesight who are exercising a normal degree of attentiveness.98

94 Id., para 66.
95 Joined cases C-427/93, C-429/93 and C-436/93 *Bristol-Myers Squibb*, paras 61-64.
96 Case C-102/77 *Hoffmann-La Roche*.
98 Joined cases C-427/93, C-429/93 and C-436/93 *Bristol-Myers Squibb*, para 71.

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The parallel importer does not, however, need to clarify on the notification whether the repackaging has been carried out with or without the authorization of the proprietor.\textsuperscript{99} The important objective of the notification requirement is that the consumer can clearly determine who has manufactured the product, and that it can be determined who is responsible for the repackaging. The ECJ has concluded that it does not matter whether the party who actually conducted the repackaging (for example a contractor hired by the parallel trader), or the party that is ultimately responsible (for example the parallel trader, who holds the authorization for resale) is displayed as the repackager.\textsuperscript{100} The important thing is that the consumer is not mislead into believing that the proprietor has packaged the product, and for the proprietor not to be responsible or liable if there are damages caused by the repackaging.

4.5.3.2.5 \textit{New packaging – damage to trade mark repute}

Even if the original condition of a good is not affected by a repackaging action, the proprietor may oppose further commercialization of the product if the repute of the trade mark or the proprietor might be impaired as a result from the new packaging.

This was stated in Bristol-Myers Squibb, where the ECJ said:

"Even if the person who carried out the repackaging is indicated on the packaging of the product, there remains the possibility that the reputation of the trade mark, and thus of its owner, may nevertheless suffer from an inappropriate presentation of the repackaged product. In such a case, the trade mark owner has a legitimate interest, related to the specific subject-matter of the trade mark right, in being able to oppose the marketing of the product. In assessing whether the presentation of the repackaged product is liable to damage the reputation of the trade mark, account must be taken of the nature of the product and the market for which it is intended".\textsuperscript{101}

"In the case of pharmaceutical products, that is certainly a sensitive area in which the public is particularly demanding as to the quality and integrity of the product, and the

\textsuperscript{99} Id., para 72.
\textsuperscript{101} Joined cases C-427/93, C-429/93 and C-436/93 Bristol-Myers Squibb, para 75.
presentation of the product may indeed be capable of inspiring public confidence in that regard. It follows that defective, poor quality or untidy packaging could damage the trade mark's reputation”.  

The ECJ thus emphasized that trade mark repute is important in the marketing of pharmaceutical products, and that the packaging must not be of poor quality, untidy or defective. It added, however, that the importance of the way a drug is displayed through its packaging varies depending on the intended purchaser; a tidy packaging is more important if the products are to be sold to a pharmacy, where the consumer will actually see the product container, than if the intended purchaser is a hospital where healthcare professionals will be the only ones viewing the packaging.

4.5.3.2.6 Prior notice to the trade mark proprietor

In order to maintain knowledge of who is reselling goods, the proprietor is entitled to prior notification from the parallel trader, regarding the fact that the trader intends to resell the goods. The proprietor may also request a specimen of the new packaging. The purpose of this requirement is that the proprietor must be able to easily control the condition of the repackaged product and that the repute of the trade mark will not be damaged. It is also meant to increase the proprietor’s possibility of preventing counterfeit products from circulating into the market.

In another case, the ECJ has held that the notification must be from the actual parallel trader, and may not come from any other source or party.

It was further stated that the notification must be given as soon as possible after obtaining the relevant licenses from the national authorities, and that the

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102 Id., para 76.
103 Id., para 77.
104 Joined cases C-427/93, C-429/93 and C-436/93 Bristol-Myers Squibb, para 78. See also Hoffmann-La Roche.
specific minimum time for prior notice is a matter for the national courts to decide (but that 15 days prior notice is likely a reasonable time). 106

4.5.4 Damage to a trade mark’s prestige

4.5.4.1 Introduction

Situations where the mere reselling of a good might damage the trade mark’s prestige or repute arise mainly in cases regarding luxury goods, but the ECJ’s jurisprudence on the protection of trade marks’ prestige has a significant impact on the interpretation of “legitimate reasons” under Article 7(2) TMD and hence also the possibilities of opposing parallel trade in general.

4.5.4.2 Case law

In Dior vs. Evora, question arose whether the way in which a reseller markets a product can constitute ‘legitimate reasons’ within the meaning of Article 7(2) TMD, if the prestigious image and aura of luxury is impaired or altered. 107

The ECJ said that there must be a balance between a trade mark proprietor’s legitimate interest in protecting its trade mark on the one hand, and the reseller’s legitimate interest in being able to resell the goods in question. 108 The ECJ went on to conclude that:

"As regards the instant case, which concerns prestigious, luxury goods, the reseller must not act unfairly in relation to the legitimate interests of the trade mark owner. He must therefore endeavor to prevent his advertising from affecting the value of the trade mark by detracting from the allure and prestigious image of the goods in question and from their aura of luxury." 109

106 Ibid.
108 Id., para 44.
109 Id., para 45.
In the *Copad vs. Dior* case from 2009,\(^{110}\) question arose *inter alia* whether a breach of a clause in a licensing agreement, preventing sales of luxury goods to discount stores on the grounds that it could damage the reputation and prestige of a trade mark, could be invoked to oppose further commercialization on the basis of Article 7(2) of the TMD.

The ECJ reinforced the ruling established in *Dior vs. Evora* and accepted, as did the Advocate General, that the prestige of a trade mark can directly contribute to the quality of the products (in addition to the material elements of the product).\(^{111}\)

### 4.6 Burden of proof

#### 4.6.1 Put on the market with the proprietor’s consent

One important secondary question that reoccurs in most cases concerning exhaustion of intellectual property rights is that of the burden of proof.

Who bears the burden of proving that an intellectual property right, to which a dispute is pertaining, has been exhausted, or more specifically, that the proprietor has consented to the goods being put on the market?

This question was addressed in *Zino Davidoff & Levi Strauss*, where the ECJ concluded that the burden of proof must be placed on the party claiming that a good has been put on the market with the proprietor’s consent;\(^{112}\) which thus will be the parallel trader, in most cases.

It should be noted that in some cases this could be difficult for the parallel trader to prove, especially when the question is whether or not a right has been exhausted at all, and when the proprietor perhaps has put the products in question on the market using an elaborate exclusive distribution network.

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\(^{111}\) Id., para 23-26.

\(^{112}\) Joined Cases C-414/99 to C-416/99 *Zino Davidoff and Levi Strauss*, para 54.
Therefore, in *Van Doren + Q*, the ECJ held that the burden of proof may be shifted to the proprietor if the parallel trader succeeds in showing that there is an appreciable risk of partitioning of the market if the parallel trader bears the burden of proving exhaustion.

### 4.6.2 Legitimate reasons to oppose further commercialization

Who bears the burden of proving whether there are legitimate reasons under Article 7(2) TFEI to oppose further commercialization of a good bearing a trade mark and that has been put on the market with the proprietor’s consent, particularly in repackaging cases?

This question was addressed by the ECJ in *Boehringer Ingelheim vs. Dowelhurst*. The questions raised were, *inter alia*, whether the parallel importer had to prove that the repackaged goods were in compliance with the relevant prerequisites for repackaging trade mark protected goods, or if it was the proprietor who had to prove that the repackaging was not compliant.

The ECJ concluded that in repackaging cases, it falls on the parallel trader to prove that the conditions for legal repackaging have been fulfilled. The proprietor thus does not have to prove that the repackaging by the parallel trader does not fulfill the requirements.

However, with regard to the repackaging prerequisites relating to the original quality of the product and the reputation of the trade mark, the ECJ introduced a slightly lighter burden of proof for the parallel trader, by stating that:

"As regards the condition that it must be shown that the repackaging cannot affect the original condition of the product inside the packaging, it is sufficient, however, that the parallel importer furnishes evidence that leads to the reasonable presumption that that condition has been fulfilled. This applies a fortiori also to the condition that the

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113 Case C-244/00 *Van Doren + Q. GmbH v Lifestyle sports + sportswear Handelsgesellschaft mbH and Michael Orth*, [2003] ECR I-3051.
114 Id., para 41.
115 C-348/04 *Boehringer Ingelheim vs. Dowelhurst*, para 52.
presentation of the repackaged product must not be such as to be liable to damage the reputation of the trade mark and of its proprietor. [...] 116

Regarding the original condition of the products and the reputation of the trade mark, the parallel trader thus only has to show reasonable presumption that the conditions have been fulfilled.

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116 Id., para 53.
5 Some economic and policy aspects

5.1 Introduction

Within the scope of this paper it is only possible to provide a brief inquiry on the economic aspects of parallel trade. The attempt has been to summarize the conditions and conclusions of some of the central studies and thus to present an accessible overview of some of the applicable economics on the subject.

Let us first return to the core question that was formulated in Section 1.2;

• Does parallel trade in pharmaceuticals result in benefits that actually accrue to patients and society, or is it merely a practice that exploits the legal principle of exhaustion of intellectual property rights to the ultimate benefit of short-term opportunists?

From this question we can extract three more specific ones;

• Does parallel trade in pharmaceuticals have a measurable effect on investment incentives for R&D and market development?
• How well does parallel imports function as price levelers in the markets for pharmaceuticals, where prices are set on a national basis by public policy?
• Does parallel trade in pharmaceuticals result in welfare gains or other benefits that accrue to consumers?

With these questions as a basis, the main issues to be examined are investment incentive, consumer benefit and market integration. First, the idea of market integration will be examined from an economic point of view. Then follow inquiries on investment incentive and consumer benefit in further detail.

As a starting point, we first briefly look at four categories of market settings where parallel trade has been found to likely reduce total economic welfare, as identified in the economic literature by Barfield and Groombridge. The
pharmaceutical market was found to involve elements from all four market settings.\textsuperscript{117}

Thus, in the following settings parallel trade is likely to reduce total welfare:

- In high-tech sectors where the sunk costs for R&D are high, where parallel trade inhibits the ability for companies to recoup their R&D investments, and thus reduce the ability to further innovate,
- In cases where public policy creates price disparities, and thus drives prices below average fixed costs in some markets,
- In situations where price discrimination will enhance welfare, and
- In situations where there are free rider problems because parallel trade can undermine authorized distribution channels with lower prices, and thus hurt information and service activities by those authorized channels.\textsuperscript{118}

These situations and their likelihood of affect total welfare provide a good basis for further inquiry. Effects on total welfare is however only interesting if we also get an idea of the allocation of welfare.

### 5.2 Market integration for pharmaceuticals within the EEA

#### 5.2.1 Price discrimination or uniform pricing?

Price discrimination is the selling of identical goods at different prices to different customers. The opposite of price discrimination is uniform pricing, meaning that identical goods are sold at the same price.\textsuperscript{119}

The principle of free movement of goods aims at creating an integrated single market within the EEA,\textsuperscript{120} and thus to reach uniform pricing for any identical


\textsuperscript{118} Barfield & Groombridge, page 187.

\textsuperscript{119} Bernanke & Frank, page 299.

\textsuperscript{120} See section 3 above.
The differences in prices for pharmaceuticals among Member States is a form of price discrimination, however parallel imports reduce the proprietor’s ability to apply an effective price discrimination strategy. This is because the high prices (where affordability and willingness to pay is high) are undermined because the parallel trade limits the extent to which price discrimination is profitable.\textsuperscript{122}

The question is then whether market based price discrimination or uniform pricing would be to prefer. Richardson\textsuperscript{123} argues that in a simple price discrimination setting, where countries simultaneously and independently choose their parallel trade policies, any Nash equilibrium will be one involving parallel trade to all importing nations, and that, despite the risk of being dropped from the market, small countries may actually prefer uniform pricing over price discrimination.\textsuperscript{124} This is because, concludes Richardson, the countries who will favor parallel trade are those who are discriminated against in its absence, namely high-income countries. While low-income, high elasticity of demand countries would favor price discrimination instead of uniform pricing, to obtain a lower price, they cannot enforce it under this setting, and hence the result of the Nash game.

Richardson thus argues in favor of parallel trade, by showing a setting where, despite a possible welfare loss of low-income countries, allowing parallel trade and aiming at uniform pricing is the likely outcome of any Nash game.

These conclusions are however argued against by Acharyya & García-Alonso, who conclude \textit{inter alia} that price discrimination (or rather: price

\textsuperscript{121} Note that the \textit{primary goal} is not necessarily uniform pricing, but free movement in order to achieve economies of scale through specialization (see Section 3.2). Uniform pricing is however at least a secondary goal, because that is how occasional arbitrage opportunities, with the result of uniform pricing, leads to an effective allocation of resources and a unified marked.


\textsuperscript{124} Author’s remark: It should be noted that this result is sensitive to the price setting ability of nations.
discrimination without interference from parallel trade) is the optimal setting as regards pharmaceuticals, both in terms of innovation, total welfare and distribution of welfare. They show that both rich countries and poor countries will prefer price discrimination under the welfare criterion. One reason why they argue that Richardson’s model will not work in real situations is that the claimed benefit for high-income countries with parallel trade does not account for the lower quality of goods resulting from parallel trade. Acharyya & García-Alonso also show that consumers in the low-income countries are worse off from parallel trade and uniform pricing, than under market based price discrimination, when there are intra-country income disparities.

5.2.2 Price convergence for pharmaceuticals

In a market characterized by effective competition, where prices are subject to normal market forces, parallel trade due to arbitrage opportunities can have the effect of eliminating price disparities and hence eliminating the possibilities to further arbitrage profits. For this reason, arbitrage is normally a fringe activity which only occurs occasionally, when attractive opportunities appear. Under such circumstances, parallel trade can have the effect of converging prices between markets and thereby creating an efficient Internal Market by ensuring free trade, high transactional liquidity and by approaching the general goal of uniform pricing within the Internal Market.

In the pharmaceutical market, the situation is different. Regulated prices for pharmaceuticals will not converge effectively as a result of parallel importation. Under current market conditions, parallel trade could go on for a long time, and there would still exist significant price gaps for certain drugs, despite the slight downward pressure on the authorized prices for parallel imported drugs in the high-price importing countries. For convergence to occur, the authorized prices in the low-price exporting countries would have to be pushed upwards in interaction with the shift in demand resulting from the parallel trade

125 Acharyya & García-Alonso in general, but see specifically page 75.
126 Regarding the impact of parallel trade on quality, see Section 5.4.3 below.
in those countries (the total demand for pharmaceuticals in the exporting countries is higher than the domestic need for drugs, yet this is not reflected in the prices). This price increase will not occur, at least not as a result from parallel trade, because the authorized national prices are fixed beneath price ceilings.\(^{128}\)

5.3 Investment incentive and the level of innovation

5.3.1 General about innovation and its effects

To promote future access to new effective medicines and medical treatments in an effort to increase life expectancy and the quality of life, it is critical to maintain a high level of pharmaceutical innovation.\(^{129}\) It is also relevant to facilitate investments in market development by the downstream authorized distributors, because this ensures effective and efficient supply channels to consumers. This chapter will examine how parallel trade and uniform pricing may affect the incentive to invest in R&D and market development, and thus how it directly affects the level of innovation and development of new high technology drugs.

5.3.2 Incentive to invest - effect of parallel trade on investment incentive

5.3.2.1 Introduction

There are several excellent studies on the topic of investment incentive and the effect of parallel trade on innovation. These studies will be reviewed in short in

\(^{128}\) See for example Guo, Shen, Hu, Bin, Zhong, Hai, ‘Impact of Parallel Trade on Pharmaceutical Firm's Profits: Rise or Fall?’ (2013), European Journal of Health Economics, Vol. 14, No. 2, pp. 345-355. However, there are assertions in the literature that the presence of parallel trade will cause the pharmaceutical firm to negotiate harder with the low-price country about the price ceiling in attempts to curb parallel trade.

\(^{129}\) For example, a 2012 study showed that between the years 2000 and 2009, the mean life expectancy in 30 developing OECD and high-income countries was increased by 1.74 years. 73% of that increase was determined to be attributed to innovative medicines: Lichtenberg, Frank R. (2012), Pharmaceutical innovation and longevity growth in 30 developing and high-income countries, 2000-2009, National Bureau of Economic Research, NBER Working Paper Series, Working Paper 18235, page 18.
the following. Focus on the conclusions and, to assess the applicability of the conclusions, the relevant features of the studies.

5.3.2.2 Economic studies

A classic study is *Malueg & Schwartz*\(^{130}\), which uses a monopolistic discriminatory pricing model to ultimately show that parallel trade can benefit consumers in the countries where the prices are high, but harm the consumers in the low-price countries. They further conclude that if demand dispersion is high between countries, total welfare will suffer and as a result, the level of innovation will suffer.

*Maskus & Li*\(^{131}\) develop a two-country model. The focus is on investment incentive in process innovation, such as cost-reducing R&D. The investment is endogenous from a manufacturer who faces competition in its own products from parallel trade. The study finds that parallel trade inhibits innovation by reducing investment in R&D, and that the reduction depends both on the legality of parallel trade and the cost of engaging in parallel trade. This is found to have a harmful effect on global welfare.

*Palangkaraya & Yong*\(^{132}\) construct a model based on vertical pricing control with a two-tariff pricing. The parallel trader is modeled as a fringe firm, in competition with the authorized distributor a dominant firm (and the competition setting is leader-fringe-follower). The most important conclusion from this study regards market development investment incentive and provides evidence that not only the presence of parallel trade reduces incentives to invest, but the mere threat posed by parallel trade has a measurable negative effect.


Likewise show that parallel trade results in a lower level of health care innovation, but unlike Malueg & Schwartz, this study places greater emphasis on examining welfare allocation. They show that the highest level of innovation will be achieved when the proprietor can price discriminate across all countries.

5.3.2.3 Concluding remarks

The studies reviewed above conclude that parallel imports deter innovation inter alia by reducing incentives to invest in R&D and market development. Deviations from this main conclusion are due to assumptions that do not apply to the market conditions of the EEA pharmaceutical market.

One way in which governments try to boost incentives to invest in R&D is to implement taxation incentives, both to the research companies and to external investors, which could perhaps mitigate the negative effects from lowered levels in private investments.133

5.3.3 Ability to re-invest – effects on proprietors’ profits

The obvious intuition when a proprietor is exposed to intra-brand competition against its own products is that the proprietor loses profits as a result. This is also most often the situation, but it should be noted that there are situations where parallel trade could raise the profits of the proprietor. Such situations were the subject of analysis in the following study on the topic.

Guo, Hu & Zhong134 construct a model where the presence of price regulations is taken into account.135 Their results show that a pharmaceutical firm’s (short

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133 Regarding public funding and national taxation incentives relating to R&D, see the report: Kanavos, Panos, Vanderoros, Sotiris, Irwin, Rachel, Nicod, Elena, Casson, Margaret, Differences in Costs and Access to Pharmaceutical Products in the EU, European Parliament, Brussels, 2011.

term) profit may either increase or decrease as a result from parallel trade. They assert that in the existence of legal parallel trade, proprietors will work harder to negotiate higher prices with the low-price countries, in order to curb parallel trade. If the market size of the low-price country is large enough, the combination of curbed parallel trade and a higher profit from the price increase, might result in higher profits than without parallel trade. In contrast, however, if the market size is small, the leverage to negotiate higher prices may not be enough to recover the profit losses from parallel trade in the high price countries, and not enough to curb parallel trade, so in this case there may be a profit loss in all markets.

The study also shows that when parallel trade is legal, the social welfare in the low-price countries is unambiguously hurt, while the social welfare in the high-price countries is ambiguous and depends on whether the increase in consumer surplus outweighs the potential profit losses of the proprietor.

5.4 Consumer benefit

5.4.1 Introductory remarks

In a simplified approach, the consumer benefit topic will be divided into two perspectives; long term and short term. The long term perspective regards future access to new effective medicines and securing the quality of life for the consumers. The short term perspective includes three pieces; quality, reliable supply and pricing.

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135 This is the first study on proprietor profit in the pharmaceutical industry where national price regulations have been an included assumption.
136 Author’s remark: It should be noted that this result is sensitive to the price setting ability of nations.
137 Author’s remark: It should be noted however, that this model fails to acknowledge the obligation in the EU for proprietors to supply products well exceeding the national demand of pharmaceuticals. Hence, the emphasis on market size may actually have been over stressed, because the volume of parallel trade carried out is not sensitive to market size of the exporting country since there will be close to unlimited supply notwithstanding market size (which also affects the balance of bargaining power between the proprietor and the national governments). This makes the results unclear as to what extent this model is applicable to the EEA markets.
5.4.2 Long term consumer welfare

This issue has a clear connection with the level of innovation – and thus also investment incentives – in the pharmaceutical industry. Long-term consumer benefit will follow from the development and marketing of innovative medicines.\(^{139}\) Thus, a decrease in the investment incentive in R&D and subsequently a lower level of innovation could have a measurable negative effect.\(^{140}\)

5.4.3 Short term consumer welfare

It follows from the Guo, Hu & Zhong study\(^{141}\) that prices will increase or stay unchanged in low-price countries and decrease in high-price countries as a result from parallel trade. An increase of the price in low-price countries is due to bargaining powers for proprietors in negotiations with the national authorities, such bargaining power depending on e.g. the market size of the exporting country and the volume of parallel trade. For consumers, the total short term consumer welfare effects with regard to pricing will thus either stay neutral in low-price countries and be improved (due to price drops) in high-price countries, or be impaired in low price countries (due to price increases) and improved in high-price countries (due to price drops).\(^{142}\) The sum of these effects will thus show the total effect on price related consumer welfare, however, any impairment of welfare in low-price countries will likely strike harder on consumers in those countries than would a corresponding welfare impairment in high-price countries.

The quality aspect is problematic. A report to the European Commission\(^{143}\) has shown quality issues and health risks resulting from parallel trade, both due to

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\(^{139}\) Supra note 124.

\(^{140}\) See Section 5.3.2 above.

\(^{141}\) See Section 5.3.3 above.

\(^{142}\) See Guo, Hu & Zhong.

human error in repackaging and an increased risk of counterfeit products entering the legitimate supply chain.\textsuperscript{144}

Supply issues will arise in low-price countries where much of the imported or manufactured medicines will be exported, while the supply will be steady in high-price countries, where there will be drugs available from both authorized channels and parallel trade.\textsuperscript{145}

\textsuperscript{144} Regarding these quality issues, see further Bart, Thomas N., ‘Parallel Trade of Pharmaceuticals: A Review of Legal, Economic and Political Aspects’ (2008), Value in Health, Vol. 11, No. 5, pp. 996-1005, page 1000 (hereinafter “Bart”).

\textsuperscript{145} For trade balances of any specific Member State, see; The European Federation of Pharmaceutical Industries and Associations, \textit{The Pharmaceutical Industry in Figures – Key Data}, 2013, page 20. The supply related issues resulting from parallel trade are also addressed in Europe Economics, \textit{Safe Medicines Through Parallel Trade – Contribution to an Impact Assessment}, 2008.
6 Analysis and discussion

6.1 Introduction

To accord with the objectives of this paper, the following section will aim to analyze and discuss the issues identified throughout the previous sections, with the aim of benchmarking and balancing the interests of the different stakeholders and to reach de lege ferenda conclusions in relation to the issues.

The chapter will set off with an analysis of the current legal status and some remarks on the jurisprudence of the ECJ, including a discussion on the balance between intellectual property rights and the free movement of goods. The chapter then continues with an effects based analysis of parallel trade, based on the issues pertaining to innovation, consumer benefit and market integration.

6.2 Extracting the current paradigm from the case law

6.2.1 Legal analysis of the current legal regime

It should first be noted that the case law from the ECJ appears very consistent and the coherence is impressive. This is especially true for the repackaging cases, with special prominence to Bristol-Myers Squibb, which is detailed and explanatory enough to be considered a handbook to repackaging. As a result, the legal consciousness is high among the different market players and the constantly arising legal disputes seem to be engendered from the different stakeholders in the parallel trade arena hoping to gain momentum in their legal positions, or trying to find loopholes in the current legislation. This consistency however comes at a cost; it may result in formalistic rules that leave little room for overall consideration of specific circumstances in the individual cases. Neither have there been any notably elaborate balancing assessments between the interests of the parties, but instead the ECJ seems to over stress the importance of free movement to the degree that the principle may be arbitrarily

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146 As set out in Section 1.2.
147 See, in particular, Section 4.5.3 above.
enforced even where it is not suitably applicable. Such can be the case for example in relation to repackaging of pharmaceuticals.\textsuperscript{148} A specific issue on that topic is that the ECJ, in Merck vs. Paranova, ruled that it is up to the national courts to determine what constitutes ‘objective necessity’ of repackaging. This is good in a way – in theory it leaves room for adequate assessments in each individual case. In practice, however, there is a risk that the rules on objective necessity will not be uniform throughout the EEA.

What is more, the very possibility of legal repackaging can be considered controversial. Not only because of the substantive adverse effects it can have on a trade mark, its proprietor or on the quality of the products, but because the effect of generally permitting this activity is an unbecoming extension of the exhaustion doctrine. The reason for this is that further to the legality of importing and reselling products relating to an exhausted right – which is a passive activity in relation to the trade mark – it is also permitted to actively reproduce the brand and to affix the trade mark to new packages. This is an active activity which was never permitted under national exhaustion,\textsuperscript{149} and the very nature of reproducing a brand and affixing it to new packaging should be considered to interfere with the specific subject matter of trade marks as defined in Hoffmann-La Roche and Centrafarm v Winthrop.\textsuperscript{150}

Does this mean that the right to repackaging should be banned in general? No, not necessarily; it should be reminded\textsuperscript{151} that the (conditional) legality of repackaging may very well be necessary from a ‘free movement of goods’ point of view. This is because any other approach would likely facilitate a partitioning of the Internal Market by allowing proprietors a too wide loop hole to oppose parallel trade in general, due to the increased possibility of raising

\textsuperscript{148} An example is cases is how easily repackaging is deemed objectively necessary in relation to pharmaceuticals, and that the repackaging is seldom deemed to impair the original condition of the product. Case C-1/81 Pfizer Inc. v Eurim-Pharm GmbH, [1981] ECR 2913. It is however not strange, as regards legal technicality, that the ECJ has taken this approach. This is because of the differentiated regulations for pharmaceutical packaging between Member States; a more restrictive approach on ‘objective necessity’ would risk facilitating an artificial partitioning of the market.

\textsuperscript{149} See section 4 above and see further: Hays, page 96.

\textsuperscript{150} See section 4.2 above.

\textsuperscript{151} See Section 4.5.3.1 above.
barriers to entry. Despite this tricky balancing situation, the solution to which cannot be calculated but varies with opinion, it is well worth giving a thought as to whether the trade-off between the opposing interests regarding this issue is proportionate or not.

Consistency in the jurisprudence does not necessarily mean that the established case law is desirable in every aspect. For example, analyzing the recent jurisprudence of the ECJ with regard to damage to trade mark prestige under Article 7(2), especially *Dior vs. Evora* and *Copad vs. Dior*,152 it seems the court finds it more pertinent to accept "legitimate reasons" under Article 7(2) relating to protecting the repute and prestige of luxury goods, rather than the more serious concerns relating to parallel trade in pharmaceuticals.153 We shall see in Section 6.3 why the pharmaceutical cases appear to deserve a higher degree of deference.

Furthermore, the broad interpretation of Article 7(2) regarding protection of the reputation of luxury goods, as widened *inter alia* in the above mentioned cases, brings risk of diluting the principle of free trade within the EEA by narrowing the scope of trade mark exhaustion for general goods. The free movement of goods principle, and thus the EEA-wide exhaustion doctrine, should aim at protecting the Internal Market by promoting free trade. The *Dior vs. Evora* and *Copad vs. Dior* cases, by ruling that the repute of a trade mark can have a direct effect on the quality of the underlying goods, may increase the risk of market segmentation and raised barriers to entry for certain regular goods in the long run, if this interpretation of Article 7(2) is broadened further.

### 6.2.2 Balancing the different interests

In general balancing terms, a typical argument for comprehensive protection of intellectual property, to the detriment of Internal Market law, is that the rights are national by nature, and that such rights should not be violated by a too broad extension of EU law. This argument is however rather blunt, because it

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152 See section 4.5.4.2 above.
153 Ibid.
is purely technical. Instead, to appropriately make a sturdy balancing of interests, one should assess the underlying importance of intellectual property rights in any peculiar context. One should thus not just arbitrarily point to the traditional nature of intellectual property, or to the enshrined principle of free movement for that matter.

From this paper, it can be argued that in the balance between intellectual property rights and the principle of free movement, the main objective of intellectual property protection in the context of pharmaceuticals may be to facilitate an innovation friendly climate, and thus to promote investment incentive. Thus, the Internal Market should strive at reaching a balance where free trade is the main rule, but where there is satisfactory protection of investments made and where investment incentives are facilitated.

As regards the current substantive law on the topic of opposing parallel trade, it should be noted first of all that the possibilities for a trade mark proprietor to oppose further commercialization of goods relating to exhausted trade mark rights on the grounds that the products have been repackaged, are severely limited. This is at least the case with regard to pharmaceutical products. The principles established in Hoffmann-La Roche and Bristol-Myers Squibb to determine and condition the legality of repackaging and relabeling – the five cumulative criteria\(^ {154} \) – are not difficult to fulfill for a serious parallel importer.

However, even in cases where the criteria for repackaging are fulfilled, there are serious issues to be taken into consideration from a balancing-of-interests point of view. One of the most important issues, due to its potential adverse health effects, is the quality of goods aspect. Even though it is a criterion for repackaging that the original condition of the goods must not be adversely affected,\(^ {155} \) there is no guarantee for the proprietor or the end consumer that such will always be the case. There are recorded examples of human error in

\(^ {154} \) Described in Section 4.5.3.2.
\(^ {155} \) See Section 4.5.3.2.3 above.
the repackaging process, which has ultimately led to unfortunate quality implications on the drugs that were subject to repackaging.\textsuperscript{156}

The balance in this case is \textit{inter alia} between the right for the parallel trader to offer for sale the goods which he has purchased and repackaged, and the interests of the proprietors and the consumers as regards safe pharmaceuticals of high quality as well as securing future supply of innovative medicines. On the one hand, if we examine merely the effects and substantial quality impairment risks involved, free trade seems the more important objective to protect, because the recorded cases of impaired drug quality as a result of repackaging are rather far apart, and the free trade objective is important to maintain. On the other hand, we also have to observe potential uncertainty among customers as well as general policy aspects. For example, consumers would likely never accept repackaging of their food, so why should this be accepted for pharmaceuticals, which in general are more sensitive as regards special requirements in transportation, storage and care in handling, than food? The adverse effects of consuming a drug of which the quality has been impaired can in some cases be severe. The activity of designing, developing and manufacturing pharmaceuticals is strictly regulated enterprises because of the absolute necessity of keeping these processes safe. Yet, once the products get on the market, the safety reins are lightened by the possibility of repackaging. Is this really appropriate and proportionate?

6.3 Economic aspects

6.3.1 General – market impact of parallel trade

With an estimated market value at € 5 billion annually\textsuperscript{157} and still growing, whether the EU legislator likes to accept it or not, parallel trade is now ‘Big Business’, with a massive impact on the market. The trade volume and scale of a multi-billion Euro intra EEA industry is of course enormous, which makes the market force that this trade brings too important to ignore. It is important to

\textsuperscript{156} See section 5.4.3.
\textsuperscript{157} See section 2.2.2 above.
point out that this €5 billion industry is not evenly distributed over the Member States, but exportation and importation are concentrated to certain countries with exceptionally low and high prices respectively, which further leverages the effects in those nations. 158

Drug parallel traders are no longer small, fringe firms operating in the outskirts of the pharmaceutical industry, but have become major players in the mid-large size corporate category, whose actions have large impact. With the high leverage that comes with such a large scale, it is necessary to examine what effects are actually generated and promoted when the principle of free movement of goods takes clear legal precedence over other interests related to intellectual property rights, and the parallel traders are given a ‘free for all’ open goal.

6.3.2 Effects on investment incentive

Investment incentive is perhaps the most crucial piece of the issues relating to parallel trade in pharmaceuticals. This is because R&D is a cornerstone in not only securing future access to effective medicines worldwide, but it is also the competitive edge of the European pharmaceutical industry, and a driving force in securing the future of one of the most significant industries as regards technological innovation, turnover, employment and potential profit in Europe.

The conclusions of the economic studies on investment incentives159 point in the direction that parallel trade is harmful to innovation. In fact, the results are rather startling; not only the existence of parallel trade is detrimental to investment incentive by reducing the willingness to invest and diminishing profits that would have been available for reinvestment, but already the mere threat of parallel trade seems to have a measurable negative effect.160 This is of course severely dangerous for the future of the European pharmaceutical sector, because due to the high costs and high risks of development of new or

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158 See further, Bart, page 999.
159 See Section 5.3.2.2 above.
160 See Palangkaraya & Yong under Section 5.3.2.2 above.
existing drugs, both internal and external investments and access to capital is essential in funding R&D.

There are public measures to increase willingness to invest, such as indirect tax incentives.161 This is a step in the right direction, as it implies that the national governments care about R&D and are aware of its importance. National taxation reduction incentives by all means; they may work, short term. Fiscal incentives, as such, are however not enough to compensate for a lack of real investment incentives in any particular sector. Incentives to invest to make long term profits must be based on the very underlying objective of the investment – to generate a surplus of resources, not just to redistribute existing resources or support short term liquidity. Thus the motivation should be that the target industry of the investment is (allowed to be) lucrative for private entities to make high risk engagements, not that there is public funding to loot.

**6.3.3 Market integration for pharmaceuticals – at what price?**

The model of national pricing for pharmaceuticals constitutes a problem as long as the Internal Market aims at uniform pricing for drugs. In fact, it could be considered one of the most important underlying problems relating to parallel trade in pharmaceuticals within the EEA. The reason is the following: To protect and facilitate equality in health care in the low-income Member States, national pricing is necessary. This is acknowledged by the EU, who allows for national pricing policy.162 While this creates an ineffective form of forced first degree price discrimination if parallel trade is permitted,163 the Commission and the CJEU nonetheless claim to aim at integrating the market through parallel imports – in other words – to establish uniform pricing. This approach by the Commission and the CJEU is not only facilitating an inefficient market due to the inappropriate form of price discrimination that is forced, it is also hurting the consumers both short term and in the long run.164

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161 See Section 5.3.2.3.
162 For example, regarding the fact that national statutory price fixing of pharmaceuticals does not constitute a quantitative restriction under Article 34, see section 3.4 above.
163 See Section 5.2.1.
164 See Section 5.4.
It seems on this issue, solving one problem will just beget another unless one focuses on the right objectives. The question that must be asked is perhaps not \textit{how} to force market integration, but instead: Is price convergence, with the result of uniform pricing, really the desirable effect at this stage of integration?

Economic theory provides support for allowing an effective price discrimination policy, rather than aiming at uniform pricing, namely on the grounds that current market conditions provide for a welfare gain if price discrimination is applied; the main portion of which would be allocated to the consumers in the low-income countries short term, and all consumers long term.\textsuperscript{165}

While parallel import arbitrage can be an important component in equalizing prices in many markets (and indeed, in the case for many product categories, parallel trade within the Internal Market can likely be very beneficial), this is clearly not the case for pharmaceuticals, where prices are set nationally. In such cases where the advantages of market integration disappear and all parties but the parallel traders themselves lose on this ongoing failing attempt at market integration, the question must be asked whom the legal system should be designed to protect. \textit{De lege lata}, parallel traders seem to enjoy the most legal privileges and arguably all economic benefits. Under the circumstances at hand, however, the parallel traders appear revealed to be nothing more than just traders, looking to ’make a quick buck’, and deserving no particular deference or protection.

All in all, perhaps the Internal Market is not ready for an integrated, uniform priced ’single market’ for pharmaceuticals just yet?

\textsuperscript{165} See Section 5.2.1.
7 Author’s concluding remarks

7.1 Introduction

This section summarizes the author’s conclusions on the discussed topics. The reader is advised to remain critical to the conclusions and to observe that the remarks in this chapter are solely and explicitly the opinions of the author.

7.2 Conclusions

Parallel traders turn out to be neither dubious villains nor glorious heroes, but instead just somewhat legitimate businesses claiming lawful arbitrage opportunities – perhaps with a good cause in mind, perhaps not. The pharmaceutical industry evidently suffers profit losses as a result of this gray market trade, but that is hardly an issue worthy of a grand legal policy debate.

However, all circumstances combined, parallel trade in pharmaceuticals within the EEA seems detrimental to everyone; to the Internal Market, to consumers, to innovation and to the competitive edge of the European pharmaceutical industry. The economic studies examined in this paper unambiguously point in this direction.

Even though the intensity of the public discussion on pharmaceutical parallel imports seems rather calm at the moment, the positions of the opposing parties are far apart and the topic is tense and politically charged. The debate seems infected with ambiguity and biased opinions. The de lege ferenda discussion has been stalled for decades and most arguments put forward by the debaters are awkwardly uninformed. These are likely the most pertinent reasons why the ECJ repeatedly looks away from the real issues in the pharmaceutical cases while instead resorting to legal technicalities, and why the EU legislator appears reluctant to confront the matter once and for all. Meanwhile, the world is watching as the European pharmaceutical research industry is slowly
undermined from within, and consumers are left uncertain as to what extent their welfare interests are really looked after by policy makers.

7.3 Looking forward

The focus of the EU legislator should be shifted as regards pharmaceuticals in the Internal Market; from curbing prices for the rich consumers in high-income member states and facilitating never-ending arbitrage for parallel traders, to looking after the benefit and protection of all consumers while promoting an innovation friendly research and business climate within the EEA.

It is difficult to draw any conclusions regarding legislative ways of solving the issues outlined in this paper. Elaborating freely – one solution could be the creation of a separate artificial internal market for medicines, with a categorical distinction between prescription drugs, non-prescription drugs, patented drugs and drugs that are no longer enjoying patent protection (generic drugs). Within this separate internal market, it would be possible to set distinctive rules relating to inter-EEA trade in pharmaceuticals, in consideration of the peculiar market conditions and all the industry specific objectives worthy of special protection. Regardless of how such a distinctive legislation were to be constructed, in this setting it could carried out without the risk of distorting the Internal Market relating to the free movement of ‘normal’ goods.
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