

BLURRY VISION: PARALLEL IMPORTS, MEDICAL DEVICES, AND COMPETITION IN THE EUROPEAN MARKET FOR CONTACT LENSES

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Abstract

Shopping for prescription contact lenses is part of a daily routine common to many consumers in major parts of the world. Consumers usually choose to buy their prescription contact lenses from either their local eye care professional or a secondary online supplier. This freedom of choice benefits consumers and enables manufacturers of prescription contact lenses to expand distribution and increase sales. This Article provides an analysis of the market for prescription contact lenses in the European Union (EU). The Article explores the branding and pricing of contact lenses and posits that consumers who wear prescription contact lenses benefit from the option to purchase contact lenses online or offline. In addition, the Article argues that the nature of parallel trade in the EU facilitates such benefits for consumers. Therefore, the main goal of the Article is to determine whether and how the sale and pricing of contact lenses in the EU affects consumers, competition, and competition law. The research found that there is a healthy dose of competition in the market for contact lenses, that European consumers prefer shopping online for contact lenses, and that eye care professionals generally direct their customers to their online stores to purchase contact lenses as opposed to selling them offline in their brick-and-mortar operations.

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I. INTRODUCTION

In this era of online commerce, price and brands are all that matter to consumers; they seek the flexibility to choose and shop wherever and however, provided that the items can be delivered to their doorsteps. In order to satisfy the demands of consumers, there should be no prohibitions against online shopping for certain medical devices such as contact lenses. In adapting to the era of electronic commerce, the intellectual property rights-holders need to control how their property rights are being exploited, particularly online. But, at the same time, intellectual property rights-holders must also encourage shopping on the Internet without taking steps that may be deemed anticompetitive or preventing the market from functioning competitively. These are the stakes in today’s reality of “one-click shopping.”

The intertwining of intellectual property rights with competition

(antitrust) law¹ has shifted the foundation of what trade used to be, largely in part due to Internet shopping. During the latter years of the twentieth century, shopping over the Internet emerged.² Since then, electronic commerce has been tried, tested, and proven.³ The laws that were developed during the emergence of Internet shopping were catered to the *old* system of trade prior to the 1990s, and little flexibility was put in place to accommodate the new format for online commerce.⁴ Because the rules were catered to the pre-online system of commerce, the courts and authorities interpreted those same rules in a piecemeal fashion when it came to online intellectual property infringement cases.⁵ The various businesses in goods and services that were affected adjusted slightly to accommodate the new legal opinions pertaining to electronic commerce.⁶ But those accommodations can only be temporary; the ground underneath online commerce is shifting at a significant level. Two particular areas of law, trademark law and competition law, will not only need radical reform, but a new construct in order to accommodate the shifting gravity of commerce, including those conducted online.

In this Article, I turn the focus to one area of online commerce that affects consumers in a specific geographic region, the European Union, in order to determine the effects of online commerce on consumer welfare (defined broadly to include perceived benefits, anticompetitive activities, and pricing). This Article's focus is on: the market for prescription contact lenses; its connection to medical devices; the welfare benefits to consumers purchasing lenses online and offline; the effects of antitrust law pricing, co-branding, and lock-in theory (from the realm of antitrust economics); and, finally, the role of parallel trade (re-importation). As I will argue below, prescription contact lenses are medical devices—one of the most popular medical devices that the average consumer comes into contact with—and dependence on contact lenses has led to a rapid increase in revenues of contact lens manufacturers and their parent companies in the medical device industry.⁷

1. In this Article, “competition” may refer to two competing firms in the marketplace, but in certain contexts, “competition” is also a reference to “antitrust” under the competition rules under Articles 101 and 102 of the Treaty on the Functioning of the European Union (TFEU), formerly Articles 81 and 82 European Community (EC) Treaty. Consolidated Version of the Treaty on the Functioning of the European Union arts. 101–02, Mar. 30, 2010, 2010 O.J. (C 83) 47, 88–89 [hereinafter TFEU]. These provisions are also identical to antitrust provisions of the Sherman Act, sections 1 and 2. *Id.*; The Sherman Antitrust Act §§1–2, 15 U.S.C. § 1 et. seq. (2006). The TFEU introduced certain changes in terminology, such as the replacement of “Community” with “Union” and “common market” with “internal market.” See Treaty of Lisbon Amending the Treaty on European Union and the Treaty Establishing the European Community art. 1(2)(b), art. 2(2), Dec. 13, 2007, O.J. (C 306) 1 (“The Union shall replace and succeed the European Community.”). The Treaty of Lisbon served as the precursor to the TFEU. Protocol A to the Treaty of Lisbon Amending the Treaty on European Union and the Treaty Establishing the European Community, Dec. 13, 2007, 2007 O.J. (C 306) 148.

2. Phillip M. Nichols, *Electronic Uncertainty Within the International Trade Regime*, 15 AM. U. INT'L L. REV. 1379, 1380–90 (2000) (arguing that the World Trade Organization is in a position to remedy the anomalous situation created when technological ability surpasses legal infrastructure).

3. *Id.* at 1384–88.

4. See *id.* at 1402–03 (describing how international law has been slow to adapt to online commerce).

5. *Id.* at 1406–07 nn.99–103.

6. *Id.* at 1388–89 nn.22–27.

7. See ERNST & YOUNG, PULSE OF THE INDUSTRY: MEDICAL TECHNOLOGY REPORT 2011, at 2 (2011), available at [http://www.ey.com/Publication/vwLUAssets/Pulse_of_the_industry/\\$FILE/Pulse-of-the-industry](http://www.ey.com/Publication/vwLUAssets/Pulse_of_the_industry/$FILE/Pulse-of-the-industry).

I argue that there is concern for antitrust/anticompetitive harm regarding the branding and pricing of contact lenses. But despite these concerns, there is little evidence in the structure of the contact lens market to suggest that there is antitrust harm, and this is due in part to the medical nature of contact lenses. Following this introduction, Part II offers a review of the historical emergence of contact lenses and then frames the section against the background of trademark law and medical devices. To this end, the section discusses the branding of contact lenses and what benefits a consumer derives from both the branding and the usage of contact lenses. Part III then introduces the concept of parallel trade (re-importation) and explains how contact lenses are only but one set of goods that traverse this complex area of law where intellectual property rights-owners cannot mount challenges once their goods have been placed on the market. The part introduces free movement principles in EU law via parallel trade then discusses and argues whether the intellectual property rights-holders of contact lenses or whether a member state in the EU can prevent the sale of contact lenses online. An examination of the European Union Court of Justice (CJEU) decision, *Ker-Optika v. ÁNTSZ*,⁸ reveals the answers to the arguments raised in this section. The antitrust law issues and possible harms in this Article are explored in Part IV, particularly, the nature of pricing, lock-in theory, private labeling, and abuse of a dominant position. The section examines how contact lenses are sold both online and offline and the pricing of contact lenses by various sellers. A broader discussion on the structure of the European contact lenses market also emphasizes how antitrust law plays a part in the market for contact lenses and explains possible violations of the law. The section draws on a sample of pricing and other branding evidence to suggest that consumers are better off with the status quo of the European market for contact lenses. Part V concludes the discussion.

When the European Commission released its inquiry into the Pharmaceutical Sector in 2008, the inquiry did not cover the contact lens sector—a medical device—so to speak.⁹ After a close examination of the inquiry, I felt that there was a need to investigate one of the most common prescription products that concern European and global consumers—contact lenses, because there had been no comprehensive legal analysis regarding contact lenses and European consumers (at least none that I was made aware of while researching this Article).¹⁰

This Article is an attempt to highlight the contact lens industry in the EU both from a consumer and antitrust point of view. In particular, it focuses on

pdf (detailing business trends in the medical products industry).

8. Case C-108/09, *Ker-Optika bt v. ÁNTSZ Dél-dunántúli Regionális Intézet*, 2010 E.C.R. I-12213.

9. “Contact lenses” in this Article refers to prescription contact lenses. Where there is a difference between prescription and cosmetic contact lenses, this will be pointed out.

10. There are numerous industry reports on contact lenses often carried out by market research organizations for the industry players such as manufacturers, lobby associations, and eye care professionals. These studies are often expensive (at least for the average academic), ranging from \$3,000 upwards and none were bought for purposes of this Article. See, e.g., *Contact Lens Market Research*, EUROMONITOR INT’L, <http://www.euromonitor.com/contact-lenses> (last visited Sept. 11, 2012) (selling country-by-country market research reports about contact lenses).

issues such as co-branding, lock-in theory, and pricing in the market for contact lenses. Part of the conclusion of the Pharmaceutical Report was that the Commission will “pursue any antitrust infringement in the sector” and that “[a]ction can also be taken at [sic] national level and *in areas which were not the primary focus of the inquiry or are outside its scope*.”¹¹ Whether or not contact lenses (as medical devices) were covered by the Pharmaceutical Report, the sale and distribution of contact lenses are still subject to antitrust law, and the Commission may enforce the antitrust provisions of the Treaty on Functioning of the European Union (TFEU).¹²

According to the Commission, in the context of competition law, the Pharmaceutical Report’s main focus was “company behavior” and concentrated “on those practices which companies may use to block or delay generic competition as well as to block or delay the development of competing originator products.”¹³ The Commission further explained that the primary focus of the inquiry was “the competitive relationship between originator and generic companies and amongst originator companies.”¹⁴ It is in a similar spirit that this Article is based: possible anti-competitive relationships in the contact lens industry. The Article will address the competitive relationships in the industry, specifically the crucial questions of whether there are any abuses of dominance and if the pricing of contact lenses indicates anti-competitive practices.

II. THE EMERGENCE OF CONTACT LENSES AND THEIR BRANDING

A. *Historical Perspectives*

The emergence of contact lenses as an aid for poor eyesight dates back at least some 500 years.¹⁵ However, it is widely accepted that the real breakthrough for the modern contact lens was in 1887 by Frederick A. Muller, whose concept was improved upon a year later by Adolf Fick.¹⁶ The eccentric Italian inventor and painter Leonardo da Vinci described a water filled glass sphere to be placed directly on the eye, inspiring attempts by people such as the French philosopher, Rene Descartes, and the British astronomer, John

11. EUROPEAN COMM’N, COMPETITION DG, PHARMACEUTICAL SECTOR INQUIRY FINAL REPORT 522 para. 1564 (July 8, 2009) [hereinafter PHARMACEUTICAL REPORT], available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf (emphasis added).

12. See TFEU, *supra* note 1, arts. 101–02 (describing prohibited situations incompatible with the internal market that may affect trade between Member States).

13. PHARMACEUTICAL REPORT, *supra* note 11, at 13 para. 15. The Commission defines originator as “a novel drug that was under patent protection when launched onto the market.” *Id.* at 9.

14. See *id.* at 13 para. 16 (“As the industry is strongly regulated and the behaviour of the company needs to be assessed in the context of the existing regulatory framework, the sector inquiry also looked in broad terms at aspects of the regulatory framework, its implementation and alleged shortcomings reported by stakeholders. In this respect it concentrated on the legislation governing patents, marketing authorisations and pricing and reimbursement.”).

15. Leonardo da Vinci has been credited for introducing the concept of contact lenses in 1508. See, e.g., CONTACT LENS PRACTICE 4 (Nathan Efron ed., 2005) (presenting historical discussion of contact lenses).

16. *Id.* at 4.

Herschel, who proposed a glass capsule filled with animal jelly to correct astigmatism.¹⁷ Prior to 1887, there is little evidence to show for these attempts. It was the innovative and pioneering works of Muller, Fick, Kalt,¹⁸ and other contemporaries of their time that paved the way for what the twenty-first century has come to depend on for clear vision—contact lenses. The timeline on the emergence of contact lenses illustrates that a number of attempts have been made by various *innovators* for a device to cover the eye—the cornea in particular—and to enhance vision.¹⁹ However, the most significant period in the development of contact lenses was in the last 100 years. This latter period saw the technology for contact lenses fully developed.

Many of the dates regarding the development of contact lenses prior to the 1880s (and some thereafter) are still open to debate, but I think for the purposes of this Article, it is best to group the emergence of contact lenses from a historical perspective into two periods. The first period was from 1887–1936, which I will refer to as the age of the *glass* (contact lenses),²⁰ and the second period, 1937–1997, which I shall refer to as the age of the *plastic* (silicone and soft contact lenses).²¹ Though Leonardo da Vinci has been credited for the *discovery* of contact lenses, scholars agree that it is somewhat difficult to establish any serious attempt at perfecting or making contact lenses prior to 1887.²² Contact lenses during the latter part of the glass period were initially 17–21 or 10–13 millimeters in diameter and spanning a radius of 8–14 millimeters.²³ During the plastic period, contact lenses developed during this time were further broken down into two distinct categories: polymethyl methacrylate (PMMA) (1936–1956), or hard contact lenses; and (soft) silicone (1971–1998),²⁴ made from a hydrated polymer hydroxyethyl methacrylate (HEMA).²⁵

The majority of contact lenses today are made from soft lens, silicone-based, and other materials which allow for the flow of oxygen through the

17. *Id.* at 3–4.

18. *Id.*

19. *See generally id.* at 8–9 (presenting a historical timeline of contact lens development).

20. *See id.* at 4–5 (discussing history of glass scleral lenses).

21. *See generally id.* at 5–9 (providing historical overview of evolution of contact lens technology).

22. Joseph T. Barr, *History and Development of Contact Lenses*, in CLINICAL CONTACT LENS PRACTICE 1, 1 (Edward S. Bennett & Barry A. Weissman eds., 2005).

23. *Id.*

24. *Id.* at fig. 1.1; *see also* Jack Schaeffer, O.D. & Jan Beiting, *The Early History of Contact Lenses*, REV. OPTOMETRY (CONTACT LENS PIONEERS), Sept. 16, 2009, at 3, available at http://cms.revoptom.com/contactlens/pdf/clp_3.pdf (explaining the composite materials of contacts through time); S.M. MacRae et al., *The Long-Term Effects of Polymethylmethacrylate Contact Lens Wear on the Corneal Endothelium*, 101 OPTHALMOLOGY 365 (1994) (discussing the long-term effects of hard contact lenses).

25. *See* Fehim Findik, *A Case Study on the Selection of Materials for Eye Lenses*, 2011 ISRN MECHANICAL ENGINEERING 1, 2 (2011), <http://www.isrn.com/journals/me/2011/160671/> (“PMMA is now obsolete and is replaced with rigid plastics, mostly hydrophobic materials with high oxygen permeability. These lenses are called rigid gas permeable (RGP) lenses. For the manufacture of soft lenses, HEMA is being replaced by polymers which contain as much as 80% water. These soft lenses, often called hydrogels because of the amount of water, and they have high oxygen transfer while retaining shape despite high water content. These new materials used in the manufacture of contact lenses as well as thinner lenses and greater oxygen transfer have reduced corneal issues, but there are still other possible complications.”).

contact lens to the eye.²⁶ The third period in the development of contact lenses is the disposable period—mostly from the late 1980s to present day.²⁷ In this period, contact lenses are simply bought through online and offline mediums and can be worn from one to thirty days and then disposed. It is in this period, rather than the glass and plastic periods, that the sale and manufacturing of contact lenses has changed substantially (the substance of the discussion in this Article). The third period in the selling and manufacturing of contact lenses has spurred innovation and competition and even contact lenses for recreational use: cosmetic contact lenses. Furthermore, this period has seen a multitude of brands while manufacturers compete intensely against each other.²⁸ Also, even eye care professionals who usually prescribe manufacturers' contact lenses are now prescribing their own private label contact lenses.²⁹ All these developments have implications on a number of grounds, and due to the propensity of private labeling, antitrust law or intellectual property rights such as trademarks may become involved.

B. *Trademark Law and Regulation in Consumer Healthcare*

Consumers are accustomed to the fact that trademarks are everywhere and that trademarks are an indicator of origin, signal quality, and price. In the market for contact lenses, the major manufacturers own several trademarks and brands in different categories of contact lenses, and occasionally those same manufacturers use (or license) the trademarks to brand other private labels of contact lenses for selected eye care professionals.³⁰ At the same time, other main players in the market for contact lenses such as major retailers—both online and the traditional brick-and-mortar operations—have grown into reputable operations, and hence a successful name in contact lenses retailing.³¹ The success of the online retailers in contact lenses, for example, have driven

26. See Christina Monis, Hydrogel Contact Lenses, (Fall 2002) (unpublished student paper, San Jose State University), available at <http://www.sjsu.edu/faculty/selvaduray/page/papers/mate115/christinamonis.pdf> (“Analyzing the history of contact lens material shows an engineering trend of making a more softer [sic] and permeable polymer material.”); see also *Contact Lenses – The Material Benefits*, CONTAMAC, <http://www.contamac.com/files/Contact%20Lenses%20The%20Material%20Benefits.pdf> (describing the evolution of contact lens technology); Karen French, *Contact Lens Material Properties*, OPTICIAN, Oct. 7, 2005, at 20, available at <http://www.opticianonline.net/assets/getAsset.aspx?ItemID=1156> (describing the surface wettability of contact lens material).

27. CONTACT LENS PRACTICE, *supra* note 15, at 8–9. See generally *Daily Disposable Contact Lenses*, CONTACT VISION (Mar. 4, 2009), <http://www.contact-vision.com/lenses/lens-type/daily-disposable/>.

28. See generally FED. TRADE COMM'N, THE STRENGTH OF COMPETITION IN THE SALE OF RX CONTACT LENSES: AN FTC STUDY (2005) [hereinafter FTC, RX STUDY]. This study helped me to develop some ideas in later parts of this Article.

29. *Id.*

30. *Id.*

31. See, e.g., *1-800 Contacts, Inc. v. Lens.com, Inc.*, 755 F. Supp. 2d 1151, 1175 (D. Utah 2010) (“Indeed, [w]hat is infringed is the right of the public to be free of confusion and the synonymous right of a trademark owner to control his product [or service’s] reputation.”) (alteration in original) (citation omitted)). In another case, *Lens.com v. 1-800 Contacts.com, Inc.*, a complaint filed in Nevada in 2008, 1-800 Contacts was accused of antitrust violations, alleging that 1-800 Contacts tried to restrict trade and to gain a monopoly in the industry. Prior to the *Lens.com v. 1-800 Contacts.com* Nevada complaint, the seeds for contact lens litigation were sown in a Florida case in 1996. *In re Disposable Contact Lens Antitrust Litigation*, 170 F.R.D. 524 (M.D. Fla. 1996).

competitors and start-ups to use similar-sounding names like the more established rivals they are competing against in order to gain more customers.³² In the hostile environment of selling contact lenses on the Internet and competing against established players in the market, there tends to be confusion as to the owners of a particular website or whether the trademark is owned by a major manufacturer or one of the more established players in the market for online contact lenses.³³ If a customer uses the keyword “lenses” while searching the Internet for contact lenses, he may come across several websites with the keywords “lens” or “lenses.” This may have an effect on the consumer; he or she may be confused as to the true nature and ownership of a site that appears in the search results, or the consumer may be left with little option in choosing an online vendor.³⁴ For example, in *1-800 Contacts, Inc. v. Lens.com, Inc.*, it was alleged that the defendant used the plaintiff’s service marks to generate keyword advertising and therefore led customers to the defendant’s website.³⁵

One of the core functions of trademark law is to prevent confusion in consumers so that, for example, a retailer who uses the keyword “lens” in his trademark does not pass itself off as its major rival using the same keyword. But trademark law has evolved over the years, and the challenge trademark law is faced with was evident in several disputes that involved keyword advertising, such as *Google France v. Louis Vuitton*³⁶ and others. The nature of electronic commerce has changed the game for trademark law, and therefore, trademark law will have to adapt to this new game. One possible solution could be to change trademark law to adapt to such competitiveness or to exclude keyword advertising that is used in electronic commerce from the realm of trademark law. The expansion of the Internet has brought with it many serious concerns for trademark owners. On the one hand, trademark owners are constantly fighting off infringement of their trademarks by dishonest online vendors who free ride on the good reputation of an established trademark.³⁷ Yet at the same time, there is an even darker secret which often goes unnoticed: trademarks may influence manufacturers to gain market power, and market power acquired via trademarks, has an impact on how firms offering a similar product advertise their products to consumers.³⁸

32. *E.g.*, *1-800 Contacts*, 755 F. Supp. 2d at 1151.

33. *See id.* at 1173 (explaining the potential consumer confusion).

34. For example, Lens.com also trades as JustLenses.com and JustLens.com and owns the trademarks 1-800Lens.com and 1-800-get-lens.com.

35. *1-800 Contacts*, 755 F. Supp. 2d at 1157 (“[B]ecause Defendant’s sponsored links were generated when a consumer entered ‘1800Contacts’ as the search term, the sponsored links were likely to cause confusion as to source . . .”).

36. Joined Cases C-236, C-237 & C-238/08, *Google Fr., S.A.R.L. v. Google, Inc.*, 2010 E.C.R. 13–15.

37. Deborah F. Buckman, Annotation, *Lanham Act Trademark Infringement Actions in Internet and Website Context*, 197 A.L.R. Fed. 17 (2004) (“Cyberspace presents unique trademark-related issues. One Court of Appeals has quipped that ‘attempting to apply established trademark law in the fast-developing world of the [I]nternet is somewhat like trying to board a moving bus.’” (citing *Bensusan Rest. Corp. v. King*, 126 F.3d 25, 44 (2d Cir. 1997))).

38. *See, e.g.*, *1-800 Contacts, Inc. v. WhenU.com, Inc.*, 414 F.3d 400, 402 (2d Cir. 2005) (noting that Defendant’s website led consumers to Plaintiff’s competitors). *See generally* Robert Feinberg, *Trademarks, Market Power, and Information*, 2 REV. INDUS. ORG. 376 (1985).

Another factor to consider is the role of regulation in the consumer healthcare industry (and for the purposes of this Article, the contact lens industry). Regulation exists to protect both the consumers and also to ensure that standards are adhered to. In the consumer healthcare industry for contact lenses, the regulations relating to contact lenses as medical devices and for consumer protection, have been known to provide benefits overall for consumers.³⁹ In addition to regulations such as the Fairness to Contact Lens Consumers Act (FCLCA)⁴⁰ that exist in the United States or the European consumer protection directives,⁴¹ there are also other regulatory measures to combat counterfeiting medical products. In the EU, there have been cases of counterfeit contact lenses,⁴² and there has been legislation and cooperative enforcement activity to fight this trend.⁴³

C. Modern Branding of Contact Lenses

It is possible that you are reading this Article with a pair of contact lenses from one of the big manufacturers that you obtained online or through your local eye care professional. It is also possible that your eye care professional sold you a brand of contact lens that is only unique to that eye care professional. The argument in this section is that there are dozens of different

39. See Press Release, European Commission, New EU Rules on Consumer Rights to Enter into Force (Oct. 10, 2011), available at <http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/11/675&type=HTML> (anticipating consumer benefits as a result of the European Union Consumer Rights Directive).

40. Fairness to Contact Lens Consumers Act, Pub. L. No. 108-164, 1117 Stat. 2024 (2003).

41. See Press Release, European Commission, *supra* note 39, at para. 1 (stating that one of the benefits for consumers in the new directive is that “consumers will be protected against ‘cost traps’ on the Internet,” where “fraudsters try to trick people into paying for ‘free’ services, such as horoscopes or recipes”); see also Directive 2011/83/EU, of the European Parliament and of the Council of 25 October 2011 on Consumer Rights, Amending Council Directive 93/13/EEC and Directive 1999/44/EC of the European Parliament and of the Council and repealing Council Directive 85/577/EE and Directive 97/7/EC of the European Parliament and of the Council, 2011 O.J. (L 304) 64, available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:304:0064:0088:EN:PDF> (“[T]he Union is to contribute to the attainment of a high level of consumer protection.”).

42. See, e.g., Memorandum from Euromcontact, Euromcontact Contribution to the Public Consultation of the European Commission in the Context of the Study on Distribution Channels for Medical Devices (Feb. 4, 2008) (on file with author) (“[C]ounterfeit contact lenses have been found [in France] in 2004 with confirmed serious adverse events.”); see also *id.* (“Counterfeiting of contact lenses . . . can put human vision and health at risk, undermines customer confidence and trust in brands and has obvious negative impact on the legitimate business players; consequently it should be considered a criminal offence . . .”).

43. Activities include customs actions at ports of entry (seizure), criminal law prosecution, and international cooperation, in addition to legislative actions in pharmaceuticals and the protection of intellectual property rights. See generally, Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 51, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299; 33 I.L.M. 1197 (1994) (defining counterfeit goods as: “any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation”); United States Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(g)(2) (2006) (“The term ‘counterfeit drug’ means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.”).

brands of contact lenses that are available on the market. There are various brand names for contact lenses that are dispensed from your local or online supplier, but despite different brand names, they can all be traced back to one of the big manufacturers of contact lenses.⁴⁴ One of the most popular suppliers of contact lenses in America is 1-800 Contacts, and a simple click on their website reveals immediately that the customer can select from a number of manufacturers' brands. From the more than twelve brands available, four manufacturers (Johnson & Johnson, CIBA Vision, CooperVision, and Bausch & Lomb) dominate the list.

TABLE 1: Top Four Manufacturers and Their Brands Available Online at 1800Contacts.com⁴⁵

Manufacturer	CIBA Vision	CooperVision	Bausch & Lomb	Johnson & Johnson
Brands	Air Optix	Avaira	Purevision	Acuvue
	Focus	Biofinity	Softlens	
	Freshlook	Biomedics		
		Frequency		
		Proclear		

The above table represents only the more popular manufacturers' brands on the site when a customer selects "sort by." If the customer selects "view all" brands, CooperVision and Johnson & Johnson top the list with the most brands, with leading brands such as Acuvue, Focus, and Biomedics. This is represented in TABLE 2 below.

44. See *Contact Lens Sales: Is Market Regulation the Prescription?: Hearing Before the Subcomm. on Commerce, Trade, and Consumer Protection of the Comm. on Energy and Commerce*, 109th Cong. 1–2 (2006) (statement of Rep. Cliff Stearns, Chairman, H. Subcomm. on Commerce, Trade, and Consumer Protection) [hereinafter *Congressional Hearing*] ("There are essentially two types of mass marketed lenses for consumer purchase, those distributed exclusively to eye care professionals by a contact lens manufacturer and those distributed freely to all retailers, including eye care professionals and aftercare providers like 1-800 Contacts.").

45. The data in TABLE 1 was collected in October 2011.

TABLE 2: Sample of How the Seven Top Brands Are Marketed on 1800Contacts.com⁴⁶

ACUVUE	BIOFINITY	SOFTLENS	AIR OPTIX
1 Day Moist 30 Pack	Biofinity Toric	Softlens Daily Disposables 90 Pack	Air Optix Aqua
1 Day Moist 90 Pack	Biofinity Multi-Focal	Softlens Multi- Focal	Air Optix Aqua Multi-Focal
1 Day TruEye 30 Pack	Biofinity	Softlens Toric (Softlens for Astigmatism)	Air Optix for Astigmatism
1 Day TruEye 90 Pack		Softlens 38	Air Optix Night and Day Aqua
Acuvue			
Acuvue 2			
Acuvue 2 Colors			
Advance for Astigmatism			
Advance Plus 24 Pack			
Advance Plus 6 Pack			
Advance with Hydraclear			
Biofocals			
Oasys for Astigmatism			
Oasys for Presbyopia			
Oasys with Hydraclear			
1 Day 30 Pack			

46. The data in this table was collected in October 2011.

TABLE 2 continued

FOCUS	BIOMEDICS	PUREVISION
Dailies AquaComfort Plus 30 Pack	Biomedics 1 Day 90 Pack	Purevision Purevision 2
Dailies AquaComfort Plus 90 Pack	Biomedics 38 Biomedics 55	Purevision 2 HD for Astigmatism
Focus 1-2 Week Softcolors	Biomedics 55 Evolution	Purevision Multi-Focal
Focus DAILIES 30 Pack	Biomedics 55 Premier	Purevision Toric (PureVision Toric For Astigmatism)
Focus DAILIES 90 Pack	Biomedics EP (Proclear EP)	
Focus DAILIES Progressive 30 Pack	Biomedics Toric Biomedics XC	
Focus DAILIES Toric 30 Pack		
Focus DAILIES Toric 90 Pack		
Focus Monthly Softcolors		

The above tables represent a sample of contact lens sales in the American market via the website www.1800contacts.com. The situation is no different from any of the major European markets. Moreover, the same brands are often used for marketing of contact lenses in the major European markets, and in some markets, only a slight name change is made. However, the name of the manufacturer will be listed in the fine print as required by the law.⁴⁷

The unique thing about TABLE 1 and TABLE 2 is that they reflect only manufacturers and their major brands and sub-brands (marketing pack). The sub-brands are used for different purposes for contact lens wearers. Thus, a person who has severe astigmatism will normally opt for lenses that are known to correct such blurry vision.

The success of one brand also depends on the relationship an eye care professional (and lately, online retailers of contact lenses) has with the manufacturer, as a brand is prescribed or recommended by doctors. One brand may be more expensive or popular than the other, and the prescription from the doctor will determine the sales volume for that brand. Thus, it would suggest

47. *Infra* Part II.E.

that doctors are complicit in brand-building at the expense of the consumers. But, this would only be the case where the eye care professional does not market his own brand. It can also be argued that some brands are made specifically for certain types of eye abnormalities such as astigmatism and/or high myopia (severe shortsightedness), and therefore, only a few brands are geared towards these defects.

TABLE 3: Top Ten Sub-Brands in Finland (According to One Popular Online Retailer)⁴⁸

1. 1-Day Acuvue Moist
2. Acuvue Oasys
3. Air Optix Aqua
4. Biomedics 55 Evolution
5. Dailies Aqua Comfort Plus
6. Focus Dailies
7. Focus Dailies Toric
8. Focus Monthly
9. FreshLook ColorBlends
10. Freshlook Oneday

This table representing Finland is only a sample of the many online retailers for contact lenses in Finland. The sale of contact lenses in Finland has been quite popular and there are a number of other retailers that operate cross-border in the country. Though LensWay operates a lensway.fi website for taking contact lens orders, oftentimes orders are shipped from other countries where the site operates or a particular stock may be in abundance.⁴⁹

D. Consumer (Welfare) Benefits

I offer the following hypothesis: the users of prescription contact lenses are the ultimate beneficiaries, and will reap those benefits when they wear contact lenses that improve their vision. To test this hypothesis, the question becomes: are consumers benefiting from the market for contact lenses? Logic dictates that the answer is “yes” because consumers of contact lenses receive benefits whether there is one or several contact lens manufacturers. This hypothesis assumes the sole benefit of enhancing the vision of those who don’t want to use spectacles or consumers with severe myopia (short-sightedness; for example, minus six (-6) and below, or those consumers who have minus one (-

48. The data is from www.lensway.fi, a popular online supplier of contact lenses in Europe. Note that LensWay operates in several European markets and the data was taken from its Finnish site only. Sub-brands refer to when a major brand is used for marketing several types of contact lenses. The data was collected in October 2011.

49. One order was placed by this author, and the packaging was postmarked in the Netherlands and delivered to Finland. See EUROPEAN COUNCIL OF OPTOMETRY & OPTICS, ECOO BLUE BOOK 33 (2008), available at http://www.ecoo.info/mm/ECOO_BlueBook2008.pdf (noting the rank order of where most corrective contact lenses are sold: 1. Optical outlets; 2. Pharmacies; 3. Shops; 4. Hospitals; 5. The Internet).

1) in one eye and minus six (-6) in the other eye). For those with complications in the latter category, spectacles would send conflicting signals to the brain, whereas contact lenses bring the ultimate benefit of curing their blurry vision.

But, let's examine the same argument from a more scientific (economic) perspective. The economic literature tells us that a welfare test generally purports to measure how "well off" people are, as a result of a particular practice, or as Robert Bork calls it, "merely another term for the wealth of the nation."⁵⁰ There is no consensus on the precise meaning of the term "consumer welfare." By dubbing consumer welfare as merely another term for "the wealth of the nation," Bork is telling us that the term is in a state of flux.⁵¹ In general, most textbooks in economics do not provide a definition of "consumer welfare," and economists tend to define "consumer surplus" instead. Oz Shy, for example, explained that "consumer surplus" is "the welfare measure that approximates the welfare gain associated with the opening of [the] market."⁵² One reason "consumer welfare" lacks a definition by economists is that it is a complicated area and no one definition is likely to satisfy a broad field of economists.⁵³ Another reason is in general, economists focus on social welfare and leave out any nexus between consumers and manufacturers (producers). In other words, consumer welfare is too citizen-focused and does not take into account the welfare of firms (producers).

One practical approach to arrive at a precise definition of "consumer welfare" is to analyze both the terms "consumer" and "welfare" in economics. For instance, economists often view welfare as the level of utility, which is how much satisfaction a consumer derives from a commodity or a basket of commodities.⁵⁴ Instances where consumers are willing to pay over and above what they actually pay for something (thus generating a surplus) are essential to a meaning of consumer welfare⁵⁵ because changes in consumer welfare can

50. See ROBERT H. BORK, *THE ANTITRUST PARADOX: A POLICY AT WAR WITH ITSELF* 90, 107–15 (1978) ("Consumer welfare is greatest when society's economic resources are allocated so that consumers are able to satisfy their wants as fully as technological constraints permit. Consumer welfare, in this sense, is merely another term for the wealth of the nation.").

51. *Id.*; see also RICHARD E. JUST ET AL., *THE WELFARE ECONOMICS OF PUBLIC POLICY: A PRACTICAL APPROACH TO PROJECT AND POLICY EVALUATION* 98 (2004) ("The definition of a measure of economic welfare for the consumer has been one of the most controversial subjects in economics.").

52. OZ SHY, *INDUSTRIAL ORGANIZATION: THEORY AND APPLICATIONS* 52 (1995) ("We define a measure that approximates the utility gained by consumers when they are allowed to buy a product at the ongoing market price."); see also *Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 221 (1993) (referring to the "'antitrust laws' traditional concern for consumer welfare and price competition"); David Miller, Exec. Dir., Jam. Fair Trading Comm'n, *Consumer Welfare Within Competition Policy: Institutionalizing Competition Policy in the CSME* 9 (Mar. 18, 2010) (paper presented at the Competition and Consumer Welfare Sensitization Workshop), available at http://www.jftc.com/Libraries/Speeches_and_Presentations/Institutionalizing_Competition_Policy_in_the_CSME_-_Mr_David_Miller.sflb.ashx.

53. See, e.g., Stephen Turnovsky et al., *Consumer's Surplus, Price Instability, and Consumer Welfare*, 48 *ECONOMETRICA* 135, 135 (1980) ("[T]he concept of consumer's surplus as a measure of economic welfare has never been fully accepted by the economics profession.").

54. PER-OLOV JOHANSSON, *AN INTRODUCTION TO MODERN WELFARE ECONOMICS* 147 (1991) (stating that "utility . . . is a property that is common to all commodities that are desired[,] and that economists can 'analyse consumer choice in terms of utility'").

55. *Id.* at 42 ("Consumer surplus is a real part of economic welfare and not some fiction invented by

be measured by changes in consumer surplus.⁵⁶ Furthermore, as Professor J. Brodley, explains, “consumer welfare can be defined as consumer surplus, which is that part of the total surplus that accrues to consumers.”⁵⁷ The transposition of the term consumer welfare in modern economics is more or less the work of antitrust specialists, such as Bork, and subsequent adaptations by the courts. The courts in general often refuse to define consumer welfare, but opt for an indirect linkage of consumer welfare and the need to protect consumers.⁵⁸

In European antitrust law, the Commission provides guidance on how one should interpret consumer welfare when discussing Article 102 TFEU.⁵⁹ According to the Commission, the exclusionary conduct of a dominant undertaking is liable to have harmful effects on consumers,⁶⁰ and the aim of its enforcement activity in relation to exclusionary conduct is to ensure that dominant undertakings do not impair effective competition by foreclosing their competitors in an anti-competitive way.⁶¹ The Commission did not specifically define consumer welfare, but further explained that dominant firms should not engage in anti-competitive behaviors that will have “an adverse impact on consumer welfare, whether in the form of higher price levels that

economists.”).

56. JEAN TIROLE, *THE THEORY OF INDUSTRIAL ORGANIZATION* 7 (1988); *see also* Herbert Hovenkamp, *Distributive Justice and Consumer Welfare in Antitrust* 6 (unpublished manuscript), available at <http://ssrn.com/abstract=1873463> (“Formally, ‘consumer welfare’ looks only at the surplus that goes to consumers, ignoring that which goes to sellers. The consumer welfare principle must be counted as ‘distributive’ to the extent that it mandates outcomes that shift wealth or resources in favor of consumers even though an alternative outcome would produce greater total wealth. These outcomes can result from both ‘overenforcement’ and ‘underenforcement,’ assuming that wealth maximizing position is accepted as the baseline.”).

57. Joseph F. Brodley, *The Economic Goals of Antitrust: Efficiency, Consumer Welfare and Technological Progress*, 62 N.Y.U. L. REV. 1020, 1033 (1987). *See generally*, John M. Currie et al., *The Concept of Economic Surplus and Its Use in Economic Analysis*, 81 ECON. J. 741 (1971) (providing background on economic surplus and its controversial usage).

58. *See, e.g.*, *Danielson Food Prod., Inc. v. Poly-Clip Sys.*, 120 F. Supp. 2d 1142, 1143 (N.D. Ill. 2000) (“[T]he overarching standard, as the courts interpret it today, is whether the defendants’ actions diminish competition and injure consumer welfare.” In many respects, antitrust law is geared towards the promotion of consumer welfare, and the courts have repeatedly stressed this in their rulings. For instance in *Northern Pacific*, the U.S. Supreme Court explained that the Sherman Act was to, among other things, promote consumer welfare, by protecting the competitive process.; *see N. Pac. R.R. Co. v. United States*, 356 U.S. 1, 356 (1958) (“The Sherman Act was designed to be a comprehensive charter of economic liberty aimed at preserving free and unfettered competition as the rule of trade. It rests on the premise that the unrestrained interaction of competitive forces will yield the best allocation of our economic resources, the lowest prices, the highest quality, and the greatest material progress . . .”).

59. Article 102 TFEU prohibits any abuse of a dominant position in the internal market of the Union, but does not prohibit dominance itself; as such, it is essential to first establish that whether there is a dominant position by an undertaking and then determine whether any abuse of that dominant position has taken place. TFEU, *supra* note 1, art. 102. Also, case law over the years has interpreted Article 102. *See, e.g.*, *Case 27/76, United Brands Co. v. Comm’n*, 1978 E.C.R. 209 ¶ 65 (1978) (interpreting Article 102).

60. *E.g.*, Memorandum from the European Comm’n, Antitrust: Consumer Welfare at the Heart of Commission Fight Against Abuses by Dominant Undertakings, IP/08/1877, 1 (Dec. 3, 2008), available at <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/08/1877&format=HTML&aged=0&language=EN&guiLanguage=en>.

61. *Communication from the Commission – Guidance on the Commission’s Enforcement Priorities in Applying Article [102] of the [TFEU] to Abusive Exclusionary Conduct by Dominant Undertakings*, O.J. (C 45) 7, 9 (Feb. 24, 2009) [hereinafter Article 102 Guidance Paper].

would have otherwise prevailed or in some other forms such as limiting quality or reducing consumer choice.”⁶² This guidance on consumer welfare by the Commission is not the law, but rather one possible way consumer welfare should be seen in the application of European antitrust rules, in particular that of Article 102 TFEU. However, the rulings out of the CJEU do not necessarily define consumer welfare either—and they are more likely to adopt the broad term “consumer welfare” without elaboration.⁶³ One interpretation of how the court treats consumer welfare was in *Commission v. Microsoft*,⁶⁴ where the court wanted to leave room for debate on the exact meaning of consumer welfare. A broad treatment of consumer welfare serves a greater good in that such broad treatment entails all the possible economic definitions of “welfare” that benefits consumers, including that of social welfare and consumer surplus.⁶⁵ It can be argued that the definition of consumer welfare does not have an impact on the development of legal rules, or, on the other hand, the definition of consumer welfare guides how legal rules are developed, but in *Microsoft v. Commission* there was little discussion as to what role consumer welfare played.⁶⁶

My hypothesis in this section is that consumers feel rewarded and satisfied through the use of a product regardless of whether there is one or several manufacturers. If there is a substitute for the product, consumers will have a choice to turn to that substitute if they are not satisfied. On the other hand, even without a substitute, the product performs an essential function for consumers. Under current market prices, consumers are better off having the clear vision that contact lenses offer than living with blurry vision. Some customers who suffer from severe myopia cannot rely on eyeglasses because they serve as a poor substitute. By participating in the market for contact lenses, consumers are rewarded with the increased satisfaction than they otherwise would be if they had not participated in the market. A definition of consumer surplus that includes consumer welfare considers the fact that consumers gain additional satisfaction from the purchase and use of contact lenses beyond the price they actually paid for them. The result is that consumers have greater satisfaction from using contact lenses, in particular, when they are made available at market price or less.

E. Contact Lenses as Medical Devices

The medical devices industry is a major employer⁶⁷ in most parts of the

62. *Id.*

63. *See, e.g.*, Case T- 201/04, *Microsoft Corp. v. Comm’n*, 2007 E.C.R. II-3635 ¶ 41 (mentioning “consumer welfare” without any formal discussion).

64. *Id.*

65. Brodley, *supra* note 57, at 1033. *See generally* Currie et al., *supra* note 57.

66. *See generally* *Microsoft*, 2007 E.C.R. at 3635.

67. According to figures provided by the European Commission, medical devices have become an increasingly important area in relation to their impact on health and influence on healthcare expenditure; in 2007, some 529,000 people across Europe were employed by the industry with total sales of €7,260,000,000 of world market share of €219,000,000,000 and is the second largest market after the United States. *Medical Devices: Competitiveness – Facts and Figures*, EUROPEAN COMMISSION, <http://ec.europa.eu/health/medical->

world and continues to be one of the most innovative sectors. In the 2008 revision of the European medical devices directives,⁶⁸ most of the industry players noted the fact that contact lenses are medical devices, a fact that often seems to be ignored. But such ignorance may be due to the blurriness between medical devices and contact lenses. Contact lenses are low to medium risk medical devices and they are legally regulated under European law as Class IIa medical devices.⁶⁹ A contact lens is essentially a thin medical device in the shape of a disk which is designed to cover the cornea. Contact lenses are able to act as a physical barrier to normal tear-cornea-lid mechanics and corneal metabolism, and as medical devices, contact lenses are supported by the lids, cornea, conjunctiva, and tear film.⁷⁰

The legal definition of contact lenses as medical devices in the EU was confirmed in *Ker-Optika v. ANT SZ*, where the court said, “contact lenses come into direct contact with the eyes and constitute medical devices.”⁷¹ In this case

devices/competitiveness/facts-figures/index_en.htm (last visited Sept. 4, 2012).

68. The recast of the medical devices directives took place in 2008 with a series of public consultations. Three pieces of legislation concerning medical devices were the focus of attention, these were: Council Directive 93/42/EEC, 1993 O.J. (L 169) 1 (EC) [hereinafter MDD]; Council Directive 90/385/EEC, 1990 O.J. (L 189) 1 (EC) [hereinafter AIMDD]; Council Directive 98/79/EC, 1998 O.J. (L 331) 1 (EC) [hereinafter IVDMD]. This legislation has been amended on several occasions. See *Medical Devices – Legislation*, EUROPEAN COMMISSION, http://ec.europa.eu/health/medical-devices/regulatory-framework/legislation/index_en.htm (last visited Sept. 4, 2012) (including a chart of the AIMDD, MDD, and IVDMD amendments). One of the latest amendments was Council Directive 2007/47/EC, 2007 O.J. (L 247) 21 (EC) [hereinafter Directive 2007/47/EC] (amending Council Directive 90/385/EEC, Council Directive 93/42/EEC and Council Directive 98/8/EC, 1998 O.J. (L 123) 1 (EC)). In response to allegations of faulty breast implants in France in 2012, the European Commission proposed further amendments to the medical devices directives that would result in, among other things, clearer rules and an expanded database of medical devices to ensure that medical devices such as contact lenses can be freely and fairly traded in the Union. See generally *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of Regions* COM (2012) 540 final (Sept. 26, 2012), available at http://ec.europa.eu/health/medical-devices/files/revision_docs/com_2012_540_revision_en.pdf; *Proposal for a Regulation of the European Parliament and of the Council on Medical Devices, and Amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009* COM (2012) 542 final, 2012/0266 (COD) (Sept. 26, 2012), available at http://ec.europa.eu/health/medical-devices/files/revision_docs/proposal_2012_542_en.pdf. The Proposal lists contact lenses as a medical device covered by the definition of Medical devices. *Id.* at annex XV.

69. MDD, *supra* note 68, annex IX(4)(4.3)(rule 15); Memorandum from the European Comm’n, Memo/12/710, Questions and Answers: Commission Tables Proposals for a New EU Regulatory Framework for Medical Devices and *In Vitro* Diagnostic Medical Devices (Sept. 26, 2012), available at http://ec.europa.eu/health/medical-devices/files/revision_docs/qa_20120926_en.pdf; see also *Congressional Hearing*, *supra* note 44, at 56 (“[C]ontact lenses are a medical device regulated by the Food and Drug Administration, and manufacturers must monitor sales and take action if patient safety issues arise.”). Certainly if contact lenses that are known to have defects are placed on the market, the process of recalling such contact lenses often takes the form a medical device recall notice to eye care professionals. See, e.g., Press Release, CibaVision, Important Medical Device Recall Notice (July 2006) (recalling Focus Dailies Toric with a note that “a small amount of lenses in these lots may be labeled with incorrect power”) (on file with author); see also Laurent Belsie, *Contact Lens Recall: Dramatic Expansion for CooperVision*, CHRISTIAN SCI. MONITOR, Nov. 16, 2011, <http://www.csmonitor.com/Business/2011/1116/Contact-lens-recall-dramatic-expansion-for-CooperVision>; Darren Tobin, *Silicone Oil Residue on CooperVision Contact Lenses Causes Torn Corneas*, THE LEGAL EXAM’R (Nov. 22, 2011, 2:23 PM), <http://atlanta.legalexaminer.com/defective-and-dangerous-products/silicone-oil-residue-on-cooper-vision-contact-lenses-causes-torn-corneas.aspx?googleid=296274> (detailing a recall incident of contact lens which were contaminated by oil residue).

70. KEN DANIELS, OD, CONTACT LENSES 2–5 (1999).

71. Case C-108/09, *Ker-Optika bt v. ANT SZ Dél-dunántúli Regionális Intézete*, 2010 E.C.R. I-12213

the court confirmed contact lenses are a medical device; however, in order to fully comprehend the nature of medical devices, attention must be turned to its proper legal definition in the MDD.⁷² According to the MDD, a medical device:

[M]eans any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.⁷³

Another definition in the MDD is that of a “custom-made device,” which “means any device specifically made in accordance with a duly qualified medical practitioner’s written prescription which gives, under his responsibility, specific design characteristics and is intended for the sole use of a particular patient.”⁷⁴ One interpretation of this definition is that it is applicable to contact lenses given that they are prescription-based and patients have unique requirements for their eyes. The recast of the medical devices directives brought certain changes, and perhaps the most controversial change was the inclusion of software into the medical devices lingua.⁷⁵ Though the changes in the revised MDD, at first glance, are hard to detect, they are broad in nature and the overarching change is that medical devices are defined to include software.⁷⁶ The classification of a number of devices has changed,

¶ 35; *see also* Press Release, Court of Justice of the European Union, EU Member States Cannot Prohibit the Selling of Contact Lenses via the Internet (Dec. 2, 2010), *available at* <http://curia.europa.eu/jcms/upload/docs/application/pdf/2010-12/cp100117en.pdf> (explaining the decision to define contact lenses as medical devices and the restrictions the decision imposes on its online sales).

72. MDD, *supra* note 68, art. 1(2)(a).

73. *Id.* The definition of medical device in the European Union is thus similar to the definition adopted in other jurisdictions such as the United States, Canada, and Australia. *See Medical Devices Regulations*, DEPARTMENT OF JUSTICE CANADA (Sept. 19, 2012), <http://laws-lois.justice.gc.ca/eng/regulations/SOR-98-282/page-1.html#docCont> (Canada); *infra* note 84 (United States); *infra* note 85 (Australia).

74. MDD, *supra* note 68, art. 1(2)(d).

75. *Id.* art. 1(2)(a).

76. It has been suggested that, in practice, whether software falls under the Medical Device Directives depends on its placement within three classifications. “[S]oftware itself is a medical device (stand-alone software) or is an accessory to a medical device; or software is a component or an integral part of a medical device; . . . all other software . . . is not covered by the Directives.” Mathias Klumper & Erik Vollebregt, *The Regulation of Software for Medical Devices in Europe*, 7 J. MED. DEVICE REGULATION 5, 6 (2010).

thus opening a Pandora's Box as to the extent of what can be classified as a medical device.⁷⁷

But to complement the definition of medical device in the MDD, the AIMDD and the IVDD set out the requirements for medical devices and their accessories to be placed on the market, put into services and used, as well as the applicable procedures for conformity assessment purposes.⁷⁸ However, the definition of "medical device" in the MDD must be approached with caution, as the term "medical device" covers a vast range of equipment essential for patient care in an industry worth over 260 billion USD,⁷⁹ and for a device to be labeled as "medical," it must meet the requirements set out in the MDD.

Unlike the EU definition of "medical device," the World Health Organization (WHO) proposed a harmonized definition for "medical device," which does not include "accessory." According to the WHO, a medical device means "any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings"⁸⁰ The WHO's proposed definition does not include "accessory," and therefore generally does not consider accessories to be medical devices.⁸¹ This does not mean—at least by the definition from the WHO—that any accessory related to a medical device should not be classified as a medical device. To the contrary, "an accessory is intended specifically by its manufacturer to be used together with the 'parent' medical device to enable the medical device to achieve its intended purpose."⁸² The WHO definition of "medical device" is similar to that of the U.S. Food, Drug, and Cosmetic Act (FD&C Act), which defines a device as "an instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar or related article, including any component part, or accessory."⁸³ This latter definition includes a definition of "accessory" similar to the definition of "medical device" in EU regulations, and as such, there is a degree of harmonization in the major markets as to what a medical device is or what a medical device is not.⁸⁴

77. *Id.*

78. *Id.*

79. WORLD HEALTH ORG., MEDICAL DEVICE REGULATIONS: GLOBAL OVERVIEW AND GUIDING PRINCIPLES vii–viii (2003), available at http://www.who.int/medical_devices/publications/en/MD_Regulations.pdf.

80. *Id.* at vii.

81. *Id.* In the MDD, accessory is defined as "an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device." MDD, *supra* note 68, at 169. The European Commission medical device guidance document lists contact lens-care products such as those for disinfecting, cleaning, solutions for rinsing and hydrating, and those which aid in inserting and/or wearing contact lenses as examples of medical device accessories. European Comm'n, *Guidelines Relating to the Application of: The Council Directive 90/385 on Active Implantable Medical Devices, The Council Directive 93/42/EEC on Medical Devices* 8 (Mar. 12, 2009), available at http://ec.europa.eu/health/medical-devices/files/meddev/2_1_3_rev_3-12_2009_en.pdf.

82. WORLD HEALTH ORG., *supra* note 79, at vii.

83. 21 U.S.C. § 321(h) (2006).

84. In Australia, for example, the *Therapeutic Goods Act of 1989* defines a medical device as "any

The MDD further groups medical devices in the EU into four classes, ranging from low risk to high risk: Class I;⁸⁵ Class IIa; Class IIb; and Class III.⁸⁶ The classification rules are based on the vulnerability of the human body and take into account the potential risks associated with the technical design and manufacture of the devices.⁸⁷ Because of the harmonizing of rules pertaining to medical devices in the EU (and also internationally), the manufacturers of medical devices must comply with those rules and technical specifications by signing a “declaration of conformity,”⁸⁸ which is normally issued by the manufacturer for products that fall into the Class I category (low risk). There must be explicit prior authorization issued by the appropriate Notified Body for the highest risk category, Class III⁸⁹ (a “certificate of

instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings.” *Therapeutic Goods Act 1989* (ACT, NT) ch 4 pt 4-1 div 2 s 41BD(1)(a) (Austl.); *see also Therapeutic Goods (Medical Devices) Regulations 2002* (Cth) div 3.2 (Austl.); *Medicines, Poisons and Therapeutic Goods Act 2008* (ACT) pt 2.3 (Austl.). China has adopted the definition of medical device based on the EU’s definition in Directive 93/42/EEC in its Standard Management of Medical Devices and the People’s Republic of China Standardization Law in order to assure the safety and effectiveness of medical devices and to guarantee human health and safety. EUR.-CHINA STANDARDS INFO. PLATFORM, MEDICAL DEVICE GUIDE 1 (2009), http://eu-china-standards.eu/cn/manuals/manual_Medica_CN_EnglishVersion.pdf.

85. According to recital 11 of Directive 2007/47/EC, “manufacturers of class I sterile and/or measuring medical devices should be given the option of using the full quality of assurance conformity assessment module in order to provide them with more flexibility in the choice of compliance modules.” Directive 2007/47/EC, *supra* note 68, at 247/22.

86. MDD, *supra* note 68, at annex IX. The United States also classifies medical devices as Class I, II, and III; although there are some similarities between the European and American classification systems, they are technically not the same.

87. Directive 2007/47/EC, *supra* note 68, recital 22.

88. *Id.* annex II (amending Annexes 1–7 of the MDD). “The EC declaration of conformity is the procedure whereby the manufacturer who fulfills the obligations imposed by Section 1 ensures and declares that the products concerned meet the provisions of this Directive which apply to them.” *Id.*

“The manufacturer must affix the CE marking in accordance with Article 17 and draw up a written declaration of conformity. This declaration must cover one or more medical devices manufactured, clearly identified by means of product name, product code or other unambiguous reference and must be kept by the manufacturer.” *Id.*; *see also* MDD, *supra* note 68, ¶ 9(a)(1) (“The EC declaration of conformity is the procedure whereby the manufacturer or his authorized representative who fulfills the obligations imposed by Section 2 and, in the case of products placed on the market in a sterile condition and devices with a manufacturing function, the obligations imposed by Section 5 ensures and declares that products concerned meet the provisions of this Directive which apply to them . . .”).

The CE (*Conformite Europeenne* or European Conformity) marking certifies that a product has met EU consumer safety, health or environmental requirements and is required in order to place a product onto the European market. *See generally* Council Directive 93/68/EEC, 1993 O.J. (L220) 1 (EC).

89. National Bodies in the EU are coordinated by a pan-European organization, the Notified Body Operations Group (NBOG), which was established in 2000 in response to concerns “that the performance of Notified Bodies in the medical device sector, and that of the Designating Authorities responsible for them, was variable and inconsistent.” NOTIFIED BODY OPERATIONS GROUP, <http://www.nbog.eu/index.html>. The amended directive on Medical Devices introduced several changes or clarifications, which Notified Bodies have to respect when they carry out conformity assessment activities. Directive 2007/47/EC, *supra*, note 68, arts. 1–3. The Council explains that, for example, they will have to check the technical documentation of Class IIa and IIb devices on a representative basis. *Id.* annex II. Furthermore, where a manufacturer has subcontracted the design, manufacture, final inspection, or testing of a medical device to another party, the Notified Body will have to assess that the manufacturer applies the appropriate control to this third party. *Interpretative Document of the Commission’s Services: Implementation of Directive 2007/47/EC Amending Directives 90/385/EEC, 93/42/EEC and 98/8/EC*, COM (2009) 19003 final 3 (June 5, 2009) [hereinafter *Medical Devices Guidance Paper*]. For a list of Bodies Notified under Directive 93/42/EEC, *see generally*,

conformity”). An assessment of the design documentation is required in order to be placed on the market to be in conformity.⁹⁰ The reason for the explicit authorization is that those devices are labeled high risks. However, in general, medical devices do not need marketing authorization in order to be placed on the market—so long as they fulfill the basic requirements. The relevant national authority (working in conjunction with the European Commission) may from time to time carry out inspection visits and/or request detailed information, including technical specification on a medical device, and therefore, the information should be readily available.⁹¹ According to the recitals, certain information related to medical devices and their conformity with Directive 93/42/EEC, such as those relating to registration, vigilance reports, and certificates, should be made available to any interested party.⁹² The Commission has issued a guideline to assist both the relevant parties in the manufacturing of medical devices and government agencies—such as the Notified Bodies and other competent authorities—that are responsible for the standards and classification of devices.⁹³

The key argument in this section is that contact lenses are medical devices, and that has been confirmed by the court in *Ker-Optika* and the MDD.

III. PARALLEL TRADE ENCOURAGES THE SALE OF CONTACT LENSES ONLINE

During the revision process of the medical devices directives, the European Commission initiated a public consultation process in which a number of responses were submitted to the Commission. The responses poured in from national regulators, healthcare lobbyists in Brussels, individual companies, academics, standardization bodies, and consumers, among others.⁹⁴ The Commission, on its website, listed 200 individual responses to the recast

OBELIS, LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC MEDICAL DEVICES (2012), available at http://ec.europa.eu/enterprise/newapproach/nando/index.cfm?fuseaction=directive.pdf&drc_refe_id=13&type_dir=cmp&refe_cd=93/42/EEC&drc_desc_v2=93/42/EEC Medical devices&requesttimeout=900.

90. Directive 2007/47/EC, *supra* note 68, at 247/22 recital 2 (“In performing its duties under the quality assurance and verification conformity assessment modules for all other classes of devices, it is essential and necessary for a notified body, in order to be assured of the compliance of the manufacturer with Directive 93/42/EC, to review the design documentation for the medical device. The depth and extent of this review should be commensurate with the classification of the device, the novelty of the intended treatment, the degree of intervention, the novelty of the technology or construction materials, and the complexity of the design and/or technology. This review can be achieved by taking a representative example of design documentation of one or more type(s) of devices from those being manufactured. Further review(s), and in particular the assessment of changes to the design that could affect conformity with the essential requirements, should be part of the surveillance activities of the notified body.”).

91. *See id.* at 247/38 (“The evaluation procedure shall include an inspection on the manufacturer’s premises and, in duly substantiated cases, on the premises of the manufacturer’s suppliers and/or subcontractors to inspect the manufacturing processes.”).

92. *Id.* at 247/22 recital 16.

93. *Medical Devices Guidance Paper*, *supra* note 89.

94. *See Medical Devices – Recast of Medical Devices Directives – Individual Responses*, EUROPEAN COMMISSION, http://ec.europa.eu/health/medical-devices/results_en.htm (last visited Sept. 11, 2012) (listing the organizations that responded to the public consultation questionnaire).

of the Medical Devices Directives.⁹⁵ Of those 200, some 54 responses (most of which were position papers supported by interested parties) were made publicly available online and included endorsing a comment, supporting a federation, or providing substantive comments.⁹⁶ The four major categories of contributors were national regulators in the EU/EFTA, lobbyists (industry and federation representatives), individual companies, and a combination of healthcare professionals and academics.⁹⁷ One of the substantive comments was from Novartis (CibaVision/Sandoz)⁹⁸ regarding contact lenses (as an annex).⁹⁹ On the issue of parallel trade, Novartis responded that “[p]arallel trading increases the chances for counterfeiting” in particular contact lenses.¹⁰⁰ Novartis argued:

[P]arallel traders of medical devices (e.g. contact lenses) do not have specific expertise in the field [P]arallel traders tend to buy from [the] so-called “grey zone” providers, with little guarantee about the origin and thus quality of the product. Many of these products end up being sold by quickly growing [I]nternet or mail order channels, in which customers have no way to ensure that the products they are being shipped are safe and fit for their specific eye needs.¹⁰¹

Novartis argued that the European Commission should “consider requiring parallel traders of medical devices[, and by and large, those concerning contact lenses,] to obtain a special license to import/export, as in the case for medicinal products.”¹⁰² The view on parallel trade was similarly echoed by the Irish Medicines Board, which said that the development of legislative rules for parallel trade could be one measure that could help defeat counterfeit medical devices.¹⁰³ The Irish comments were not elaborated upon, and furthermore, the current rules in the EU promote the freedom of movement of goods so as to drive competitiveness in the EU market.¹⁰⁴

The concern by Novartis regarding the possibility that contact lenses are exposed to counterfeiting is legitimate. However, what doesn’t sit well with me is their argument that parallel traders of contact lenses should be required to have a special license. A special license would only restrict the re-

95. *Id.*

96. *See id.* (varied responses). The questionnaire form is available at http://ec.europa.eu/health/medical-devices/files/recast_docs_2008/public_consultation_en.pdf.

97. *Id.*

98. *See* Letter from Novartis, to European Comm’n, Novartis Contribution to the Public Consultation of the Recast of the Medical Devices Directives (July 15, 2008), available at http://ec.europa.eu/enterprise/newsroom/cf/_getdocument.cfm?doc_id=4830 [hereinafter Novartis Comments] (stating that Novartis welcomes the initiative of the European Commission).

99. *See id.* annex (arguing that “amendment of the legislation to require Member States to regulate the distribution of all contact lenses on the basis of a valid specification would assure a safe distribution for these products” and reduce the potential for counterfeits).

100. *Id.*

101. *Id.*

102. *Id.*

103. Letter from Irish Meds. Bd., to European Comm’n, Irish Medicines Board Response to Proposed Recast of MDD 23 (July 1, 2008), available at http://ec.europa.eu/health/medical-devices/files/recast_docs_2008/responses/012-r-1_en.pdf [hereinafter Irish Comments].

104. *See, e.g.,* TFEU, *supra* note 1, pt 3 tit. II (Free Movement of Goods).

importation of contact lenses in the EU market, in particular if certain criteria must be met to get acquire such a license. Furthermore, it distorts the competitive process in the internal market, thereby placing the fundamental principle of the free movement of goods at stake. One solution that could offset the need for a special license is self-regulation, where parallel traders of contact lenses agree to joint rules and report to a national agency or other notified body. This solution supposes that parallel traders of contact lenses are small and medium size firms that operate both online and offline stores. If parallel traders are small and medium size firms, then they can also ensure that an appropriate regulatory agency approves them as legitimate sellers of contact lenses in order to dispel any concern about the quality of the contact lenses they sell.

In this section, I will offer an overview of the situation regarding parallel imports in the EU and its relation to the contact lenses. For this, I will turn to parallel trade cases coming out of the courts in particular as they relate to contact lenses, medicinal products, and medical devices in general to form a coherent view of the situation in Europe.

A. *The Legal Framework of Parallel Trade*

In the crowded field of antitrust harm, parallel trade (re-importation) is only one such concern that intertwines with the competition provisions of the TFEU. Manufacturers of contact lenses are genuinely concerned about the impact of parallel trade on their product, in particular, when counterfeiting may be involved. But because parallel trade is enshrined in the EU free movement of goods principles, it has long been the target of legal scrutiny. To fully comprehend parallel trade and contact lenses, a primer on the current legal status of parallel trade in the EU is necessary.¹⁰⁵ The origin of parallel trade is arguably as old as *trade* itself. The acquisition of intellectual property rights was not meant to limit trade, but rather to ensure that innovation is nurtured, which in turn fosters competitive trade. Though the manufacturer of a good within the EU has been granted exclusive rights upon application and is entitled to prevent third parties from using his trademark in the course of trade, his rights are limited once the good has been placed on the market. This has been well established in early cases such as *Centrafarm*¹⁰⁶ and later cases.

A parallel trade good is not a counterfeit good, but rather a legitimate good that has been brought into a new market without the manufacturer's approval.¹⁰⁷ In other words, parallel trade is the process where goods protected by intellectual property rights are placed on one market and (re-)imported into a second market without the authorization of the initial

105. See TFEU, *supra* note 1, arts. 34–36 (regulating the free movement of goods between Member States). See generally Case C-142/05, *Aklagaron v. Mickelsson & Roos*, 2009 E.C.R. I-4273; Case C-59/08, *Copad SA v. Christian Dior Coutre SA*, 2009 E.C.R. I-3421.

106. Case 16/74, *Centrafarm BV v. Winthrop BV*, 1974 E.C.R. 1194.

107. CHRISTOPHER STOTHERS, *PARALLEL TRADE IN EUROPE: INTELLECTUAL PROPERTY, COMPETITION AND REGULATORY LAW* 2 (2007).

intellectual property rights-holder. As Christopher Stothers explained in his excellent work on the subject, parallel trade occurs “when the goods are subsequently transferred to a second country by another party [who may be the end user].”¹⁰⁸ There seems to be a consensus on when parallel trade occurs and furthermore, the accepted rationale for the existence of parallel trade lies in price discrimination. Because the price of a product can vary in different markets, one consistent scenario that fosters parallel trade is where there is one price in the home market and a lower price in a different market for the same product, creating an incentive for exporting back into the home market while intellectual property rights are exhausted.¹⁰⁹ This *re-importation* of goods has its advantages and disadvantages and has not escaped the wrath of all parties involved in parallel trade, in particular, the manufacturers who are the intellectual property owners.

There is merit to the arguments raised by Novartis¹¹⁰ that parallel trade in the EU can lead to counterfeit contact lenses. Manufacturers of contact lenses might suffer from lost sales potential when their lenses are re-imported or counterfeit lenses use their trademarks, and they may lack the ability to defend themselves because their intellectual property rights are exhausted.

B. *When Are Rights Exhausted?*

Within the context of trademark law, the most important question is when are rights exhausted under the principle of exhaustion?¹¹¹ Article 7 of the EU Trade Mark Directive (TMD) titled “Exhaustion of the Rights Conferred by a Trademark,” provides that “the trademark shall not entitle the proprietor to prohibit its use in relation to goods which have put on the market in the [EU] under that trademark by the proprietor or with his consent.”¹¹² Furthermore, the Article stipulates that that the provision of Article 7(1) “shall not apply where there exist legitimate reasons for the proprietor to oppose further commercialization of the goods, especially where the condition of the goods is changed or impaired after they have been put on the market.”¹¹³ These provisions in Article 7 of the TMD constitute the exhaustion doctrine of trademarks within the EU and thereby form a “regional [EU] exhaustion regime.”¹¹⁴ The provision has been interpreted consistently in several cases

108. *Id.* at 2.

109. *Id.*

110. *Supra* notes 98–104 and accompanying text.

111. *See generally* Case C-59/08, Copad SA v. Christian Dior Coutre SA, 2009 E.C.R. I-3421; Case C-127/09, Coty Prestige Lancaster Grp. GmbH v. Simex Trading AG, 2010 E.C.R. I-4965.

112. Council Directive 2009/95/EC, art. 7(1), 2008 O.J. (L 299) 25 (EC) [hereinafter TMD], replacing Council Directive 89/104/EEC, art. 7(1), 1989 O.J. (L 40) 5 (EC).

113. *Id.* art. 7(2).

114. Legislative development in Germany at the turn of the twentieth century has been credited for the introduction of the term “exhaustion” in the legal literature. For instance, authors have cited the German Supreme Court (*Reichsgericht*), case law of 1902 when it held that: “The effect of a patent (for a process) is that no-one, except the proprietor (or the persons whom he has authorized) may manufacture a product by the said process and put it on the domestic market. By this act, however, the effect of the protection conferred by the patent is exhausted. The proprietor who has manufactured the product and has put it on the market under this protection which excludes competition from other parties, has enjoyed advantages under this protection,

over the years but often with mixed results.

The intellectual property rights in goods are essentially exhausted once they have been placed on the market by the owner, and the use of intellectual property rights to prevent resale within the EU is forbidden. In other words, the proprietor of a trademark protected by the legislation of a Member State cannot rely on that legislation to prevent the import or marketing of a product that has been put on the market in another Member State by him or with his consent.¹¹⁵ In *Bristol-Myers*, the court did not mince words with what it saw as a non-starter regarding the EU doctrine of exhaustion, stating that trademark rights “are not intended to allow their owners to partition national markets and thus promote the retention of price differences which may exist between Member States.”¹¹⁶ Under this circumstance, a good has been exhausted the moment it’s been placed on the market and the intellectual property rights owner loses his right to prevent re-importation in a different part of the EU. There is no doubt this limitation fuels a growing market for parallel trade, and the different prices across the Member States of the EU present commercial opportunities for entrepreneurs to exploit.

Courts first interpreted Article 101’s competition principles in *Deutsche Grammophon*, where the doctrine of exhaustion first surfaced.¹¹⁷ *Deutsche Grammophon* was a case referred to the CJEU by a Hamburg court for a preliminary ruling on issues relating to copyright, the free movement of goods and competition. The court investigated whether the “exclusive right of distributing . . . [intellectual property rights-protected] sound recordings may, without infringing . . . [EU] provisions, prevent the marketing on national territory of products lawfully distributed by such manufacturer or with his consent on the territory of another Member State.”¹¹⁸ The court explained that there was a “general duty for the Member States, the actual tenor of which depends in each individual case on the provisions of the Treaty or on the rules derived from its general scheme.”¹¹⁹ Furthermore, the court held that the exclusive right falls under Article 101(1): “each time it manifests itself as the subject, the means or the result of an agreement which, by preventing imports from other Member States of products lawfully distributed there, has as its effect the partitioning of the market.”¹²⁰ The court went on to discuss the principles concerned with the attainment of a single market as set out in former

has enjoyed advantages which the patent confers upon him, and has thus exhausted his right.” STOTHERS, *supra* note 107, at 41 (citations omitted); *see also* Ian S. Forrester, *The Repackaging of Trade Marked Pharmaceuticals in Europe: Recent Developments*, 11 EUR. INTELL. PROP. REV. 512, 513–14 (2000) (attributing the first use of “exhausted” to the use of the word “epuise” in the Belgian courts in 1871).

115. *See, e.g.*, Joined Cases C-427, C-429 & C-436/93, *Bristol-Myers Squibb v. Paranova*, 1996 E.C.R. I-3528 (“[T]he owner of a trade mark protected by the legislation of a Member State cannot rely on that legislation to prevent the importation or marketing of a product which was put on the market in another Member State by him or with his consent . . .”).

116. *Id.* at 3532.

117. Case 78/70, *Deutsche Grammophon Gesellschaft mbH v. Metro-SB-Grossmärkte GmbH & Co. KG*, 1971 E.C.R. 489.

118. *Id.* at 498.

119. *Id.* at 499.

120. *Id.*

Article 3(g) and those on the free movement of goods in former Article 30, which outlined “a system ensuring that competition in the [EU] is not distorted.”¹²¹ The court then held that:

If a right related to copyright is relied upon to prevent the marketing in a Member State of products distributed by the holder of the right or with his consent on the territory of another Member State on the sole ground that such distribution did not take place on the national territory, such a prohibition, which would legitimize the isolation of national markets, would be repugnant to the essential purpose of the Treaty, which is to unite national markets into a single market.

That purpose could not be attained if, under the various legal systems of the Member States, nationals of those States were able to partition the market and bring about arbitrary discrimination or disguised restrictions on trade between Member States.¹²²

The court further explained that it would be in conflict with the provisions prescribing the free movement of products within the EU for a manufacturer of a sound recording to exercise the exclusive right to distribute goods protected by intellectual property rights “in such a way as to prohibit the sale in that State of products placed on the market by him or with his consent in another Member State solely because such distribution did not occur within the territory of the first Member State.”¹²³

As the leading case law that introduced the principle of exhaustion in the EU, *Deutsche Grammophon* set the tone for what was to follow in later cases that dealt with the question of exhaustion. Though the language used by the court was soft in *Deutsche Grammophon*, it nevertheless sent a signal that the court treated the issue seriously, and those who plan to subvert the course of trade within the EU by invoking their exclusive intellectual property rights will not go unpunished. Furthermore, the provisions of the former Article 5, as interpreted by the court, were also a warning to Member States that they have a duty not to encourage breaches of EU law.¹²⁴ A number of cases specifically dealing with exhaustion would later emerge following the *Deutsche Grammophon* ruling. These include *CNL v. Hag*¹²⁵ and *IHT v. Ideal-Standard*.¹²⁶ The court in *Pharmacia v. Upjohn* confirmed that under Article 7(1) of the TMD that “exhaustion of the rights conferred by the trade mark” exists “only in relation to goods which have been put on the market . . . by the [trademark owner] or with his consent.”¹²⁷ *Centrafarm v. Winthrop*¹²⁸ was the

121. *Id.*

122. *Id.* at 500.

123. *Id.*

124. See Case 5/79, Procureur Général at the Cour d'Appel v. Buys, 1979 E.C.R. 3205 (holding that a Member State would be in breach of the former Article 5 if it enacted legislation calculated to bring about or to encourage such agreements, decisions, or concerted practices that would breach Article 101 TFEU).

125. Case C-10/89, SA CNL-Sucal NV v. Hag GF AG, 1990 E.C.R. I-3752.

126. Case C-9/93, IHT Internationale Heiztechnik v. Ideal Standard, 1994 E.C.R. I-2836.

127. Case C-379/97, Pharmacia & Upjohn v. Paranova, 1999 E.C.R. I-6954.

128. Case 16/74, Centrafarm v. Winthrop, 1974 E.C.R. 1184.

next major case that followed *Deutsche Grammophon*. In that case, the court held that trademark rights guarantee that the owner of the mark has the exclusive right to place goods on the market for the first time, “and therefore [was] 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 trademark.”¹²⁹ There were two noticeable things about *Centrafarm v. Winthrop*. First, the case was before the TMD was adopted, and second, there were two intellectual property concerns at stake, (a) patents and (b) trademarks.¹³⁰ But in explaining its reasoning for the exhaustion of trademark rights, the *Centrafarm* court explained that:

An obstacle to the free movement of goods may arise out of the existence, within a national legislation concerning industrial and commercial property, of provisions laying down that a trade mark owner’s right is not *exhausted* when the product protected by the trade mark is marketed in another member state, with the result that the trade mark owner can prevent importation of the product into his own member state when it has been marketed in another Member State.¹³¹

The court said, “such [an] obstacle [would not be] justified when the product has been put on the market in a legal manner in the Member State from which it has been imported . . . ,”¹³² and if a trademark owner could prevent the import of protected goods marketed by him or with his consent in another Member State, he would be able to partition off national markets and restrict trade between Member States.¹³³ In *Ideal Standard*, the CJEU held that the principle of exhaustion was applicable only where the owner of the trademark is the same economic entity in both the importing and exporting state and “economically linked” such as through a licensee, parent company, subsidiary, or exclusive distributor.¹³⁴

These cases that involved parallel trade and exhaustion in conjunction with regulatory provisions in the TMD and the TFEU acted as a form of arbiter to prevent the owners of intellectual property rights from distorting the competitive process in the EU. Any reliance on the intellectual property rights to distort the competitive process in the EU and prevent the free flow of goods that have already been placed on the market would be in direct contravention of the competition rules.¹³⁵ A similar view regarding differential pricing was

129. *Id.* at 1194.

130. *See generally* TMD, *supra* note 112 (demonstrating that the TMD was adopted after *Centrafarm* was decided). *Centrafarm* resolved who is considered the patent holder and what constitutes trademark infringement. *Centrafarm*, 1974 E.C.R. at 1185.

131. *Centrafarm*, 1974 E.C.R. at 1194 (emphasis added).

132. *Id.* at 1195.

133. *Id.*

134. Case C-9/93, IHT Internationale Heiztechnik v. Ideal Standard, 1994 E.C.R. I-2846.

135. The core case law, such as *Deutsche Grammophon*, and the others discussed in this section related mostly to the free movement of goods provisions in the TFEU. The application of competition law has been more or less incidental since cases such as Case C-306/96, *Javico Int’l & Javico AG v. Yves Saint Laurent Parfums SA*, 1998 E.C.R. I-1983, among others. I am grateful to Professor Tuomas Mylly for pointing this out. However, parallel trade is enshrined in the free movement of goods principles and therefore, case law

echoed in *Bristol-Myers Squibb*,¹³⁶ where the court said, “[trademark] rights are not intended to allow their owners to partition national markets and thus promote the retention of price differences which may exist between Member States.”¹³⁷ But there is a fine line to be drawn between the interface of trademark law and competition law whenever the doctrine of exhaustion is invoked due to complexity of the issues involved. One way of breaking down the complexities is to ascertain whether or not there had been consent. In *Zino Davidoff*¹³⁸ several parallel importers argued that consent within the meaning of *Silhouette*¹³⁹ and *Sebago*¹⁴⁰ could be implied. In the next section, I will focus on one (creative) method of placing goods on the market and how the courts have interpreted this (creativity)—it’s the same wine in different bottles.

C. *As Good as Manufactured: Repackaging of Original Items*

For different reasons, parallel traders often alter the original packaging of a manufactured good. This alteration can take several forms, such as relabeling, rebranding, and repackaging, or a combination of all three. All three have their distinct legal requirement, and often times overlap, and one of the most common reasons to alter the original good is due to linguistic and/or country regulatory requirements. Another reason could be that distributors would like to present the goods as their own. The rest of the discussion in this section will focus specifically on repackaging as this often affects how relabeling and rebranding (co-branding) happen.

1. *Repackaging*

The issue of repackaging of goods is quite prevalent in the pharmaceutical sector. The case law of the CJEU relating to the repackaging of pharmaceutical goods by parallel importers without the trademark owner’s consent was first addressed in *Hoffmann-La Roche*,¹⁴¹ which laid down the guiding principles on repackaging. In *Hoffmann-La Roche*, the court addressed the prohibition of measures restricting imports laid down in the former Article 30 of the EEC Treaty (now Article 34 of the TFEU), and the justification of such measures on grounds of the protection of industrial and commercial property provision of the former Article 36 EEC Treaty (now Article 34 TFEU).¹⁴² In recent times, the CJEU has been asked to clarify what parallel importers are authorized to do when affixing marks on repackaged

performs an important function in how parallel trade is contextualized in jurisprudence.

136. Joined Cases C-427, C-429 & C-436/93, *Bristol-Myers Squibb & Others v. Paranova*, 1996 E.C.R. I-3528.

137. *Id.* at 3532.

138. Joined Cases C-414, C-415, & C-416/99, *Zino Davidoff v. A & G Imports Ltd.*, 2001 E.C.R. I-8753.

139. Case C-355/96, *Silhouette Int’l Schmied GmbH & Co. KG v. Hartlauer Hardelsgesellschaft mbH*, 1998 E.C.R. I-4822.

140. Case C-173/98, *Sebago, Inc. v. GB-Unic SA*, 1999 E.C.R. I-4114.

141. Case C-102/77, *Hoffmann-La Roche & Co. AG, Basel v. Centrafarm Vertriebsgesellschaft Pharmazeutischer Erzeugnisse mbH*, 1978 E.C.R. 1140.

142. *Id.* at 1163.

goods. In *Boehringer v. Swingward*,¹⁴³ the court held that parallel traders must fulfill five conditions in order for repackaging to be permissible.¹⁴⁴ The case concerned a group of pharmaceutical companies who opposed the marketing of parallel imported products in the UK and was referred to the CJEU for a preliminary ruling regarding the interpretation of Article 7(2) of the Trade Mark Directive.¹⁴⁵ The *Boehringer* court invoked the five conditions that were established in *Bristol-Myers Squibb* and said that for trademark owners to lawfully oppose further marketing of a repackaged pharmaceutical product; it is sufficient that one of the five conditions left unfulfilled.¹⁴⁶ The court also said that the burden of proving that the five conditions are met falls on the parallel trader.¹⁴⁷ Thus, the court in its ruling was able to elaborate more on the rules that parallel importers need to fulfill when putting on the market a repackaged good.¹⁴⁸ The ruling also “gives importers the flexibility to inject

143. Case C-348/04, *Boehringer Ingelheim KG v. Swingward Ltd.*, 2007 E.C.R. I-3430. See generally Alex Battenon & Benedict Bird, *Drugs Repackaging: Welcome News for Importers and Brand Owners*, 4 J. INTEL. PROP. L. & PRAC. 399, 399 (2009) (reviewing *Boehringer Ingelheim v. Swingward*).

144. *Boehringer*, 2007 E.C.R. at 3469. See Joined Cases C-427, C-429 & C-436/93, *Bristol-Myers Squibb and Others v. Paranova*, 1996 E.C.R. I-3414, for an initial discussion of these five principles. The court in *Bristol Myers Squibb* held:

Article 7(2) of [the Trademarks Directive] is to be interpreted as meaning that the trade mark owner may legitimately oppose the further marketing of a pharmaceutical product where the importer has repackaged the product and reattached the trade mark unless:

- it is established that reliance on trade mark rights by the owner in order to oppose the marketing of repackaged products under that trade mark would contribute to the artificial partitioning of the markets between Member States; such is the case, in particular, where the owner has put an identical pharmaceutical product on the market in several Member States in various forms of packaging, and the repackaging carried out by the importer is necessary in order to market the product in the Member State of importation, and also carried out in such conditions that the original condition of the product cannot be affected by it . . .
- it is shown that the repackaging cannot affect the original condition of the product inside the packaging . . .
- 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.

Id. at 3541–42. In *Boehringer*, the Advocate General whose opinion was issued prior to the ruling was impartial or perhaps parallel importers would have benefited more from such a ruling. The CJEU differed on a few points with the Advocate General, such as the interpretation of over-sticking, which the court described as the “attachment of a label to the original packaging,” as opposed to Advocate General Sharpston who argued that given that both the internal and external packaging remained intact, over-stickering did not impair the “guarantee of origin function” of the trademark. *Boehringer*, 2007 E.C.R. at 3454, 3399.

145. *Boehringer*, 2007 E.C.R. at 3435. The cases had been going through the British and European courts for a while and the judgment was a follow-up of an earlier judgment in the CJEU, Case C-143/00, *Boehringer Ingelheim and Others v. Swingward*, 2002 E.C.R. I-3762, in which the court answered preliminary questions of the English High Court, Chancery Division. See TMD, *supra* note 112, art. 7(2) (“Paragraph 1 shall not apply where there exist legitimate reasons for the proprietor to oppose further commercialization of the goods, especially where the condition of the goods is changed or impaired after they have been put on the market.”).

146. *Boehringer*, 2007 E.C.R. 3467.

147. *Id.* at 3472–73.

148. See Robert C. Bird & Peggy E. Chaudhry, *Pharmaceuticals and the European Union: Managing Gray Markets in an Uncertain Legal Environment*, 50 VA. J. INT’L L. 719, 746 (2009) (describing that the *Boehringer* ruling provides that “importers need only show that repackaging is necessary to enter the target

pro-competitive designs within compulsory legal or professional requirements.”¹⁴⁹ In a public memorandum on the case, the counsel who represented *Boehringer* warned that “significant litigation will still undoubtedly arise concerning factors that may damage a trademark’s reputation.”¹⁵⁰ Though the issue of repackaging is well-settled in the case law of the CJEU, sometimes national courts, in determining repackaging of parallel traded goods, offer a new interpretation of the *Bristol-Myers Squibb* conditions governing where repackaging is permissible. For example, the Finnish Supreme Court has said that repackaged product creates an “erroneous impression among consumers.”¹⁵¹ The connection of *Boehringer* to parallel trade in contact lenses is twofold: repackaging and pricing. While there is no strong evidence (in this research) regarding repackaging of contact lenses, it is not unusual for eye care professionals to use private labels in contact lenses.¹⁵² Both high street opticians and major eye care professionals may enter into an agreement with a contact lens manufacturer for a well-known brand of contact lens to be rebranded with the eye care professional’s own trademark creating a private label.¹⁵³ Such private labels are a broadly repackaged (or rebranded) form of contact lenses.¹⁵⁴ The practice of repackaging (rebranding) contact lenses is widespread in some jurisdictions and a possible effect of this rebranding of contact lenses is to “lock in” the customer into the eye care professional’s “supply system” and limit the choice of available contact

market and need not justify every detail in manner, shape, or style as necessary” (citing *Boehringer*, 2007 E.C.R. at 3457)).

149. *Id.*

150. Memorandum from Cleary Gottlieb LLP, *Repackaging of Pharmaceutical Products by Parallel Importers: ECJ’s Judgment in Case C-348/04 Boehringer Ingelheim and Others v Swingward and Others 5* (May 4, 2007), available at <http://www.cgsh.com/files/News/732b0651-7a6d-465f-a83a-7fbcd8b91c5a/Presentation/NewsAttachment/43f8366e-689f-46b3-952c-81b30148fad8/repackaging.pdf>.

151. Korkein Oikeus [KKO] [Supreme Court of Finland] Aug. 19, 2010, KKO:2011:7 ¶ 16 (Fin.), available at <http://www.kko.fi/53466.htm> (“Kerrotunlaisen näkyvän ja erottamiskykyisen tunnusmerkin käyttäminen pakkauksen etusivulla yhdessä lääkkeen alkuperäisen tavaramerkin kanssa on ollut omiaan antamaan lääkkeen ostamista harkitsevalle samoin kuin lääkettä jo ostaneelle yleisölle sen tosiasioita vastaamattoman mielikuvan, että Paranova Oy:n ja kysymyksessä olleiden lääkevalmisteiden välillä on jokin muu erityinen suhde kuin vain se, että Paranova Oy tuo lääkettä Suomeen.”). The case concerned a well-known Nordic parallel importer of pharmaceuticals, Paranova, that imported two pharmaceutical products into Finland, which had been first placed on the European market by the Dutch company N.V. Organon under the trademarks Mercilon and Marvelon. For the products to be sold on the Finnish market, Paranova repackaged them and affixed its own trademarks on the exterior of the new packages together with the trademark of Organon. The front of the new packages showed high up the Mercilon or Mervelon trademark, respectively, and below, that of Paranova’s figure mark and the word mark “Paranova” in stylistic font. Just above Paranova’s trademark it was indicated that Paranova was a “parallel importer” and “repackager.” Korkein Oikeus [KKO] [Supreme Court of Finland] Aug. 19, 2010, KKO:2011:7 (Fin.), available at <http://www.kko.fi/uploads/u9x1f5dbtpur03q.pdf>; see also Sami Sunila, *Co-branding of Pharmaceuticals Prohibited. Parallel Imports Case From the Finnish Supreme Court*, IPR U. CENTER (Feb. 2011), http://www.iprinfo.com/page.php?page_id=53&action=articleDetails&a_id=873&id=53 (reviewing KKO:2011:7).

152. See *Rebranded Contact Lenses*, LENS SHOPPER.CO.UK, <http://www.lensshopper.co.uk/rebranded-contact-lenses.asp> (last visited Sept. 14, 2012) (providing a database of the most common manufacturer brand of contact lenses that are rebranded by the major eye care professionals in the UK). According to www.lensshopper.co.uk, “many customers are not aware of the fact that it is possible to buy the exact same contact lens online, to a much better price, often as low as 30% of the price offered by the high street optician.” *Id.*

153. *Id.*

154. *Id.*

lenses.¹⁵⁵

The second concern is the pricing of contact lenses. It is no secret there are significant differences in the prices of contact lenses in different Member States of the EU.¹⁵⁶ It is this price difference that drives parallel traders to buy less expensive products in one Member State and to resell them in another Member State where the product costs more. Furthermore, because the sale of contact lenses on the Internet is widespread, there is no guarantee that a cheaper version of contact lenses meant for a particular market has not ended up in other markets when ordered online. One of the impacts of parallel imports in general, is that consumers should benefit from the price difference of the products. However, this may not necessarily be the case. The consumer, instead of reaping the benefits of parallel trade, suffers if there are unscrupulous vendors in the market whose sole intention is to make a profit on the backs of the consumers.¹⁵⁷ Furthermore, one of the conditions that may disadvantage consumers is the availability of counterfeit goods. Parallel imports are not counterfeit goods, but rather the opposite—they are legitimate goods of the intellectual property rights-owner.¹⁵⁸ However, it is sometimes difficult to detect counterfeit goods that are passed off as legitimate goods under the guise of parallel trade.¹⁵⁹ Many lobbying groups, such as those aligned with the medical sector, have long highlighted the effects of counterfeit medicines, and some have pointed directly to online pharmacies as blatantly complicit in counterfeit medicines.¹⁶⁰

2. *Repacking and Harm to Trademark Rights: Orifarm v. Merck*

On July 28, 2011, the CJEU handed down a preliminary ruling in which it said that a trademark owner has no legitimate interest in requiring that the name of the undertaking which actually repackaged the product should appear on the packaging merely because the repackaging is liable to affect the original

155. *Id.* See generally FTC, RX STUDY, *supra* note 28, at 21.

156. See generally SCOTT BRADFORD & ROBERT LAWRENCE, INST. FOR INT'L ECON., HAS GLOBALIZATION GONE FAR ENOUGH?: THE COSTS OF FRAGMENTED MARKETS 33 (2004), available at http://www.piie.com/publications/chapters_preview/349/3iie3497.pdf (discussing the price differences amongst EU nations, including pharmaceutical and optical goods).

157. See generally JACOB ARFWEDSON, INST. FOR POLICY INNOVATION, RE-IMPORTATION (PARALLEL TRADE) IN PHARMACEUTICALS (2004), <http://www.ipi.org/docLib/PR182-ParallelTrade.pdf-OpenElement.pdf> (describing some of the pitfalls of parallel trade for consumers).

158. See Brian Beirne & Michael Tucker, *Reimportation of Canadian Prescription Drugs into the United States: Regulatory, Economic, and Policy Implications*, 10 MICH. ST. U. J. MED. & L. 491, 496 (2006) (describing that parallel imports are legitimate products under trademark).

159. See generally Donald deKieffer, *Trojan Drugs: Counterfeit and Mislabeled Pharmaceuticals in the Legitimate Market*, 32 AM. J.L. & MED. 325, 325–26 (considering the practical and legal dimensions of trade in “Trojan drugs”).

160. See, e.g., EUROPEAN ALLIANCE FOR ACCESS TO SAFE MEDS., THE COUNTERFEITING SUPERHIGHWAY (2008) (reporting on the likelihood of medicines purchased online being counterfeit, substandard, or otherwise illegal, and developing recommendations that will protect patients and consumers from the potentially lethal outcomes of access to such products); Kristina M. Lybecker, PhD, *Economics of Reimportation and Risks of Counterfeit Pharmaceuticals*, MANAGED CARE, Mar. 2004, at supp. 10 (explaining that consumers want access to affordable, safe prescription drugs, describing the issues involved with counterfeit drugs, and making policy recommendations).

condition of the product and might therefore cause harm to his trademark rights.¹⁶¹

The case was referred to the CJEU by the Danish Supreme Court after Merck brought two actions before the Maritime and Commercial Court against Orifarm on the grounds that the name of the actual repackager did not appear on the packaging of the medicinal products in question.¹⁶² The CJEU explained that any form of disguised restriction on trade within the EU is a breach on the free movement of goods and that a disguised restriction within the meaning of Article 36 TFEU “will exist where the exercise by the trademark proprietor of his right to oppose repackaging contributes to artificial partitioning of the markets.”¹⁶³ The court added that the repackaging must protect the legitimate interest of the trademark owner and that “if the repackaging is carried out in conditions which cannot affect the original condition of the product inside the packaging, the essential function of the trade mark as a guarantee of origin is safeguarded.”¹⁶⁴ In this scenario, the CJEU citing its earlier decisions in *MPA Pharma* and *Bristol-Myers Squibb*, said the “consumer or end user is not misled as to the origin of the products, and does in fact receive products manufactured under the sole supervision of the trade mark proprietor.”¹⁶⁵ The *Orifarm v. Merck* court explained that, based upon the relevant case law, the trademark owner may not legitimately oppose the further marketing of a pharmaceutical product bearing his trademark.¹⁶⁶

In *Orifarm v. Merck*, it was the third condition, that the new packaging clearly indicates the repackager of the product and the name of the manufacturer, which was of concern to the court and prompted it to rule:

Article 7(2) of [the TMD] must be interpreted as not allowing the proprietor of a trade mark relating to a pharmaceutical product which is the subject of parallel imports to oppose the further marketing of that product in repackaged form on the sole ground that the new packaging indicates as the repackager not the undertaking which, on instructions, actually repackaged the product and holds an authorisation to do so, but the undertaking which holds the marketing authorisation for the product, on whose instructions the repackaging was carried out, and which assumes liability for the repackaging.¹⁶⁷

Though the ruling did not establish any new grounds, the case, raises a

161. Joined Cases C-400/09 & C-207/10, *Orifarm A/S v. Merck Sharp & Dohme Corp.*, 2011 E.C.R. ¶ 31.

162. *Id.* ¶¶ 11–12.

163. *Id.* ¶¶ 23–24 (citing Case C-348/04, *Boehringer Ingelheim & Others*, 2007 E.C.R. I-3391 ¶¶ 16–17).

164. *Id.* ¶ 25.

165. *Id.* (citations omitted); see also *id.* ¶ 26 (establishing that, to protect the interests of proprietors, importers must abide by certain requirements in marketing proprietors' products).

166. Joined Cases C-400/09 & C-207/10, *Orifarm A/S v. Merck Sharp & Dohme Corp.*, 2011 E.C.R. ¶ 31; see also Case C-348/04, *Boehringer Ingelheim & Others*, 2007 E.C.R. I-3391 (listing the five conditions for repackaging that must be met).

167. *Orifarm*, 2011 E.C.R. ¶ 36.

number of concerns. First, it should be considered whether indicating the repackager on the packaging—if the repackager is already part of a group—will have any practical impact on the consumer. In most cases, a consumer is more likely concerned with whether the prescription drug was manufactured by a large corporation, which guarantees a product’s origin and *safety*. In addition, though the repackager may want to pass on any likely wrongful lawsuits to the manufacturer, an indication of the origin of repackaging does not bring any added value to the original trademark. If anything, it is to the contrary: it damages the reputation of the original mark. However, instances where the seller fails to indicate the repackager—attempting to distort competition by using the trademark in an abusive manner—illustrate that when legal principles are expanded or created to get to a particular outcome, there is a potential for conflicting rules and unwanted surprises.

*D. Can a Member State Prohibit the Online Sale of Contact Lenses?:
The KER-Optika Decision*

The selling of contact lenses was once the purview of qualified opticians.¹⁶⁸ However, that has changed in recent years as the availability of contact lenses on the Internet has blossomed into a successful business for specialist vendors in contact lenses.¹⁶⁹ Opticians merely provide the first prescription for contact lenses and the customer then subsequently orders the required lenses online.¹⁷⁰ The courts have been asked to look into the online sales of contact lenses on different occasions, and, in *Ker-Optika v. ANTSZ*, the High Court in Europe held that a Member State of the EU cannot prohibit the selling of contact lenses on the Internet.¹⁷¹ The court said a Member State of the EU “may require the economic operators concerned to make available to the customer a qualified optician whose task is to give to the customer, at a distance, individualized information and advice on the use and care of the contact lenses.”¹⁷² Thus, if a EU consumer buys contact lenses on the Internet from another Member State, the Member State in which the contact lens vendor is located can be compelled by the competent authorities to provide the distant consumer a qualified optician. The case concerned laws in Hungary which require that contact lenses be sold in a specialist shop (with a minimum of eighteen square-meters separated from the workshop) using the services of an optometrist or ophthalmologist qualified in the field of contact lenses.¹⁷³ The Hungarian health authorities¹⁷⁴ prohibited Ker-Optika from selling contact

168. GARY D. HAILEY ET AL., FED TRADE COMM’N, A COMPARATIVE ANALYSIS OF COSMETIC CONTACT LENS FITTING BY OPHTHALMOLOGISTS, OPTOMETRISTS, AND OPTICIANS 10–14 (1983).

169. *Id.*

170. *Id.*

171. Case C-108/09, *Ker-Optika bt v. ANTSZ-Del-dunatuli Regionális Intezete*, 2010 E.C.R. I-12213.

172. *Id.* ¶ 73.

173. *See id.* ¶ 7 (“Each Member State shall insure that the information society services provided by a service provider established on its territory comply with the national provisions applicable in the Member State in question which fall within the coordinated field.”).

174. South Transdanubian Regional Directorate of the National Public Health and Medical Devices, Hungary.

lenses on its website on the grounds that, in Hungary, contact lenses could not be sold on the Internet.¹⁷⁵ Ker-Optika objected¹⁷⁶ and challenged the prohibition in the local district court which referred it to the CJEU for a preliminary ruling.¹⁷⁷ In its petition, Ker-Optika argued that the sale of contact lenses on the Internet was an “information service” under the Directive on Electronic Commerce (2000/31/EC).¹⁷⁸ The Hungarian District Court in the County of Baranya asked the European High Court whether EU law precludes the Hungarian legislation from authorizing the selling of contact lenses only in shops which specializes in the sale of medical devices and, consequently, from prohibiting the selling of contact lenses on the Internet.¹⁷⁹

The European High Court in its judgment said the Hungarian legislation violated the free movement of goods in the EU. According to the court, “the prohibition on selling contact lenses by mail order deprives traders from other Member States of a particularly effective means of selling those products and thus significantly impedes access of those traders to the market of the Member State concerned.”¹⁸⁰ On the other hand, the court also said it was the prerogative of the state in which the vendor is located to decide whether there is a need for the vendor to provide the distant customer access to a qualified ophthalmologist for contact lens advice.¹⁸¹

The implications of the ruling by the court in *Ker-Optika* on the face of it should not be so surprising or devastating; all Member States of the EU are required to implement the EU directives and also comply with the rules on the free movement of goods. It is well established in EU case law that prohibitions on the free movement of goods violates the EU Treaty. Had the court found in favor of the Hungarian health authorities, it would have essentially put a break on the completion of the internal market. Thus, the ruling by the court was the appropriate balance, and the Hungarian legislation essentially violated the *federal* European law on electronic commerce, the Electronic Commerce Directive,¹⁸² and the law on distance selling.¹⁸³

175. *Ker-Optika*, 2010 E.C.R., at 12213 ¶2.

176. *See id.* ¶ 17 (“[T]he sale of contact lenses via the Internet cannot be subject to restrictions in light of Article 3(1) of the Law on Electronic Commerce, which safeguards the right of an information society service provider to pursue that activity freely.”). The Local Health Authority argued that Recital 18 of Directive 2000/31 makes it clear that the scope of the Law on Electronic Commerce cannot encompass the sale of contact lenses via the Internet. *Id.* ¶ 18.

177. *Id.* ¶ 19.

178. *Id.* ¶ 17.

179. *Id.* ¶ 19.

180. *Id.* ¶ 54.

181. *Id.* ¶ 63.

182. Directive 2000/31/EC, of the European Parliament and of the Council of 8 June 2000 on Certain Legal Aspects of Information Society Services, in Particular Electronic Commerce, in the Internal Market, 2000 O.J. (L 178/1) at 1.

183. *See generally* Directive 97/7/EC, of the European Parliament and of the Council of 20 May 1997 on the Protection of Consumers in Respect of Distance Contracts, 1997 O.J. (L144) 19. *But see* Directive 2011/83/EU, *supra* note 41, para. 12 (repealing Directive 2000/31/EC).

IV. COMPETITION, PRIVATE LABELS, AND PRICING IN THE EUROPEAN MARKET FOR CONTACT LENSES

A. *The Market for Contact Lenses*

One of the root causes for a parallel trade regime is the existence of discrepancies in pricing in different member states. A bottle of popular table wine (0.75 liters) sold in five distinct markets in the EU—Spain, Belgium, Romania, Sweden, and Finland—varies in price from a low of €0.77 in Romania to a high of €5.94 in Sweden.¹⁸⁴ The discrepancies in price encourage parallel traders to buy goods in markets where the goods cost less and sell them in markets where they fetch higher prices. The price discrepancies of the wine industry can also be found in the contact lens industry, a market related to healthcare. The application of competition rules “in the healthcare industry is exceedingly tricky.”¹⁸⁵ As Wayne Klein said in his congressional testimony, part of the difficulty in applying competition rules in the healthcare industry stems from the fact that “separating the medical decisions from the financial ones . . .” is very difficult.¹⁸⁶

Examinations of the contact lens market, from both a competitive and consumer perspective, have been carried out in major studies in other parts of the world including the United States.¹⁸⁷ It is also possible that other studies were carried out in other parts of the world including Europe in languages other than English. However, I am not aware of those studies. Thus, this Article is biased towards studies available in English. One such study is what I believe to be the first empirical study on the United States contact lens industry. It was published in 1987. In the empirical study, researchers found that prices are significantly higher in markets with tying requirements where there are many sellers.¹⁸⁸ This study on the United States contact lens industry

184. According to the WHO Alcohol Database 2011, a bottle of wine (0.75 liters), costs €0.77 in Spain, €2.44 in Belgium, €1.55 in Romania, €5.94 in Sweden, and €4.65 in Finland. *Alcohol*, WORLD HEALTH ORG., <http://data.euro.who.int/alcohol/Default.aspx?TabID=2422> (last visited Sept. 6, 2012) (Price Comparison Table). The costliest country for the same bottle of wine was Norway, a member of the EEA but not the EU, where it costs €11.21. *Id.* It should be noted that the EU is the world’s largest supplier, consumer, exporter, and importer of wine, and in 2011, imports were expected to expand moderately on stronger demand for inexpensive imported wines. U.S. DEP’T OF AGRICULTURE, WINE: WORLD MARKETS AND TRADE (2011), available at <http://www.fas.usda.gov/info/Wine%204-11.pdf>; see also Case C-167/05, *Comm’n v. Kingdom of Sweden*, 2008 EUR-Lex CELEX LEXIS (Apr. 8, 2008) (challenging Swedish excise tax rules on the grounds that they afford indirect protection to beer, which is mainly produced in Sweden, as compared to wine, which is mainly imported from other EU Member States); Jan Bentzen & Valdemar Smith, *Wine Prices in the Nordic Countries: Are they Lower than in the Region of Origin?*, Conference Presentation at the Economic Society of Australia’s 31st Conference of Economists 3 (Sept. 2002) (transcript available at <http://www.hha.dk/nat/workshop/Vs2110.pdf>).

For developments in the EU in general (unrelated to wines), see, e.g., Daniel O. Acquah, *Developments in the EU External IP and Trade Competence up to Lisbon: New Wine in Old Bottles or Imprimatur?*, 5 NORDISKT IMMATERIELLT RATTSSKYDD 423 (2011).

185. *Congressional Hearing*, *supra* note 44, at 27.

186. *Id.* at 29.

187. See generally FTC, RX STUDY, *supra* note 28.

188. Deborah Haas-Wilson, *Tying Requirements in Markets with Many Sellers: The Contact Lens Industry*, 69 REV. ECON. & STAT. 170, 170–75 (1987) (examining the effect of tying requirements on the

was released when the industry was in its infancy.¹⁸⁹

By the 1990s, the contact lens industry expanded and more patients were wearing prescription contact lenses.¹⁹⁰ At the same time, the manufacturers of contact lenses invested heavily in research and development in order to offer more contact lenses on the market. At this time, the industry was in the hands of a few specialized companies (to some extent this is still true today), and the manufacturers (allegedly) gained market dominance to shore up their revenues from the sale of contact lenses.¹⁹¹ In 1990, the *Los Angeles Times* ran a headline that should have sent a warning to the manufacturers of contact lenses: “An Eye on the Contact Lenses Industry.”¹⁹² Those very same concerns regarding anti-competitive sales practices, among others, are still an issue in the contact lens industry today. The market for prescription contact lenses is a huge industry with benefits accruing to both the manufacturers of contact lenses and their end customers. The middlemen (distributors and retailers) also gain from contact lenses, such as private labels and/or price control, as discussed later in this Article.¹⁹³

The sale of contact lenses continues to grow significantly globally, with sales in Europe for contact lenses in 2008 over 1.2 billion USD.¹⁹⁴ Furthermore, it has been predicted that the global contact lens and solution market will see sales increase to 12 billion USD by 2015.¹⁹⁵ The wearer base for contact lenses across Europe varies, but statistics based on sales in 2009 suggests that the Nordic region has the highest usage of contact lenses, at about 20%, followed by Switzerland, at 7.77%.¹⁹⁶ In the UK, an average of 6% of

prices and qualities of goods and services offered by sellers with some degree of market power and suggesting that “the evaluation of the legality of tying requirements in the market for contact lenses should include an assessment of the effect of the tying requirement on both price and quality”).

189. See *infra* section IV(B)(1) for a review of later studies. See generally Hass-Wilson, *supra* note 188.

190. FTC, RX STUDY, *supra* note 28, at 34.

191. *In re Disposable Contact Lens Litigation*, Nos. 3:00-94 MD 1030, 3:97-CV-861, 3:97-CV-698, 3:97-CV-928, 3:98-CV-93, 3:98-CV-511, 3:98-CV-515, 3:98-CV-536, 3:98-CV-638, 2001 WL 203964 (M.D. Fla. Jan. 5, 2001); see also Press Release, Office of Attorney Gen., Tex., Contact Lens Antitrust Lawsuit Settles – Lens Wearers Eligible for Benefit (May 22, 2001), available at <https://www.oag.state.tx.us/newspubs/newsarchive/2001/20010522j&jsettlement.htm> (referencing the out-of-court settlement of *In re Disposable Contact Lens Litigation*). It is still believed that some lens manufacturers collude with eye care professionals to restrict the sale of disposable contact lens through all forms of discount sales, including the Internet, mail order, pharmacies, and mass merchandisers. See, e.g., John Tennis, Assistant Attorney Gen., Md., Statement at the FTC Public Workshop on Possible Anticompetitive Efforts to Restrict Competition on the Internet (Oct. 9, 2002), available at <http://www.ftc.gov/opp/e-commerce/anticompetitive/panel/tennis.pdf>.

192. Paul Jacobs, *An Eye on Contact Lens Industry*, L.A. TIMES, June 4, 1990, at A3.

193. See *infra* part IV.B.1 for further information on how distributors and retailers benefit from anti-competitive sales practices.

194. EUROMCONTACT A.I.S.B.L., A COMPARISON OF SOFT CONTACT LENS AND LENS CARE MARKETS IN EUROPE IN 2008, at 3 (2008) [hereinafter EUROMCONTACT 2008], available at http://www.euromcontact.org/documents/ws_mo_rpt_ec_commentary_statistics_2008_public.pdf; see also EUROMCONTACT A.I.S.B.L., A COMPARISON OF SOFT CONTACT LENS AND LENS CARE MARKETS IN EUROPE IN 2009, at 4 (2009) [hereinafter EUROMCONTACT 2009], available at http://www.euromcontact.org/documents/2009_publication.pdf (addressing the growth of the contact lens industry). Euromcontact is the Brussels-based organization that represents the contact lens industry and often publishes statistics on their website, www.euromcontact.org.

195. GLOBAL INDUS. ANALYSTS, INC., CONTACT LENSES AND SOLUTIONS - A GLOBAL STRATEGIC BUSINESS REPORT 2 (2010).

196. EUROMCONTACT, 2009, *supra* note 194, at 2.

patients who visited eye care facilities ended up choosing contact lenses.¹⁹⁷ As a result, 3.6 million, or 7.2% of the UK adult population, wore contact lenses in 2010.¹⁹⁸ As the European market for contact lenses continues to grow, the markets that recorded the highest demands for soft contact lenses were Spain, the UK and Ireland, Italy, and Denmark (2010).¹⁹⁹ The major manufacturers of contact lenses are some of the big names in the pharmaceutical industry such as the big four: Novartis (CIBA Vision); Johnson & Johnson (Vision Care); Cooper Vision;²⁰⁰ Bausch & Lomb and other players, such as: Menicon Europe; Avizor; Abbott; Clearlab; and Sauflon, among others.²⁰¹

The United States, for example, recognized that the market for contact lenses is a consumer-driven business and that those consumers needed some form of protection, so Congress passed the Fairness to Contact Lens Consumers Act (FCLCA).²⁰² The FCLCA increases consumers' ability to shop around when buying contact lenses and gives consumers certain rights, imposes duties on contact lens prescribers and sellers, and requires the Federal Trade Commission to develop and enforce implementing rules.²⁰³ A key part of the FCLCA is that it requires eye care practitioners to verify a patient's contact lens prescription. This provision of the FCLCA aims at "helping patients who seek to purchase contact lenses from a seller other than their own eye care practitioner."²⁰⁴ This development in the United States was a victory for U.S. consumers, and like their European counterparts who have long enjoyed the freedom to purchase contact lenses from any medium through the free movement principles under EU law, the consumer welfare of contact lens wearers is improved.

197. *Optics at a Glance 2010*, OPTICAL CONFEDERATION (Fed'n of Ophthalmic & Dispensing Opticians, London, U.K.), July 2011, at 1.

198. *Id.* at 2.

199. EUROMCONTACT A.I.S.B.L., A COMPARISON OF SOFT CONTACT LENS AND LENS CARE MARKETS IN EUROPE IN 2010, at 2 (2010) [hereinafter EUROMCONTACT 2010], available at http://www.euromcontact.org/documents/2010_publication.pdf. Soft Contact Lenses are generally defined as Daily Disposables (DD), Weekly/Bi-weekly and Monthly (W/B&M), and conventional soft (CS) lenses.

200. A division of the Cooper Companies responsible for 84% of Cooper's revenue and the third largest "manufacturer of soft contact lenses with approx[imately] 17% of global market share." THE COOPER COS., FACT SHEET FISCAL YEAR 2011, at 1 (2011), available at <http://www.coopercos.com/media/Factsheet.pdf>.

201. Alcon was incorporated into the Novartis group to form a new division for contact lenses including CIBA Vision in 2010, and in the second quarter financial results for 2011, Novartis reported that pharmaceuticals net sales grew 10% to 8.3 billion USD, of which Alcon contributed 2.8 billion USD of net sales in the second quarter. NOVARTIS, FINANCIAL REPORT 2 (2011), available at <http://www.novartis.com/downloads/investors/financial-results/quarterly-results/q2-2011-media-release-en.pdf>. Furthermore, Novartis reported that "[g]lobal sales of vision care products rose 10% . . . to USD 630 million" and the rise in "sales growth in contact lenses was fueled by . . . [the] strong performance of AirOptix: . . . [s]ales of contact lenses were impacted by the discontinuation of our specialty contact lens business." *Id.* at 15.

202. See generally Fairness to Contact Lens Consumers Act, Pub. L. No. 108-164, 117 Stat. 2024 (2003).

203. See *The Contact Lens Rule: A Guide for Prescribers and Sellers*, FED. TRADE COMMISSION (Oct. 2004), <http://business.ftc.gov/sites/default/files/pdf/bus62-contact-lens-rule-guide-prescribers-and-sellers.pdf> (providing guidance on the law to prescribers and sellers).

204. See Howard Beales, Director, Fed. Trade Comm'n, Prepared Statement of the Federal Trade Commission Before the Committee on Energy and Commerce U.S. House of Representatives (Sept. 9, 2003), available at <http://www.ftc.gov/os/2003/09/contactlens.shtm> (explaining how prescription verification supports greater competition between third parties and eye care practitioners).

1. *Structure of the Contact Lens Market*

As pointed out earlier, the global market for contact lenses is expanding. At the same time, the manufacturers of contact lenses are reaping the benefits of the growing demand. Asia is leading the market expansion for contact lenses. In 2010, sales in five major Asian markets grew to \$623 million USD, the market research firm GfK Asia reported.²⁰⁵ One major manufacturer of contact lenses, CooperVision, accounting for 17% of the global market share, reported that in the third quarter of 2011, the EMEA accounted for 38% of its revenue, with the Americas accounting for 40%, and Asia Pacific for 22%.²⁰⁶

Growth in the European market for contact lenses is also on the rise with the Nordic countries leading the growth rate.²⁰⁷ The European market for contact lenses is growing rapidly and is unlikely to slow down anytime soon.²⁰⁸ Part of the reason for this is that those in the 15–64 age category increasingly wear prescription contact lenses,²⁰⁹ and it has become a multibillion-euro industry.²¹⁰

One form of competition is between the manufacturers of contact lenses and private labelers, where major retailers of contact lenses use private labeling to market their contact lenses and differentiate themselves from their rivals. This is more evident in some countries—such as Sweden, the UK, and Finland—than others.²¹¹ In Sweden, for example, one of the major eye care providers, Synsam, branded the popular Biomedics and ProClear lenses as EyeQ.²¹² In Finland, Instrumentarium brands a number of lenses produced by CooperVision as iWear.²¹³ Competition in the Finnish market for optical goods, such as prescription glasses and contact lenses, has increased in recent years due largely to the British optical chain, Specsavers, which entered the

205. *More Than USD 623 Million Worth of Contact Lens Sold Across Five Major Markets in Asia in 2010: GfK*, GfK RETAIL & TECH. ASIA (Mar. 21, 2011), http://www.gfkr.com/asia/news_events/news/news_single/007512/index.en.html.

206. THE COOPER COS., FACT SHEET: FISCAL YEAR 2011 (Oct. 31, 2011); Press Release, The Cooper Cos., The Cooper Companies Announces Third Quarter 2011 Results (Aug. 31, 2011), *available at* <http://investor.coopercos.com/releasedetail.cfm?ReleaseID=602570>.

207. EUROMCONTACT 2008, *supra* note 194, at 3.

208. *Id.* at 5.

209. *Id.* at 3.

210. For example, in 2001, the trade group Euromcontact, representing contact lens and lens care solution manufacturers, approached London Business School “to investigate the profitability of contact lenses against spectacles from the eye care practitioner’s perspective,” due to what the group believed was “stagnant growth in . . . five . . . [major] European markets of France, Germany, Italy, Spain, and the United Kingdom.” *See Seeing Things Clearly: The Profitability of Contact Lenses for European Eye Care Practitioners*, LONDON BUS. SCH., May 2001, at 3, 8 [hereinafter *Contact Lenses Profitability Report*] (stating the total global market potential of glasses and contact lenses is approximately \$48 million USD, split between the United States, Europe, and all other continents). By 2009, the industry eye care professionals market value of soft contact lenses grew by 6.18% to €1.156 billion in twenty-two countries in which data was collected in the EU. EUROMCONTACT 2009, *supra* note 194, at 2.

211. *See, e.g., Rebranded Lenses Guide*, CONTACTLENSES.CO.UK, <http://www.contactlenses.co.uk/page?id=16> (last visited Sept. 11, 2012) (explaining how “high street chains” often repackage the same lenses to market them to consumers at higher prices).

212. *See Frequently Asked Questions*, SYNSAM, <http://www.synsam.se> (listing EyeQ brands for sale).

213. *See INSTRUMENTARIUM*, <https://verkkokauppa.instru.fi/> (last visited Oct. 2, 2012) (listing iWear contact lenses as a purchase option).

market in 2007 when it took over the Optika chain.²¹⁴ In the UK, the branding of contact lenses is more popular, with close to a dozen names to choose from for popular contact lenses.²¹⁵

Contact lenses come in different types and range from daily disposable, which are designed for one-time use, to monthly lenses, to extended wear contact lenses for continuous use over a seven day period.²¹⁶ The extended wear lenses and the monthly wear products can either be worn at a particular interval (that is, they are worn during the day and removed during the night) or they can be worn both night and day.²¹⁷ These types of contact lenses are usually grouped into two categories: spherical and specialty (e.g., toric or multifocal lenses).²¹⁸ Based on information published by the manufacturers of contact lenses, the product categories for contact lenses are divided into two groupings. The first, spherical lenses, includes “lenses that correct near- and farsightedness uncomplicated by more complex visual defects.”²¹⁹ The second, specialty segments such as toric and multifocal lenses, “includ[es] lenses that in addition to correcting near- and farsightedness, address more complex visual defects such as astigmatism and presbyopia by adding optical properties of cylinder and axis, which correct for irregularities in the shape of the cornea.”²²⁰ In general, it is left to the eye care provider to recommend the correct type of contact lenses to a patient; and it is conceivable that an eye care provider may recommend to a patient lenses that are costly, particularly in brick-and-mortar operations. The replacement schedule for contact lenses as outlined in the previous paragraph suggests that the market for contact lenses presents a fertile opportunity for pricing and advertising contact lenses, which in turn drives competition in the market for contact lenses.²²¹

214. Specsavers has been known for its aggressive advertising and pricing of optical goods in the Finnish market and has often been referred to as the “initiator” of price wars. *See Recession Troubles Finland’s Opticians, Already Embroiled in Price War*, HELSINGIN SANOMAT, Apr. 29, 2009, <http://www.hs.fi/english/article/Recession+troubles+Finland%E2%80%99s+opticians+already+embroiled+in+price+war+/1135245561920> (“The price war’s initiator, the rapidly expanded Specsavers, advertises even now on its website single focal lenses with ‘trendy’ frames for no more than nine euros.”).

215. *See infra* Part IV.B.2 tbl.4 (listing the brands available in the UK).

216. The market for conventional lenses that are replaced annually has shifted to disposable and frequently replaced lenses. THE COOPER COS., ANNUAL REPORT (FORM 10-K) 43 (2012) (“Disposable lenses are designed for either daily, two-week or monthly replacement; frequently replaced lenses are designed for replacement after one to three months. Significantly, the market for spherical lenses is growing with value-added spherical lenses to alleviate dry eye symptoms as well as lenses with aspherical optical properties or higher oxygen permeable lenses such as silicone hydrogel.”).

217. *See* CONTACT LENS PRACTICE, *supra* note 15, at 275 (“The term ‘extended wear’ has generally been applied to describe wear of contact lenses for periods in excess of 24 hours between removal, including sleep with the lenses on eye and regular, planned removal of the lenses.”).

218. *See* FTC, RX STUDY, *supra* note 28, at 7 (“Spherical lenses contain a single refractive power and are by far the most commonly prescribed lens. Varieties of specialty lenses include toric (to correct astigmatism), multifocal (to correct near and far-sightedness simultaneous), cosmetic tint and extended wear. According to industry data, spherical lenses accounted for 70% of dispensing visits and 57% of total soft lens sales in 2003. Within the specialty segment in 2003, toric, cosmetic tint, and multifocal lenses accounted respectively for 16%, 9%, and 5% of patient visits when contacts lenses were dispensed.” (footnotes omitted)).

219. THE COOPER COS., *supra* note 216, at 43.

220. *Id.*

221. *See generally* JOHN SUTTON, SUNK COSTS AND MARKET STRUCTURE: PRICE COMPETITION AND ADVERTISING AND THE EVOLUTION OF CONCENTRATION (1991); MARKET STRUCTURE AND COMPETITION

2. *The Meaning of ‘Placing on the Market’*

The meaning of the phrase “place on the market” is adopted from the MDD which, in this instance, refers to contact lenses that have been shipped from manufacturers to distributors, retailers, eye care professionals, and other economic entities to be sold to consumers. In the context of the MDD, the concept of “placing on the market” is applicable to all three Directives, and the Commission has explained that a product being “made available” should be interpreted to mean “distribution or use whilst making available is to be understood as the supply of a product.”²²² Thus, the “termination of the manufacture is not sufficient for a product to be placed on the market,” the European Commission says, as “it must have entered into the distribution chain.”²²³ The suggested meaning by the Commission should serve as a guide, and when in doubt, one must adopt the legal definition of “placing on the market” set forth in the Medical Devices Directives.²²⁴ However, in certain cases where a device still sits in the manufacturer’s storage facility, it can be considered “placed on the market” if it has been established that the “ownership or another right of a certain product has already been transferred to either a distributor or the end user but the product is still stored by the manufacturer on their behalf.”²²⁵ The same criteria for placing on the market of EU manufactured goods are applied to goods imported into the EU, but they are considered to be placed on the market only when they are “released for free circulation in the internal market.”²²⁶ Based on these definitions and the requirements set out in the MDD, placing a medical device on the market occurs the moment such device enters the distribution chain and not necessarily the moment its manufacture is completed. The adoption of the interpretative document is crucial to the understanding of the MDD, and the document has been seen as allowing manufacturers some flexibility “to ‘play’

POLICY: GAME THEORETIC APPROACHES (George Norman & Jacques-François Thisse eds., 2000) (applying game theory to questions of competitive markets and competition policy).

222. *Interpretative Document of the Commission’s Services: Placing on the Market of Medical Devices*, COM (2010) final 3 para. 9 (Nov. 16, 2010) [hereinafter *Placing on the Market*], available at http://ec.europa.eu/health/medical-devices/files/guide-stds-directives/placing_on_the_market_en.pdf.

223. *Id.*

224. See Council Regulation 765/2008, 2008 O.J. (L 218) 30, 34–35 (defining “placing on the market” as “the first making available of a product on the [EU] market,” and defining “making available on the market” as “any supply of a product for distribution, consumption or use on the [Union] market in the course of a commercial activity, whether in return for payment or free of charge”); Directive 98/79/EC, of the European Parliament and of the Council of 27 October 1998 on *in Vitro* Diagnostic Medical Devices, 2008 O.J. (L 331) 6 art. 1 § 2(i); Directive 93/42/EEC, of the Council of the European Communities Concerning Medical Devices, 1993 O.J. (L 169) (both defining “placing on the market” as “the first making available in return for payment or free of charge of a device . . . with a view to distribution and/or use on the Community market, regardless of whether it is new or fully refurbished”); Directive 90/385/EEC, of the Council of the European Communities on the Approximation of the Laws of Member States Relating to Active Implantable Medical Devices, 1990 O.J. (L 189) 17 art. 1 § 2(g) (defining “putting into service” as “making available to the medical profession for implantation”).

225. *Placing on the Market*, *supra* note 222, at 4 para. 14.

226. *Id.* at 4 para. 15. Moreover, “[u]nder certain circumstances, however, the placing on the market of an imported medical device does *not* coincide with its release for free circulation, namely in cases where that product has not yet been transferred from the stage of manufacture to the distribution stage” *Id.* at 4 para. 18.

with the moment when a medical device is placed on the market.”²²⁷ The next section will focus on pricing and the lock-in theory regarding private labeling of contact lenses.

B. Contact Lenses Private Labeling and the Lock-in Theory

1. Customer Lock-in Theory and Loyalty in Contact Lenses

The large manufacturers of contact lenses own various trademarks and brand names under which they package and sell their lenses. Often, a manufacturer may license a particular brand to an eye care provider, who may then sell the licensed brand under a private label. The question is whether a consumer who relies on a single eye care provider for contact lenses is then unable to use another eye care provider without incurring substantial switching costs, such as paying higher prices for eye care services or travelling a longer distance to a second eye care provider. In other words, is a consumer locked-in to a particular brand of contact lenses or are customers simply loyal²²⁸ to a certain eye care provider?

This question can partially be answered with economic theory and an understanding of consumer switching costs.²²⁹ In economic theory, switching costs exist when customers find it relatively expensive to switch from one product (and by and large, one brand) to another.²³⁰ The expense creates a

227. Erik Vollebregt & Mathias Klümper, *To Place on the Market (Or Not)?*, REGULATORYAFFAIRSMEDTECH.COM (Jan./Feb. 2011), available at <http://www.luetzeler.eu/downloads/ramjanfeb2011placingonthemarket.pdf>.

228. Similar arguments can be found in Gianmario Verona & Emanuela Prandelli, *A Dynamic Model of Customer Loyalty to Sustain Competitive Advantage on the Web*, 20 EUR. MGMT. J. 299, 299 (2002) (arguing that firms “who compete successfully on the Web do so by basing their strategies both on affiliation and lock-in” (internal citation omitted)); Gal Zauberaman, *The Intertemporal Dynamics of Consumer Lock-In*, 30 J. CONSUMER RES. 405, 405 (2003) (“Customer loyalty is a complex aspect of consumer behavior that has been studied from multiple perspectives.”).

229. See, e.g., Paul Klempere, *Price Wars Caused by Switching Costs*, 56 REV. ECON. STUD. 405, 405, 415 (1989) (noting that “price wars occur quite naturally . . . if consumers have costs of switching between competing brands of a product,” and later concluding that “[a] price war could also be caused by the entry of new consumers who are not yet committed to any particular firm, as firms cut prices to attract them”).

230. There is a wide array of literature on switching costs (until recently, most of which related to the technology sector). However, for the purposes of this section, the focus is on the lock-in theory as opposed to the full ramifications of switching costs, which require a substitute product. This Article focuses on the lock-in theory and how it affects consumers and brands in relation to contact lenses. For further discussion on switching costs, see, e.g., HAL R. VARIAN ET AL., *THE ECONOMICS OF INFORMATION TECHNOLOGY: AN INTRODUCTION* 21–22 (2004) (“[S]witching costs . . . can be so large that switching supplies is virtually unthinkable, a situation known as ‘lock-in When switching costs are significantly high, competition can be intense to attract new customers, since, once they are locked in, they can be a substantial source of profit.”); see also MICHAEL E. PORTER, *COMPETITIVE ADVANTAGE: CREATING AND SUSTAINING SUPERIOR PERFORMANCE* 286 (1985) (“Switching costs potentially arise from all the impacts a substitute has on the buyer’s value chain. Both the value activity in which the substitute is employed as well as other value activities it indirectly affects may require one-time costs of changeover.”); Joseph Farrell & Paul Klempere, *Coordination and Lock-In: Competition with Switching Costs and Networks Effects*, in 3 *HANDBOOK OF INDUSTRIAL ORGANIZATION* 1970, 1971 (Mark Armstrong & Robert H. Porter eds., 2007) (“Switching costs arise if a consumer wants a group, or especially a series, of his own purchases to be compatible with one another: this creates economies of scope among his purchases from a single firm.”).

lock-in²³¹ effect and the customer will be committed to buying the same product (or brand).²³² There can be various reasons for consumers to switch contact lens providers and it will be those reasons, and their cost, that determine the welfare effect of switching.²³³ The lock-in effect for contact lens wearers occurs mostly in situations where consumers have eye conditions that permit them to wear only one type of lens and are thus tied to a certain brand of contact lenses.

Depending on a consumer's frugality, shopping online for the lowest price requires skill and determination. Some consumers shopping for contact lenses on the Internet will scout a number of online providers for contact lenses seeking a lower price for the same prescription regardless of brand or manufacturer. This latter category forms the free switcher wearers of contact lenses, as they both free ride on the services of other providers of contact lenses and are flexible in switching from one brand to another brand of contact lenses. The free riding occurs when the consumer uses the prescription and price information from one eye care provider to seek the contact lenses at a lower price from another, even where the consumer was recommended to purchase the contact lenses from the online operations of the brick-and-mortar eye care provider. But the issue of free riding is not to be blamed squarely on the consumers. The distributors and retailers must shoulder some of the blame for any free riding that occurs. If retailers raise prices for contact lenses, a competitor is likely to benefit, since the consumer will easily turn to the competitor.²³⁴ The higher prices of contact lenses will depend on various factors which are the causes for switching, such as location, demand, and their marketing techniques.

Patients with severe eye conditions are only locked in to wearing contact lenses when they reduce blurry vision more accurately than their eyeglass

231. Because the lock-in theory is closely connected to the switching cost theory, the relationship is explained by the following statement: "When the costs of switching from one brand of technology to another are substantial, users face lock-in." CARL SHAPIRO & HAL VARIAN, *INFORMATION RULES: A STRATEGIC GUIDE TO THE NETWORK ECONOMY* 104 (1999); see also Nancy Gallini & Larry Karp, *Sales and Consumer Lock-in*, 56 *ECONOMICA* 279, 279 ("[S]ales are a mechanism by which a monopolist can increase her customer base—the stock of future captive customers of the product.").

232. See Verona & Prandelli, *supra* note 228, at 300 ("Lock-in means customers are constrained by past choices, and when they switch from one brand of technology, product[,], or website to another, they incur costs. Companies can exploit this phenomenon and 'lock them in,' increasing customer stickiness and customer loyalty. Lock-in strategies strengthen the behavioral dimension of loyalty, encouraging repeat purchasing.").

233. See OZ SHY, *THE ECONOMICS OF NETWORK INDUSTRIES* 5 (2001) ("Switching costs affect price competition in two opposing ways. First, if consumers are already locked-in using a specific product, firms may raise prices knowing that consumers will not switch unless the price difference exceeds the switching cost to a competing brand. Second, if consumers are not locked in, brand-producing firms will compete intensively by offering discounts and free complimentary products and services in order to attract consumers who later on will be locked in.").

234. See Vincent Verouden, *Vertical Agreements: Motivation and Impact*, in 3 *ABA SECTION OF ANTITRUST LAW, ISSUES IN COMPETITION LAW AND POLICY* 1813, 1820 (Wayne Dale Collins et al. eds., 2008) ("Whenever distributors raise the price at which they sell, they confer benefits on competing distributors of the product, as more consumers will turn to these other distributors. An individual distributor will normally not take this externality into account and hence set prices lower than would be optimal for the distribution level.").

substitutes.²³⁵ Furthermore, eyeglasses are less desirable in a number of situations. Customers may also be locked-in to a particular brand due to location, price differences, and loyalty, or because that brand is the label of their eye care provider. This investigation uncovered that the sales of contact lenses is increasing globally, which suggests that their popularity has increased and therefore implies that lenses have a greater ability to reduce blurry vision and their popularity may have exacerbated the lock-in effect.²³⁶ For some consumers, wearing contact lenses is a long-term necessary undertaking, due to the nature of their eye condition. For example, when an individual has (-6) in one eye and (-2) in the second eye, regular prescription glasses can send conflicting messages to the brain.²³⁷ Therefore, customers that are loyal to one eye care provider are unlikely to switch to another unless the benefits of switching outweigh the loyalty to their present eye care provider. One of the negative effects of the lock-in effect is consumers are locked in to a monopolistically high price from their eye care provider. This theory however, does not appear to stand firm in the market for contact lenses, as eye care providers prefer to refer their customers to their online website after they have been fitted in the store, where the website order will be cheaper.²³⁸ In addition, eye care providers compete intensely²³⁹ with other online sellers of contact lenses, and thus, the price of contact lenses is decreasing. This benefits the consumers, regardless of lock-in.

2. *Private Labeling of Contact Lenses*

The private labeling of contact lenses is a thriving business in a number of markets such as the UK, Finland (Instrumentarium iWear), and others.²⁴⁰ The legal question is: based on the Medical Devices Directive, who is the legal manufacturer of these private label contact lenses? The European Commission has provided some guidance to this question. According to the Commission, the “economic operator, the own brand labeler, meets the definition of

235. See, e.g., Contact Lens Mfr. Ass’n, *Wouldn’t You Rather Wear Contacts than Glasses?*, GPCONTACTLENSES, <http://www.contactlenses.org/clsglasses.htm> (last updated Sept. 2009) (comparing the utility of contact lenses to glasses).

236. See Robert J. Dolan & Youngme Moon, *Pricing and Market Making on the Internet*, 14 J. INTERACTIVE MARKETING 56, 60 (“Sometimes lock-in occurs simply as a result of familiarity with a particular Website.”).

237. See *Eyeglasses: Frequently Asked Questions*, ALL ABOUT VISION, <http://www.allaboutvision.com/faq/eyeglasses.htm> (last updated Apr. 2011) (explaining that different prescriptions in each eye can cause headaches).

238. See generally Dolan & Moon, *supra* note 236, at 58 (discussing the Internet and its effect on prices).

239. See Verona & Prandelli, *supra* note 228, at 299 (describing the Internet as creating a “hypercompetitive situation” for online commerce).

240. See Case T-147/03, *Devinlec v. OHIM— T.I.M.E. Art (Quantum)*, 2006 E.C.R. II-0011 ¶ 55 (describing private label “store brands which are conceived and used exclusively by major retail chains”). See generally *Etsikö Optikon Merkkiä? [Searching for Your Optician’s (favorite) Brand?]*, LENSON, <http://www.lenson.com/fi/linsguide.php> (last visited Oct. 10, 2012); *Rebranded Contact Lenses from the High Street Opticians*, LENS SHOPPER.CO.UK, <http://lensshopper.co.uk/rebranded-contact-lenses.asp> (last visited Sept. 4, 2012); *Wir Führen Sie zu den Besten Kontaktlisen zu Discountpreisen*, KONTAKTLINSENGUIDE, <http://www.kontaktlinsenguide.de/> (last visited Sept. 12, 2012) (all examples of private labeling).

manufacturer as set out in the medical devices Directives. . . .”²⁴¹ According to the MDD (as amended),²⁴² “the natural or legal person with responsibility for the design, manufacture, packaging, and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party,”²⁴³ is considered to be the manufacturer of the device. Thus, where an eye care professional purchases a finished (or component parts of a) medical device from the original equipment manufacturer (OEM), which he then places on the market under his own name or trademark (brand label), that economic operator or private labeler for legal purposes under the MDD is a manufacturer, regardless of whether the brand labeler actually designs, manufactures, packages, or labels the device. In addition to this requirement, the Commission explains that the “own brand labeler has the regulatory responsibility as a manufacturer due to the fact that a brand is a symbolic representation of all the information connected to the product.”²⁴⁴ Thus, where an eye care provider has privately labeled contact lenses as his own, under the MDD, the eye care provider is deemed to be the manufacturer of the lenses. One of the benefits of this provision to regular consumers is, in the unlikely event they suffer damage in the wearing of a faulty private label contact lens, they can seek redress immediately in a court of law from the eye care provider without having to go through a more lengthy process up the food chain to the manufacturer of those faulty contact lenses.

One key concern in competition law analysis is whether the private label contact lens market forms a separate market from the general contact lens market. The private label contact lens market is created by manufacturers who enter into agreements to manufacture and label contacts with a desired private label, such as an eye care professional or large retailer. Therefore, for the private label contact lens market to be considered a possible violator of competition law, the “economic capacity to cause damage to other [contact lens sellers]”²⁴⁵ will have to be assessed.

241. *Interpretative Document of the Commission's Services: Interpretation of the Medical Device Directives in Relation to Medical Device Own Brand Labellers* COM (2008) final para. 4 (Feb. 4, 2008), available at http://ec.europa.eu/health/medical-devices/files/guide-stds-directives/interpretative_fiche_obl_en.pdf.

242. MDD, *supra* note 68, art. 1(2)(f). See generally AIMDD, *supra* note 68, art. 1(2)(i) (defining what it means to place something on the market); IVDMD, *supra* note 68, art. 1(2)(f) (providing a definition of manufacturer identical to the definition provided in the MDD).

243. MDD, *supra* note 68, art. 1(2)(f). The provision further states that: “The obligations of this Directive to be met by manufacturers also apply to the natural or legal person who assembles, packages, processes, fully refurbishes[,] and/or labels one or more ready-made products and/or assigns to them their intended purpose as a device with a view to their being placed on the market under his own name.” *Id.*

244. *Interpretative Document of the Commission's Services: Interpretation of the Medical Device Directives in Relation to Medical Device Own Brand Labellers*, *supra* note 241, para. 5. “It serves to create associations and expectations around it, and it is the most reliable visible evidence of who has regulatory responsibility from the time where the products are sold until their end-of-life. Furthermore, in some instances, it is not easy to identify the actual assembler or the original equipment manufacturer. Therefore, from a consumer and patient safety perspective, own brand labellers should bear the regulatory responsibility of a manufacturer.” *Id.*

245. Case T-48/02, *Brouwerij Haacht v. Comm'n*, 2005 E.C.R. II-5259 ¶ 67; see also Case T-38/02, *Groupe Danone v. Comm'n*, 2005 E.C.R. II-4407 ¶ 472 (discussing a “private label beer cartel”); Case T-

TABLE 4: The Leading Sellers of Contact Lenses in the UK: Private Labels Compared to Their Manufacturers' Labels²⁴⁶

Manufacturer	Manufacturer Brand	Product Type	Eye Care Provider	Private Label
CibaVision	Focus Dailies	Daily Lens	Boots	Boots Daily Disposable (Diam. 13.8)
Bausch & Lomb	Softlens One Day	Daily Lens	Boots	Boots Daily Disposable (Diam. 14.2)
Wesley Jessen	Precision UV	Colored Lens	Boots	Boots High Water Monthly Replacement Soft Lens
Ocular Sciences	Biomedics 55	1-2 Week Lens	Boots	Boots Mid-Water Monthly Replacement
Ocular Sciences	Biomedics 55	1-2 Week Lens	Boots	Boots Monthly
Ocular Sciences	Biomedics Toric	Toric Lens	Boots	Boots Monthly Toric
CibaVision	Focus Progressives	Daily Lens	Boots	Boots Near & Far
Ocular Sciences	Biomedics 55	1-2 Week Lens	Conlons	Conlons Mirage Monthly Disposable
CibaVision	Focus Dailies	Daily Lens	Conlons	Conlons Mirage Dailies
Bausch & Lomb	Softlens One Day	Daily Lens	Dolland & Aitchison	Dolland & Aitchison Daily Disposable (Diam. 14.2)
CooperVision	Frequency 55	Monthly Lens	Dolland & Aitchison	Dolland & Aitchison Freshview 58UV
Ocular Sciences	Biomedics 55	1-2 Week Lens	Dolland & Aitchison	Dolland & Aitchison 55UV
Bausch & Lomb	Softlens Toric	Toric Lens	Dolland & Aitchison	Dolland & Aitchison SL 66 Toric
Ocular Sciences	Biomedics 55	1-2 Week Lens	Eye Clinic	Eye Clinic CIEL XII UV
CibaVision	Focus Dailies	Daily Lens	Eye Clinic	Eye Clinic Daily Vision (Diam. 13.8)

235/07, Bavaria NV v. Comm'n, 2011 EUR-Lex CELEX LEXIS (June 16, 2011).

246. LENS SHOPPER.CO.UK, <http://www.lensshopper.co.uk/Default.asp> (sample taken Nov. 2011). Note that Ocular Sciences was merged with CooperVision in 2005.

TABLE 4: continued

Manufacturer	Manufacturer Brand	Product Type	Eye Care Provider	Private Label
CibaVision	Focus Dailies	Daily Lens	FCUK	FCUK Daily Contact Lenses
Bausch & Lomb	Softlens One Day	Daily Lens	Specsavers	Specsavers (B&L) Encore Daily Disposable (Diam. 14.2)
CibaVision	Focus Toric	Toric Lens	Specsavers	Specsavers (Ciba) Monthly Toric
CooperVision	Frequency Xcel Toric	Toric Lens	Specsavers	Specsavers (Easyvision) Standard Monthly Toric
CibaVision	Focus Dailies	Daily Lens	Specsavers	Specsavers 1 Day, Easy Vision (diam. 13.8)
CooperVision	Frequency 55	Monthly Lens	Specsavers	Specsavers D55
Ocular Sciences	Biomedics 55	1-2 Week Lens	Specsavers	Specsavers Disposable Lenses 55DW
CibaVision	AirOptic Night & Day	Monthly Lens	Specsavers	Specsavers Easyvision All Day – All Night
CooperVision	Proclear	Daily Lens	Specsavers	Specsavers Easyvision All Day (Biocompatibles)
CooperVision	Frequency 55 Aspheric	Monthly Lens	Specsavers	Specsavers Easyvision Aspheric Daily Wear
CooperVision	Expression Colors	Colored Lens	Specsavers	Specsavers Easyvision Colors
Ocular Sciences	Biomedics 55	1-2 Week Lens	Specsavers	Specsavers Easyvision Monthly
Bausch & Lomb	Softlens One Day	Daily Lens	Specsavers	Specsavers Easyvision One Day (B&L)
CibaVision	Focus Toric	Toric Lens	Specsavers	Specsavers Easyvision Toric Lens
CibaVision	Focus Dailies	Daily Lens	Specsavers	Specsavers Encore
CooperVision	Frequency 55	Monthly Lens	Specsavers	Specsavers Frequently Disposable 58UV

TABLE 4: continued

Manufacturer	Manufacturer Brand	Product Type	Eye Care Provider	Private Label
CooperVision	Frequency 55	Monthly Lens	Specsavers	Specsavers Monthly Disposable 55
CooperVision	Frequency 55	Monthly Lens	Specsavers	Specsavers Standard Lens All Day
CibaVision	Focus Progressives	Daily Lens	Specsavers	Specsavers Varifocal Lens
CooperVision	Biofinity	Monthly Lens	Specsavers	Specsavers Easyvision Elite All Day – All Night
Bausch & Lomb	Softlens One Day	Daily Lens	Vision Express	Vision Express Daily (VE Daily) (Diam. 14.2)
CooperVision	Frequency 55 Aspheric	Monthly Lens	Vision Express	Vision Express Enhance A
CooperVision	Frequency Xcel Toric	Toric Lens	Vision Express	Vision Express Enhance H & V

Based on the private labeling of popular contact lenses by the major manufacturers, those same lenses are available from most UK high street eye care providers under a different name.²⁴⁷ Based on this form of private labeling, it is possible that customers may be locked-in to their eye care provider, and some customers simply return to their eye care provider for their *brand* of contact lenses, as it is not available *anywhere* else. But there is also a rational business decision for private labeling of contact lenses. According to Gregory Fryling, CooperVision’s COO, its private label programs “are usually sold at lower prices than the branded product.”²⁴⁸ Thus, it is possible that private label contact lenses are sold more often and hence generate more cash.

C. The Sale of Contact Lenses

1. Previous (Empirical) Studies on the Sale of Contact Lenses

In 2005–2006, the U.S. Federal Trade Commission made public the contents of a study on the sale of prescription contact lenses in the United States.²⁴⁹ The FTC Prescription Study occurred in the wake of the Fairness to

247. See *Rebranded Contact Lenses from the High Street Opticians*, *supra* note 240 (stating that it is common for high street opticians to rebrand well-known brands from top manufacturers).

248. *Congressional Hearing*, *supra* note 44, at 55; see also *id.* at 57 (“If a manufacturer tries to sell a lens under a private label to a discount chain—a common industry practice that lowers prices to consumers—other potential distributors can also claim ‘discrimination.’”).

249. See generally FTC, RX STUDY, *supra* note 28.

Contact Lens Consumers Act (FCLCA²⁵⁰) that was passed in 2003, and concluded, among other things, that “state laws and regulations have the potential to limit competition in contact lenses, which may raise consumer costs.”²⁵¹ The FTC Prescription Study also concluded that “[s]ome manufacturers . . . limit the distribution channels through which they sell their contact lenses” and that available information “[did] not support the hypothesis that sellers are able to limit competition or harm consumers by charging higher prices for limited distribution of private label lenses.”²⁵² These conclusions of the FTC Prescription Study, I believe, do not paint the overall picture of potential harm to consumers via contact lens antitrust violations. The potential harm to consumers and antitrust violations regarding the sale of contact lenses can vary, however. In the rest of this Article, I will examine two areas that may cause harm—pricing and vertical restraints. I will also question whether the dominance gained (if any) by contact lens manufacturers is likely to be abused.

Immediately after the FTC Prescription Study, the FTC Bureau of Economics conducted an empirical study in 2006 on the prices for contact lenses both online and offline, which showed that if consumers shopped for lenses online, they were more likely to “save substantially.”²⁵³ The FTC empirical study argued that one of the contributing factors to “online dispersion is that although price comparisons for contact lenses are easier online than offline, they are not costless,”²⁵⁴ and consumers are likely to save, on average, “approximately 25[%] by purchasing contact lenses online.”²⁵⁵

The findings in the FTC empirical study are not necessarily alarming, as most studies of online price dispersion²⁵⁶ are easily reproduced and supported.²⁵⁷ The conclusion on the reduction in cost of contact lenses in the

250. Fairness to Contact Lens Consumers Act, Pub. L. No. 108-164, 117 Stat. 2024 (2003).

251. FTC, RX STUDY, *supra* note 28, at 60. The FCLCA requires the FTC to “undertake a study to examine the strength of competition in the sale of prescription contact lenses.” Fairness to Contact Lens Consumers Act, § 10(a). In particular, the FTC was to examine the following: “(1) Incidence of exclusive relationships between prescribers or sellers and contact lens manufacturers and the impact of such relationships on competition[;] (2) [d]ifference between online and offline sellers of contact lenses, including price, access, and availability[;] (3) [i]ncidence, if any, of contact lens prescriptions that specify brand name or custom labeled contact lenses, the reasons for the incidence, and the effect on consumers and competition[;] (4) [t]he impact of the Federal Trade Commission eyeglasses rule (16 C.F.R. 456 et seq.) on competition, the nature of the enforcement of the rule, and how such enforcement has impacted competition[;] (5) [a]ny other issue that has an impact on competition in the sale of prescription contact lenses.” *Id.* § 10(a)(1)–(5).

252. FTC, RX STUDY, *supra* note 28, at 3.

253. James C. Cooper, *Prices and Price Dispersion in Online and Offline Markets for Contact Lenses 3* (Fed. Trade Comm’n, Working Paper No. 283, 2006), available at <http://www.ftc.gov/be/workpapers/wp283.pdf>.

254. *Id.* at 22.

255. *Id.* at 33.

256. In economic theory, price dispersion occurs when different sellers offer different prices for the same good in a given market. See Michael R. Baye, et al., *Persistent Price Dispersion in Online Markets*, in *THE NEW ECONOMY AND BEYOND: PAST, PRESENT AND FUTURE*, 122, 122–43 (Dennis W. Jansen ed., 2006), available at <http://faculty.haas.berkeley.edu/rjmorgan/ppd.pdf> (explaining price dispersion).

257. See generally *id.* at 122–43 (discussing “the persistence of price dispersion in a well-established online retail market”); Eric K. Clemons et al., *Price Dispersion and Differentiation in Online Travel: An Empirical Investigation*, 48 *MGMT. SCI.* 534, 534 (2002) (analyzing online price dispersion in travel fares); Stephen McDonald & Colin Wren, *Price Dispersion and the Ability to Search: The UK Internet Motor*

FTC empirical study echoes a similar conclusion reached in a 1984 study on the structure and competition in the contact lens industry by the Office of Technology Assessment (OTA).²⁵⁸ At present, most traditional brick-and-mortar eye care professionals, in particular those that operate large chains, have also set up online shops for contact lenses, where patients are redirected to purchase prescription contact lenses that are often 10% cheaper than the price in one of the brick-and-mortar shops.²⁵⁹ This practice has driven a number of customers to the online shops and thus they are also able to compare the prices of rival sellers (whom they may or may not purchase from). Prior to the FCLCA, eye care professionals in the United States were required to provide a patient a copy of his or her eyeglass prescription free of cost under the Ophthalmic Practice Rules (the Eyeglass Rule), but did not require an eye care professional to release a contact lens prescription to a patient after an eye exam.²⁶⁰ However, this was revised under the FCLCA, which essentially guarantees consumers the right to buy their contact lenses from any vendor.²⁶¹

2. *Sample of Online Prices for Contact Lenses in the Eurozone*

In the European Union, several channels such as optical chains, merchants, Internet firms, optometrists, and eye care practitioners handle distribution. There are no accurate statistics available describing how manufacturers distribute their contact lenses. However, one is inclined to think that the bulk of contact lenses distributed by manufacturers go through long-standing eye care professionals and other large commercial entities such as Boots in the UK.²⁶²

In TABLE 5, I will track and compare the prices for a box of daily contact lenses (disposable) in these markets provided only by online sellers (though

Insurance Market (Newcastle Bus. Sch., Working Paper No. 7, 2009), available at <http://www.ncl.ac.uk/nubs/assets/documents/workingpapers/economics/WP07-2009.pdf> (analyzing online price dispersion in the UK online automobile insurance market). On the other hand, some suggest that contact lenses purchased over the Internet pose a high risk of harming eyes. Joshua Fogel & Chaya Zidile, *Contact Lenses Purchased over the Internet Place Individuals Potentially at Risk for Harmful Eye Care Practices*, 79 OPTOMETRY 23, 23 (2008), available at <http://www.aoa.org/documents/optm-447-Fogel.pdf>.

258. OFFICE OF TECH. ASSESSMENT, OTA-HCS-31, THE CONTACT LENS INDUSTRY: STRUCTURE, COMPETITION, AND PUBLIC POLICY 4 (1984) [hereinafter OTA STUDY] (“The absolute price of contact lenses of all types has fallen significantly in the past decade Lens price reductions have resulted from large-scale entry, excess capacity, and vigorous price competition among manufacturers Total-fitting price reductions reflect these cuts in lens prices and the expanded competition among lens fitters, particularly the large chain optical houses. Continued price competition is likely, and further price declines, if less dramatic, may occur in the future.”).

259. Robert D. Atkinson, President, Info. Tech. and Innovation Found., Comments in Response to Public Versus Private Restraints on the Online Distribution of Contact Lenses: A Distinction Without a Difference 2 (July 10, 2006), available at <http://www.itif.org/files/contactlens.pdf>. See generally James C. Cooper, Public Versus Private Restraints on the Online Distribution of Contact Lenses: A Distinction with a Difference, 3 J.L. ECON & POL’Y 331 (2007).

260. FTC Ophthalmic Practice Rules (Eyeglass Rule), 16 C.F.R. § 456.2 (2012).

261. Fairness to Contact Lens Consumers Act, Pub. L. No. 108-164, 1117 Stat. 2024 (2003) (codified at 15 U.S.C. §§ 1601–10 (2006)).

262. See FTC, RX STUDY, *supra* note 28, at 12 (“Manufacturers distribute the largest share of lenses through independent [eye care professionals] and the smallest through the online/mail order channel.”).

some offline sellers²⁶³ with only brick-and-mortar operations were canvassed, they were not willing to discuss business strategies). I will use a popular brand, Focus Dailies, with the price comparison taken from LensShopper and its various national sites. Note that the LensShopper site operates in various countries, e.g., lensshopper.co.uk in Great Britain and lensshopper.nl in the Netherlands. In other markets, LensShopper operates the site using a different name, such as alltomlinser.se in Sweden.²⁶⁴ The prices below are the minimum offer for a box (30 pieces) of Focus Dailies single-use contact lenses by CibaVision.

TABLE 5: Online Prices for Contact Lenses in Selected Markets by Online Sellers Only²⁶⁵

Country	Online Vendor	Price	Total Euro
Sweden	Lensme.eu	SEK 123	13.27
Finland	Lensstore.fi	EUR 14.50	14.50
Norway	Nordiclenses.com	NOK 132	16.81
Great Britain	Lenscatalogue.co.uk	GBP 18.95	22.00
Germany	Misterspex.de	EUR 17.90	17.90
Netherlands	Lensway.nl	EUR 14.04	14.04

TABLE 5 took prices for a box containing thirty disposable single-use Focus Dailies contact lenses from sites that operate with the country's namesake domain. It should be noted that the price comparison website also includes information from other sites outside of the target country. Even though the sites from outside the target country often advertise lower prices, the site operating within the country (and having a registered address there) was used for sampling purposes, provided that site actually offered the

263. When I compared the offline and online prices for a three pack AirOptix Aqua Night and Day Monthly in Finland, Slovakia, and the Netherlands from three leading eye care professionals, only the Finnish eye care professional had both the online and offline prices. The same pack in November 2011, from the Finnish eye care provider, was offered offline for €40, while the online price was €39. In Slovakia, the offline price was €29.90, while in the Netherlands, the offline price was €41.25. The eye care providers in the Netherlands and Slovakia did not offer contact lenses online. In Finland, if a patient were to walk into the same store and have an eye examination, they would have the option to buy the lenses in store or on the store's website. These three countries were selected based on GDP, geographic location in the Eurozone, and average spending power of a consumer—also known as purchasing power parity. The purchasing power parity takes into account the relative cost of living and the inflation rates of different countries, rather than just being a nominal gross domestic product (GDP) comparison. *See, e.g.,* BARBARA KURKOWIAK, EUROSTAT, PRICE LEVELS FOR FOOD, BEVERAGES AND TOBACCO ACROSS EUROPEAN MARKET DIFFER SIGNIFICANTLY 1 (2010), available at http://epp.eurostat.ec.europa.eu/cache/ITY_OFFPUB/KS-SF-10-030/EN/KS-SF-10-030-EN.PDF.

264. *E.g.,* KONTAKTLINSENGUIDE, www.kontaktlinsenguide.de (last visited Sept. 4, 2012) (LensShopper's German version); NETTILINSSIT, www.nettilinssit.fi (last visited Sept. 4, 2012) (LensShopper's Finnish version). *Cf.* LENSPPRICES, <http://www.lensprices.co.uk> (last visited Sept. 4, 2012) (another international company offering contact lenses for sale online).

265. This data was collected on November 24, 2011. *See generally* XE: THE WORLD'S FAVORITE CURRENCY SITE, <http://www.xe.com/> (last visited Nov. 24, 2011). There were other countries and information listed by LensShopper, however, the websites listed registered addresses that did not correspond to the country's website address.

cheapest lenses.

The online vendor Netlens operates in five key European markets: Finland, Sweden, Denmark, Norway, and Great Britain. The company has its headquarters in Stockholm and purports to offer customers savings of “up to 70%” on contact lenses, over a local optician.²⁶⁶ In the following price comparison table, I will track a popular brand of monthly contact lenses—Bausch & Lomb Pure Vision Toric (six pack)—in the different markets in which Netlens operates.

TABLE 6: Prices for Purevision Toric Lenses Offered by a Single Online Vendor in Five Markets (Netlens)²⁶⁷

Country	Brand	Price	Total Euro
Great Britain	Purevision Toric (6pack)	£38.40	€44.60
Sweden	Purevision Toric (6pack)	419.00 kr	€45.22
Denmark	Purevision Toric (6pack)	352.00 kr	€47.34
Norway	Purevision Toric (6pack)	398.00 kr	€50.72
Finland	Purevision Toric (6pack)	€47.00	€47.00

3. Market Dominance and Contact Lens Raw Material

When I analyzed the data published by the contact lens industry, I found that raw material could create a concern for market dominance. Most contact lenses nowadays are produced from materials such as silicone hydrogel.²⁶⁸ According to Euromcontact, in 2009, more than 50% of contact lenses sold in the weekly, bi-weekly, and monthly segment by Euromcontact members were made from silicone hydrogel.²⁶⁹ This Article is particularly concerned with this ratio. Is a 50% share in raw material by Euromcontact members an indicator of market dominance? The data did not reveal if this raw material was the best available for making contact lenses, and furthermore, the data did not reveal any form of standardization (which would be a separate antitrust inquiry). Given the fact that Euromcontact is a representative association of contact lens

266. *About Us*, NETLENS, <http://www.netlens.co.uk/about-netlens.php> (last visited Sept. 4, 2012).

267. Note that on November 24, 2011, the Swedish site of Netlens was offering a discount of SEK 106, down from SEK 525.

268. Philip B. Morgan et al., *International Contact Lens Prescribing in 2010*, CONTACT LENS SPECTRUM (Jan. 1, 2011), <http://www.clspectrum.com/articleviewer.aspx?articleid=105084>. See generally *Silicone Hydrogels – What Are They and How Should They Be Used in Everyday Practice?*, 218 OPTICIAN 31 (1999), available at http://www.siliconehydrogels.org/pdf_old/SiliconeHydrogels_11_99.pdf (describing the use of silicone hydrogels in modern contact lenses).

269. EUROMCONTACT 2009, *supra* note 194, at 2.

manufacturers, the answer is a straightforward “no,” since no single manufacturer is responsible for 50% of the market.²⁷⁰ But there is another issue to consider when assessing market dominance: whether there is a sufficient link among firms “to adopt the same line of action on the market.”²⁷¹ According to *Atlantic Container*, it is “necessary to examine the links or factors of economic correlation between the undertakings concerned to ascertain whether those links or factors allow them to act together independently of their competitors, their customers[,] and consumers.”²⁷² The raw material for contact lenses may well be created by contact lens manufacturers or other entities that are economically linked to those manufacturers.

TABLE 7: Share of Silicone Hydrogel (Raw Material) Lenses in the W/B&M²⁷³ Segment in 2009 in Selected Markets in the EU

EU Country/Region	2009 Percentage
Nordic (FI, NO, SE, DK)	71.35
United Kingdom & Ireland	71.01
Austria	63.74
Germany	59.14
Belgium & Luxembourg	54.12

The above data was taken from countries that accounted for 50% or more of the raw material based on Euromcontact data.²⁷⁴ The overall data was collected from eight contributing companies listed by Euromcontact: AMO, Avizor, CibaVision, Johnson & Johnson Vision Care, Alcon, Bausch & Lomb, CooperVision, and Menicon Europe. Major markets such as France, the Netherlands, Italy, and Spain all fell below the 50% mark for lenses made from silicone-hydrogel.²⁷⁵

a. The Relevant (Product) Market

Assessing dominance under European legislation falls within the ambit of

270. *See id.* at 6 (listing the numerous companies that manufacture contact lenses in Europe). In *Commercial Solvents*, the court held that a raw material constituted a product market of its own; however, in that case, the market for that raw material was controlled by a single firm. Joined Cases 6 & 7/73, *Instituto Chemioterapico Itaiano SpA & Commercial Solvents Corp. v. Comm’n*, 1974 E.C.R. 267; *see also* Case T-201/04, *Microsoft v. Comm’n*, 2007 E.C.R. II-3601 para. 335 (finding that intellectual property rights “input” was seen as a potential market).

271. Case T-191/98, *Atlantic Container Line v. Comm’n*, 2003 E.C.R. II-3275 ¶ 595.

272. *Id.*

273. Denotes Weekly, Bi-Weekly, and Monthly Lenses.

274. EUROMCONTACT 2009, *supra* note 194, at 2. Note also that the Euromcontact website lists only three suppliers of contact lenses materials, namely, Bausch & Lomb (UK) Ltd, Contamac Ltd., and Vista Optics Ltd. *Information for Consumers*, EUROMCONTACT, <http://www.euromcontact.org/consumer.htm> (last visited Sept. 13, 2012).

275. Euromcontact commented that, “[o]ver the past years, daily disposables and silicone-hydrogel lenses were important drivers for the contact lenses market.” EUROMCONTACT 2009, *supra* note 194, at 4.

Article 102 of the TFEU.²⁷⁶ Under this provision, the criteria for assessing dominance depends on the relevant product market and the relevant geographic market.²⁷⁷ The scope of this Article covers the former, the relevant product market. In hindsight, the relevant market should not be difficult to define or assume, as the relevant market is the direct sales of contact lenses to consumers (in the European Union—the geographic scope). However, the concept of “relevant market” is a legal concept and should always be applied based on its legal definition.²⁷⁸ The starting point is the *Commission Notice on the Definition of Relevant Market*,²⁷⁹ which sets out the definition of “relevant product market” and “relevant geographic markets.”²⁸⁰ According to this piece of legislation, “a relevant product market comprises all those products and/or services which are regarded as interchangeable or substitutable by the consumer, by reason of the products’ characteristics, their prices and their intended use.”²⁸¹ In addition, the Commission’s *Notice on the Definition of Relevant Market* states that “the main purpose of market definition is to identify in a systematic way the competitive constraints that the undertakings involved face.”²⁸² In order to determine how undertakings behave in the market, the factors that can best demonstrate the competitive process need to be taken into consideration, and the Commission only reinforced this reasoning when it said that market definition must “identify in a systematic way” the competitive constraints.²⁸³ The rationale is that competition is a phenomenon that occurs in the market and the market can vary. In *France Télécom*,²⁸⁴ for example, the CJEU said that the concept of relevant market implies that there can be “effective competition between the products which form part of it”²⁸⁵ and that “a dominant position exists where the undertaking concerned is in a

276. TFEU, *supra* note 1, at 89.

277. *See id.* (defining and prohibiting abuse of a dominant position within an internal market).

278. The legal definition of relevant market was first discussed in *Continental Can*, where the court said that “the definition of the relevant market is of essential significance, for the possibilities of competition can only be judged in relation to those characteristics of the products in question by virtue of which those products are particularly apt to satisfy an inelastic need and are only to a limited extent interchangeable with other products.” Case 6/72, *Europemballage Corp. & Cont’l Can Co., Inc. v. Comm’n of the European Cmtys*, 1973 E.C.R. 247 para. 32.

279. *Commission Notice on the Definition of Relevant Market for the Purposes of Community Competition Law*, COM (1997) O.J. (C 372/5) final (Dec. 9, 1997) [hereinafter *Notice on Relevant Market*]. The purpose of the notice “is to provide guidance as to how the Commission applies the concept of relevant product and geographic market in its ongoing enforcement of Community completion law . . .” *Id.* at 5 para. 1.

280. *Id.* at 5–6 para. 7–8.

281. *Id.* at 5–6 para. 7. Similarly, relevant geographic markets are defined as markets that comprise “the area in which the undertakings concerned are involved in the supply and demand of products or services, in which the conditions of competition are sufficiently homogenous and which can be distinguished from neighboring areas because the conditions of competition are appreciably different in those area [sic].” *Id.* at 6 para. 8.

282. *Id.* at 5 para. 2 (“The objective of defining a market in both its product and geographic dimension is to identify those actual competitors of the undertakings involved that are capable of constraining those undertakings’ behaviour and of preventing them from behaving independently of effective competitive pressure.”).

283. *Id.*

284. Case T-340/03, *France Télécom SA v. Comm’n of the European Cmtys.*, 2007 E.C.R. II-117.

285. *Id.* at 142 para. 80.

position of economic strength which enables it to prevent effective competition being maintained on the relevant market by giving it the power to behave to an appreciable extent independently of its competitors”²⁸⁶ The Notice is only one step in interpreting what “dominance” means and how a firm with a dominant position may abuse its position. The case law only confirms that a firm which is in a dominant position can abuse that position in the product market.

b. Market Share

Similarly, under the Notice, another criteria for assessing whether a firm has abused its dominant position is market share. According to the *Relevant Market Notice*, “market shares for each supplier can be calculated on the basis of their sales of the relevant products in the relevant area.”²⁸⁷ This does not mean sales figures represent the best method of calculating market shares, but they offer a good position of the firm in relation to its competitors. There are two potential problems with sales figures. Where a (unlisted) firm believes that it has command over the relevant product market, it is possible that sales figures released publicly do not represent the true picture. This strategy is advantageous because it staves off competition authorities from initiating investigations and keeps potential competitors in the dark. The sales figures for contact lenses used in this Article are mostly those of trade associations representing contact lens manufacturers. Trade associations have been identified by the *Relevant Market Notice* as one source for gathering data on sales.²⁸⁸ The borderline range for a presumption of dominance is a 50% market share; therefore the minimum market share which a firm can attain in order to avoid the enforcement of Article 102 is below that threshold.²⁸⁹

c. Abuse of a Dominant Position

The overarching concern regarding abuse of a dominant position is

286. *Id.* at 148 para. 99.

287. *Notice on Relevant Market*, *supra* note 279, at 12 para. 53. The Commission also addressed what can be deemed as significant market power (SMP), which it defines as an attribute of an undertaking in which “either individually or jointly with others, it enjoys a position equivalent to dominance, that is to say a position of economic strength affording it the power to behave to an appreciable extent independently of competitors customers [sic] and ultimately consumers.” *Commission Guidelines on Market Analysis and the Assessment of Significant Market Power Under the Community Regulatory Framework for Electronic Communications Networks and Services*, at 14–15 para. 70, COM (2002) O.J. (C 165/03) final (July 11, 2002).

288. *Notice on Relevant Market*, *supra* note 279, at 12 para. 53.

289. The CJEU has found in other cases a lower threshold of 39.7%. *See* Case T-219/99, *British Airways v. Comm’n*, 2003 E.C.R. II-5925. “Indeed, BA’s market share fell from 47.7% at the beginning of the 1990s to 39.7%.” *Id.* at 5972. “BA’s objections to the relevance of the product market adopted by the Commission, based on the possible marginalisation of the distribution of airline tickets through the intermediary of travel agents, on the exclusive specialisation of airlines by geographical destinations, and on the independent behaviour of an airline in a monopoly situation on certain routes, therefore have no bearing.” *Id.* at 5954; *see also* ALISON JONES & BRENDA SUFRIN, *EU COMPETITION LAW: TEXT, CASES, AND MATERIALS* 329 (4th ed. 2011) (“[T]he fact there is a presumption of dominance at a 50% market share is a striking and important feature of EU competition law.”).

whether there are anticompetitive foreclosure situations such as the exclusion of competitors or harm to consumers.²⁹⁰ The evidence in this Article does not suggest that either of those elements of anticompetitive foreclosure is present in the market for contact lenses in Europe. Regarding whether competitors are excluded, the data suggests that there are more players in the market for contact lenses, particularly online, which in turn drives a healthy, competitive European market. One factor that favors the manufacturers is the medical nature of the device and therefore arguments about the exclusion of competitors are hard to make, since healthcare regulations also demand a certain level of safety to protect consumers. In this instance, only those manufacturers that are regulated would meet those requirements. The combination of competition law and healthcare regulation exclude manufacturers of contact lenses from the anticompetitive foreclosure argument, given the oddities of healthcare regulation. The second strand of argument on anticompetitive foreclosure pertains to harm to consumers. Again the evidence in this Article suggests that consumers should benefit from the vast array of contact lenses that are available on the market and in particular, private label contact lenses. Any argument that there is dominant position abuse would have to focus on other conduct under TFEU Article 102.²⁹¹ But for the time being, the Commission is focusing on anticompetitive foreclosure,²⁹² and it still remains that a firm which holds a dominant position must not allow its conduct to impair competition in the internal market.²⁹³

D. Vertical Restraints and the Market for Contact Lenses

Based on the data gathered in this Article, one major concern is vertical relations among or agreements between manufacturers of contact lenses and their distributors. A vertical agreement is defined as “an agreement or concerted practice entered into between two or more undertakings each of which operates, for the purposes of the agreement or the concerted practice, at a different level of the production or distribution chain, and relating to the conditions under which the parties may purchase, sell or resell certain goods or services.”²⁹⁴ Under Article 101(1) of the TFEU, agreements that restrict or distort competition in the EU are prohibited.²⁹⁵ However, if certain agreements

290. Joined Cases C-468/06–C-478/06, *Sot Lelos kai Sia & Others*, 2008 E.C.R. I-7139 ¶ 68.

291. The list in Article 102 TFEU is not exhaustive: “the list of abusive practices contained in that provision does not exhaust the methods of abusing a dominant position.” Case C-52/09, *Konkurrensverket v. TeliaSonera Sverige AB*, 2011 E.C.R. I-00527 ¶ 26.

292. *Communication from the Commission—Guidance on the Commission’s Enforcement Priorities in Applying Article 82 of the EC Treaty [now Article 102 TFEU] to Abusive Exclusionary Conduct by Dominant Undertakings*, 2009 O.J. (C 45/7) 2009 1–2.

293. See, e.g., Case C-202/07, *France Telecom v. Comm’n*, 2009 E.C.R. I-2369 ¶ 105.

294. Commission Regulation 330/2010, 2010 O.J. (L 102) 1, 3 (EU). For a review, see, Gianni De Stefano, *The New EU Vertical Restraints Regulation: Navigating the Vast Seas Beyond Safe Harbours and Hardcore Restrictions*, 12 EUR. COMPETITION L. REV. 487 (2010); Verouden, *supra* note 234; see also P. Sean Morris, *Vertical Restraints and Parallel Trade: Selective Distribution and Article 101 of the Treaty on the Functioning of the European Union in Light of the Revised Rules on Vertical Agreements*, 32 U. LA VERNE L. REV. 185 (2011) (providing further review).

295. TFEU, *supra* note 1, at 88.

can demonstrate that the long-term benefits outweigh the anticompetitive effects, Article 101(3) provides for an exemption of those agreements from the application of the competition rules.²⁹⁶ There are also additional safe havens for some agreements, provided that those agreements meet the requirements set out in block exemption regulations.²⁹⁷ There is no specific block exemption for medical devices and by extension, contact lenses, and therefore, it is a question of whether anticompetitive effects can be detected in the vertical relationship of contact lens manufacturers during production, distribution, and the sale of contact lenses. This is simply a matter of case-by-case analysis, given that other sectors such as agriculture and air transport have safe havens.²⁹⁸

Within the contours of vertical relations and the agreements surrounding them, is the possibility to violate competition law by such means as resale price maintenance and exclusive dealing within the contact lens industry. The manufacturers of contact lenses, contact lens resellers, and eye care professionals generally enter into agreements whereas resellers and eye care professionals can market their own lenses under a private label.²⁹⁹ However, the danger and possible harm created by this relationship is that such agreements may contain vertical restrictions, such as resale price maintenance (RPM). It is now famous that, per *Leegin*, vertical price fixing is no longer a per se violation of antitrust law.³⁰⁰ The *Leegin* decision overturned the infamous *Dr. Miles*³⁰¹ rule that withstood the test of time for almost a century in American jurisprudence.³⁰² In order to trigger a competition violation with a vertical agreement, there must be a degree of market power by at least one party to the agreement, or the agreement must contribute to such market power.³⁰³

One of the reasons behind the U.S. congressional hearing on the sales of contact lenses was the claim that some manufacturers allegedly sell their “lenses exclusively to eye care professionals,” and that some retailers felt “that

296. *Id.*; see *Commission Notice, Guidelines on Vertical Restraints*, at 6, SEC (2010) 411 final (“Article 101 applies to vertical agreements that may affect trade between Member States and that prevent, restrict or distort competition (“vertical restraints”). Article 101 provides a legal framework for the assessment of vertical restraints, which takes into consideration the distinction between anti-competitive and pro-competitive effects. Article 101(1) prohibits those agreements which appreciably restrict or distort competition, while Article 101(3) exempts those agreements which confer sufficient benefits to outweigh the anti-competitive effects.” (footnotes omitted)).

297. There are a number of block exemption regulations, or safe harbors for a number of sectors. See, e.g., Commission Regulation 461/2010, 2010 O.J. (L 129) 52; Commission Regulation 772/2004, 2004 O.J. (L 123) 11 (EC). For horizontal agreements, see, Commission Regulation 1218/2010, 2010 O.J. (L 335) 43; Commission Regulation 1217/2010, 2010 O.J. (L 335) 36 (EC).

298. E.g., Council Regulation 1184/2006, 2006 O.J. (L 214) 7 (EC); Council Regulation 1234/2007, 2007 O.J. (L 299) 1 (EC); Council Regulation 487/2009, 2009 O.J. (L148) 1 (EC).

299. See *Congressional Hearing*, *supra* note 44, (discussing private labeling of contact lenses).

300. *Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 551 U.S. 877, 882 (2007).

301. *Dr. Miles Med. Co. v. John D. Park & Sons Co.*, 220 U.S. 373 (1911).

302. *Leegin*, 551 U.S. at 882.

303. See *Morris*, *supra* note 294, at 254 (“[F]or most vertical restraints, competition concerns can only arise if there is insufficient competition at one or more levels of trade, and there is a substantial degree of market power at both the supplier and buyer levels.”).

such arrangements limit competition and ultimately harm consumers.”³⁰⁴ In the hearing, the FTC stated that a “manufacturer may want its brand associated only with a certain type of retailer to maintain a reputation for quality or may require retailers to perform certain tasks to maintain a level of quality that consumers associate with the manufacturer’s brand.”³⁰⁵ A number of contact lens manufacturers enter into exclusive sales agreements with various eye care professionals or other large contact lens sales outlets to supply them with a particular brand of contact lens and often agree not to make sales efforts in other retail outlets that would be in direct competition with the contracting eye care professional or large contact lens retailer.³⁰⁶

Most professional eye care establishments are independently owned and operated and profit-driven.³⁰⁷ In order to maximize profit, eye care professionals that prescribe contact lenses may recommend lenses that are more costly to a patient in the first instance, assuming the patient will go on to buy the recommended lenses from the eye care provider.³⁰⁸ At the same time, it is also possible that eye care professionals who prescribe a certain type of lens could collude with manufacturers for a percentage of sales in a specific geographic location. In that circumstance, the danger to consumers includes price collusion and maintenance, which results in the patient paying a higher cost for contact lenses.

Because of the vertical relationship between manufacturers of contact lenses and eye care professionals, the risk of collusion may occur where agreements, implicit and explicit, are in place; for example, agreements requiring an eye care provider to carry a certain amount of lenses from a manufacturer or only a specific manufacturer’s lenses. Where such agreements are in place, they are considered a violation of the competition rules. In *Bundesverband v. Bayer*, the court sought to pave a path to show how vertical collusion can occur within the context of Article 101, as a sort of “concurrence of wills.”³⁰⁹

[T]he concept of an agreement within the meaning of Article [101(1)

304. *Congressional Hearing*, *supra* note 44, at 2. Note that the Congressional Hearing cites the FTC Prescription Study which found that “exclusive manufacturer-retail relationships pose no threat to competition nor did any harm to consumers.” *See id.* at 12 (“Because FCLCA requires eye care practitioners to release prescriptions to patients and permit sellers to fill private label prescriptions with either brand name or other private label equivalent, it appears that eye care practitioners face significant competition in the sale of these limited distribution lenses.”).

305. *Id.* at 24–25 (“[A] supplier’s unilateral decision to restrict the distribution channels in which its product is available raises antitrust concerns only if such a restraint is likely to harm competition among rival manufacturers and if this harm outweighs any pro-competitive benefits.”).

306. *See* FTC, RX STUDY, *supra* note 28, at 14 n.38 (“[I]t is fairly common for large practices to agree to sell predominantly one manufacturer’s lenses in exchange for improved wholesale pricing.” (citation omitted)).

307. *See id.* at 9 (finding that independent eye care professionals constitute 22,500 out of approximately 38,400 retail locations).

308. *See id.* at 17 n.52 (“When it comes to prescribing contact lenses, most ECPs are free to settle in their own favor, the conflict between their interests in maximizing profits, and the patient’s interest in saving money.” (citation omitted)).

309. Joined Cases C-2 & C-3/01, *Bundesverband der eV v. Bayer AG*, 2004 E.C.R. I-23 para. 18 (quoting Case T-41/96, *Bayer v. Comm’n*, 2000 E.C.R. II-3387 para. 77).

of the TFEU] “centers around the existence of a concurrence of wills between at least two parties, the form in which it is manifested being unimportant so long as it constitutes the faithful expression of the parties’ intention.”³¹⁰

It should be noted that the court painted all agreements as forms “concurrence of wills” and did not differentiate whether such agreements are horizontal or vertical. The court needs to clarify whether vertical collusion between manufacturers and retailers harms consumers. The *Guidelines on Vertical Restraints* lists such possible consequences as “increasing the wholesale prices of the product, limiting the choice of products, lowering their quality or reducing the level of product innovation.”³¹¹ But despite the positive view of the CJEU towards vertical relations collusion as per *Bayer*,³¹² the nature of contact lens sales online will make it impossible to determine collusion in vertical relations of manufacturers and retailers of contact lenses. Even if manufacturers operate a selective system for choosing retailers for contact lenses, such a selective system will not necessarily lead to vertical collusion. Similar sentiments were echoed in *Jaguar*, regarding selective distribution of luxury motor vehicles, where the CJEU said that verification of precise content when choosing a member in a selective distribution was not necessary and therefore would not facilitate “collusive behavior.”³¹³ Even if an independent eye care provider is not authorized to sell certain brands of contact lenses online, a manufacturer would not be able to place a ban on Internet sales. The CJEU took up the question of a ban on Internet sales in cosmetics and held that such a ban would violate the competition rules.³¹⁴ This judgment also echoed the ruling in *Ker-Optika*.³¹⁵

310. *Id.* at para. 97 (quoting Case T-41/96, *Bayer v. Comm’n*, 2000 E.C.R. II-3387 para. 69). The cases concerned an appeal brought by the Bundesverband der Arzneimittel-Importeure eV and the Commission against the judgment of October 26, 2000 of the then Court of First Instance (now General Court) in Case T-41/96, *Bayer v. Comm’n*, 2000 E.C.R. II-3387, *annulling* Commission Decision 96/478, 1996 O.J. (L 201) (EC). For a discussion on the case, see generally Luke W. Reynolds, Note, *ECJ in Bayer Allows Pharmaceutical Companies to Increase Profits by Breaking Down European Union Cohesion – with Just One Pill*, 28 LOY. L.A. INT’L & COMP. L. REV. 379, 380–82 (2006).

311. Stefano, *supra* note 294, at 36 para. 101 (“[C]ollusion at the distributors’ level may harm consumers in particular by increasing the retail prices of the products, limiting the choice of price-service combinations and distribution formats, lowering the availability and quality of retail services and reducing the level of innovation of distribution.”).

312. *Bundesverband*, 2004 E.C.R. at 23.

313. Case C-158/11, *Auto Sarl v. Jaguar Land Rover Fr.*, 2012 EUR-Lex LEXIS 1107, at *15 para. 31 (June 14, 2012) (“[I]t is worth noting that it is not necessary that, with a view to verification of their precise content, the selection criteria used for the purposes of a selective distribution system be published, at the risk . . . of compromising business secrets, or even facilitating possible collusive behavior.”).

314. Case C-439/09, *Pierre Fabre SAS v. President de l’Autorite de la Concurrence*, 2011 EUR-Lex LEXIS 2461, at *22–23 para. 47 (Oct. 13, 2011) (“[A] contractual clause requiring sales of cosmetics and personal care products to be made in a physical space where a qualified pharmacist must be present, resulting in a ban on the use of the internet for those sales, amounts to a restriction by object within the meaning of [Article 101(1) TFEU] . . .”).

315. See Case C-108/09, *Ker-Optika bt v. ÀNTSZ Dél-dunántúli Regionális Intézete*, 2010 E.C.R. I-12213 para. 45–47 (finding that legislation prohibiting the selling of contact lenses via the Internet violates settled case law).

V. CONCLUSION

As a medical device, contact lenses are stirring healthy online competition in the marketing and sales efforts of manufacturers and retailers. Furthermore, once placed on the European market, the intellectual property rights in contact lenses are exhausted and can therefore be sold across borders. This Article has shown that consumers are better off getting the satisfaction of participating in the contact lens market rather than not receiving the market's benefits. European consumers gain additional satisfaction from the benefits they receive over the price they pay. Contact lens utility leads to greater satisfaction regardless of the price. Furthermore, online prices in Europe are decreasing due to the prevalence of several players and manufacturers' willingness to encourage the use of private labeling by eye care professionals and large retailers. This gives consumers a large choice from which to choose. The revision of the medical devices directives did not do much for contact lenses. As *Ker-Optika* demonstrated, there is a need for regulation of the sale of online contact lenses in the EU to eliminate the uncertainties within EU law. One possible approach would be an amendment of the distance selling regulation to provide a contact lens clause.³¹⁶

Furthermore, brands matter to consumers as they choose their contact lenses.³¹⁷ In the area of trademark and competition law, manufacturers of contact lenses are in total control of contact lenses, whether it be their own brands or the private label brands of their retailers; therefore, manufacturers of contact lenses may help retailers and eye care professionals raise prices illegally and thus breach competition rules. In cases where eye care professionals sell a large volume of contact lenses to boost their income, regulation may have an impact if they are able to charge higher fees for their services (eye care examinations). However, as a majority of European consumers are already familiar with contact lens prescriptions and know which lenses are required for their individual use, such a regulatory remedy will be of no use.

One of the policy considerations for the effective remedy of parallel trade in the medical devices industry in the EU is the imposition of a European-wide surcharge on parallel imports of medical devices. European regulators would initiate the surcharge, creating an "EU Tax." Such a surcharge should be set at a figure that equates to a quarter of the price sold for the product on the market where it was imported. The objective of the medicinal surcharge would be to enable the intellectual property rights-holders to reap the economic benefits of

316. Directive 2011/83/EU, *supra* note 42 at para. 11, (excluding healthcare from which it is applicable: "this Directive should be without prejudice to Union provisions relating to specific sectors, such as . . . medical devices"); *id.* at para. 30 ("[H]ealthcare requires special regulations because of its technical complexity, its importance as a service of general interest as well as its extensive public funding. Healthcare is defined . . . as health services provided by health professionals to patients . . . including the prescription, dispensation and provision of medicinal products and medical devices . . ."); *see also id.* art. 3(3)(b).

317. *See* Michael D. Smith & Erik Brynjolfsson, *Consumer Decision-Making at an Internet Shopbot: Brand Still Matters*, XLIX J. INDUS. ECON. 541 (2001) ("Brand is an important determinant of consumer choice.").

the product in the original market, when sold in a secondary market by the parallel importer. The surcharge would encourage consumers in the parallel market to opt for a similar product on the market in their territory. The surcharge would make the parallel traded goods almost equal in price to that of the same goods that were sold on the same market as the parallel trader by the original intellectual property rights-holder. The end result will be a level playing field in the price of goods that are imported by parallel traders in the European Union.

The manufacturers' fears of counterfeit lenses and consumer safety concerns can be addressed by EU policy makers by creating an EU-wide database. Such a database would be available for consumers who provide their contact lens prescription (given a numbered code). To protect the privacy of patients, the code will only be given to the consumer by his or her eye care professional, and it can be used each time for purchasing contact lenses. The database would create the "Amazon Effect" for consumers—a feeling of safety and security while shopping online, while alleviating the concerns of manufacturers and online sellers. Notified bodies could assign a "green certificate" to online sellers who complied with self-imposed regulation for access to the database.