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EXPANDING GLOBAL TRADEMARK REGULATION

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I. INTRODUCTION

The concept of trademark regulation is fairly new when one considers the length of time trademark protection has been available. Primarily, trademark law was a common law creature, and the rights given were territorial. When a federal system was implemented in 1870 that gave trademark rights to individuals who registered with the United States Patent Office, the Supreme Court ruled it unconstitutional. The Court held that the regulation was applicable to all trade, to commerce at all points (and not just interstate), and as such was an excess of Congress' power. Yet when the Trademark Act of 1946 (Lanham Act) was enacted, a federal trademark regulation system took form. It took some time and multiple efforts, but eventually, in passing the Lanham Act, the United States recognized the need for a unified, federal system of trademark regulation.

In 1994, there was a noted expansion in trademark regulation with the formation of the World Trade Organization and the Agreement on Trade Related Aspects of Intellectual Property Rights ("TRIPS").⁵ TRIPS serves, among other things, as a guideline for trademark use and recognition by the members of the WTO,⁶ which currently consists of 153 members⁷ representing more than 97% of total world trade.⁸ To date, this is the most comprehensive and sweeping regulation of trademarks, reaching all corners of the globe. However, there remains a need for expanding this existing regulation.

To understand the argument for extending global trademark regulation, one must initially understand the purpose of trademarks. According to the Lanham Act, the purpose of a trademark is "to identify and distinguish... goods...from those manufactured or sold by others and to indicate the source of the goods." TRIPS identifies a

⁴ GINSBURG ET AL., supra note 1, at 16.

 $^{^{1}}$ Jane C. Ginsburg, Jessica Litman & Mary L. Kevlin, Trademark and Unfair Competition Law 13 (4th ed. 2007).

² Trade-Mark Cases, 100 U.S. 82, 92, 99 (1879).

³ *Id.* at 95-97.

MICHAEL BLAKENEY, TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: A CONCISE GUIDE TO THE TRIPS AGREEMENT 7, 17-18 (1996).
Id.

⁷ World Trade Organization, Understanding the WTO: The Organization–Members and Observers, http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (last visited Mark 27, 2010).

⁸ World Trade Organization, The WTO in Brief: Part 2–The Organization, http://www.wto.org/english/thewto_e/whatis_e/inbrief_e/inbr02_e.htm (last visited March 27, 2010).

⁹ Trademark Act of 1946, 15 U.S.C. § 1127 (2006).

trademark as "capable of distinguishing the goods or services of one undertaking from those of other undertakings." ¹⁰

The common factor between these definitions is that trademarks are meant to distinguish one's goods from another's goods. This appears to be a universally accepted purpose of trademarks that initiates little, if any, argument. However with the globalization of travel, a new purpose presents itself: distinguishing one's goods from one's goods. This is an argumentative and new approach to the idea of trademark regulation. Before exploring this new goal, a closer look at the idea and regulation of distinguishing one's goods from another's is warranted.

II. DISTINGUISHING ONE'S GOODS FROM ANOTHER'S GOODS

A. PHARMACEUTICAL TRADEMARKS: WHEN LIKELIHOOD OF CONFUSION BECOMES DEADLY

Tim's bags are packed, and he is ready to go. This summer he will be emerging himself in new cultures, experimenting with local cuisine, and sleeping in hostels along the way as he backpacks through Europe. In preparation for the trip, he booked plane tickets months in advance, made sure all of his immunizations were current, and purchased traveler's cheques, which are now inconspicuously stowed in multiple pockets of his rucksack. Like millions of global travelers this year, Tim is leaving the familiarity of home and venturing across the seas.

Although Tim will be experiencing new languages, street signs, and local customs, he will seek comfort in the familiarity of trademarked brands. With the globalization of commerce, whether Tim is in London or Rome, he will always be within a Tube or Metro ride of a brand he recognizes, like McDonald's. But if Tim becomes ill during his trip, or needs to refill preventative medication, culture shock may quickly become anaphylactic shock.

Although manufacturers market and distribute pharmaceutical medicines globally, such marketing and distribution is still regulated locally. Thus, to market a product in any particular region,

¹⁰ General Agreement on Tariffs and Trade: Multilateral Trade Negotiations Final Act Embodying the Results of the Uruguay Round of Trade Negotiations, Apr. 15, 1994, Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1C, Art. 15 ¶ 1, 33 I.L.M. 1140, 1203 (1994) [hereinafter TRIPS].

¹¹ McDonald's has restaurants in over one hundred countries. McDonald's Corp., Annual Report (Form 10-K), at 3 (Feb. 26, 2010).

pharmaceutical manufacturers must seek local trademark registration, and if required by local law, apply for regional marketing authorization. Due to the lack of a uniform, global registration and authorization process, pharmaceutical medicines with very different active ingredients are currently marketed in different regions of the world under identical trade names, also called invented names.¹²

An American traveling in Serbia refilled his prescription for Dilacor XR, which is an invented name for diltiazem extended release, a high blood pressure medication marketed by U.S. company Watson Labs. The Serbian pharmacist filled the prescription with digoxin 0.25 mg because Dilacor is an invented name for digoxin, marketed by a Serbian company. Digoxin treats heart failure and abnormal heart rhythms, and patients who take digoxin require blood testing to monitor drug levels to "avoid serious adverse events." The patient unwittingly ingested digoxin, believing it was diltiazem, and upon returning to the U.S. had to be hospitalized with life-threatening drug toxicity.

In January 2006, the U.S. Food and Drug Administration (FDA) issued a public health advisory cautioning American travelers who fill prescriptions abroad that the drug they receive may have the same brand name as their prescription, but contain different active ingredients. As of the advisory, the FDA found 18 foreign pharmaceutical products with identical names as U.S. products, and over 100 foreign pharmaceutical products with names that were confusingly similar to U.S. products.

In the U.S. and Europe, several substances marketed by different companies share identical invented names. ¹⁹ These substances can contain different active ingredients, and are used to treat varying maladies. ²⁰ In addition to Dilacor, discussed above, the

 $^{^{12}}$ MEDICATION ERRORS 103-04 (MICHAEL R. COHEN ed., 2d ed. 2007).

¹³ See U.S. Food and Drug Admin., FDA Public Health Advisory January 2006 Consumers Filling U.S. Prescriptions Abroad May Get the Wrong Active Ingredient Because of Confusing Drug Names, http://www.fda.gov/Drugs/DrugSafety/PublicHealthAdvisories/ucm173134.htm (last visited March. 27, 2010)[hereinafter FDA Public Health Advisory].

¹⁴ See id.

¹⁵ *Id*.

¹⁶ *Id*.

¹⁷ *Id*.

¹⁸ *Id.* (noting that the list is non-exhaustive and subject to change).

¹⁹ MEDICATION ERRORS, *supra* note 12, at 104.

²⁰ *Id*.

four other examples are Flomax, Norpramin, Trexan, and Vivelle.21 See the table²² below for details:

Invented Name	Active ingredient; intended use & manufacturer (U.S.)	Active ingredient; intended use & manufacturer (Europe)
Flomax	Tamsulosen; enlarged prostate; Boehringer Ingelheim	Morniflumate; fever/pain reliever; Chiesi (Italy)
Norpramin	Desipramine; depression, Aventis	Omeprazole; peptic ulcer/heart burn; CEPA (Spain)
Trexan	Naltrexone; opioid dependence; DuPont	Methrotrexate; Rheumatoid arthritis; Orion (Finland/Hungary)
Vivelle	Estradiol; estrogen deficiency/menopausal disorders/osteoporosis; Novartis	Ethinyl estradiol, norgestimate; acne/oral contraceptive; Janssen-Cilag (Austria)

Additionally, over 118 other brand names for varying active substances have been deemed confusingly similar by the U.S. Food and Drug Administration.²³ For example, Amyben is an amiodarone (irregular heartbeat medication) marketed in the U.K.²⁴ It "is for use only in life-threatening situations" and "has the potential to cause side effects that could be fatal."²⁵ Ambien is a U.S. sleep-aid that contains the active ingredient zolpidem, a sedative. 26 The names sound very

²² See id. (showing more exhaustive table of pharmaceutical products marketed in the U.S. and Europe with identical names).

²³ See FDA Public Health Advisory, supra note 13. ²⁴ *Id*.

²⁵ Amiodarone Information, Drugs.com, http://www.drugs.com/amiodarone.html (last visited Apr. 10, 2010); accord CHARLES F. LACY ET AL., LEXI-COMP'S DRUG INFORMATION HANDBOOK 89-92 (13 ed. 2005) (detailing the side effects and risks associated with amiodarone).

²⁶ LACY ET AL., *supra* note 25, at 1591.

similar, especially when spoken with an accent, but taking Amyben instead of Ambien can lead to "disastrous results."²⁷

Unknowingly ingesting a different active ingredient marketed under a familiar brand name can lead to severe discomfort, adverse consequences and possibly even death. Thus, a uniform, global pharmaceutical marketing authorization process with integrated globally-recognized trademark registration is necessary to protect global travelers and prevent the prevalence of pharmaceutical products with confusingly similar or identical invented names.

B. THE CURRENT STATE OF
PHARMACEUTICAL TRADEMARK
REGISTRATION AND MARKETING
AUTHORIZATION IN EUROPE AND NORTH
AMERICA

The World Health Organization (WHO) has a constitutional mandate "to develop, establish and promote international standards with respect to food, biological, pharmaceutical and similar products." In furtherance of this goal, the WHO provides a single nomenclature of worldwide acceptability for each active substance marketed as a pharmaceutical; these are called International Nonproprietary Names ("INNs"). 29

INNs are derived from common stems, and selected when an INN request form for a new active substance is submitted to a committee of WHO experts.³⁰ After the experts agree on a name for the new substance, the proposed name is published in *WHO Drug Information*.³¹ Following publication, the proposed name faces a fourmonth objection period; if no successful objections are made during that period, then the name becomes a recommended INN, meaning it can be used world-wide on packaging and labeling of the substance.³² The WHO advises that INNs should not be registered as trademarks because such registration would prevent other parties from using them.³³ Additionally, the WHO contends deriving invented names

²⁷ MEDICATION ERRORS, *supra* note 9, at 105.

²⁸ Constitution of the World Health Organization, art. 2, para. u, July 22, 1946, 62 Stat. 2679, 14 U.N.T.S. 185.

²⁹ World Health Org., Guidelines on the Use of International Nonproprietary Names (INNs) for Pharmaceutical Substances, WHO/PHARM S/NOM 1570, *available at* http://whqlibdoc.who.int/hq/1997/WHO_PHARM_S_NOM_1570.pdf (last visited Mar. 27, 2010).

³⁰ *Id.* at 3, 6.

³¹ *Id.* at 3.

³² *Id*.

³³ *Id*.

from INNs, and particularly INN common stems, should be avoided because it can lead to confusion.³⁴ As discussed below, not all local trademark laws adhere to this recommendation.

Pharmacological trademarks registered in European Union member states must meet not only EU directives³⁵ as interpreted by the European Court of Justice and the Court of First Instance, but also national regulations and the interpretation of EU directives as determined by national courts.³⁶ National interpretation of EU directives varies by region and tends to be more restrictive than the intended meaning of original directive.³⁷

Before a pharmaceutical product can be marketed in any EU member states, an additional and separate analysis is undertaken by the European Medicines Agency ("EMEA"). 38 This lengthy and difficult process determines whether the requested mark is clear and valid in every EU member state.³⁹ As part of the authorization process, the EMEA's (Invented) Name Review Group ("NRG") evaluates whether the invented name given to a product "could create a publichealth concern or potential safety risk.",40 According to the NRG, an invented name "should not be liable to cause confusion in print, handwriting or speech with the invented name of an existing medicinal product."41 The NRG rejects over 50% of the trademarks applied for in the context of pharmaceutical marketing authorization.⁴²

The Intellectual Property Code, which governs trademark law in Italy, distinguishes between "strong" trademarks, which are similar to arbitrary and fanciful marks in the U.S., and "weak" trademarks,

35 See Council Directive 2008/95/EC, 2008 O.J. (L 299/25) (EC) (setting forth standards for trademark registration and protection within the European Community).

³⁸ European Meds. Agency, Committee for Medicinal Products for Humans (CHMP) - Overview http://www.emea.europa.eu/htms/general/contacts/CHMP/CHMP.html (last visited Mar. 27, 2010) [hereinafter CHMP Overview].

³⁴ *Id* at 7.

³⁶ Michael Best & Udo Pfleghar, Germany, in World Trademark Review, PHARMACEUTICAL TRADEMARKS 2009 – A GLOBAL GUIDE, 23, 23 (2009), available http://www.worldtrademarkreview.com/issues/Article.ashx?g=7087869f-2acb-47e4-a92a-efc28b862e9e.

AURÉLIA MARIE, FRANCE, in WORLD TRADEMARK REVIEW, PHARMACEUTICAL Trademarks 2009 – A Global Guide, 19, 20 (2009), available at http://www.worldtrademarkreview.com/issues/Article.ashx?g=a1b23f95-9e29-474fa305-7250b8d78482.

⁴⁰ European Meds. Agency, Committee for Medicinal Products for Humans (CHMP) - Other CHMP-associated Groups, http://www.emea.europa.eu/htms/general/ contacts/CHMP/CHMP_INRG.html (last visited Mar. 27, 2010) [hereinafter Other CMPH-associated Groups].

⁴² BEST & PFLEGHAR, *supra* note 36, at 24.

which are similar to suggestive and descriptive marks in the U.S.⁴³ When evaluating "weak" pharmaceutical trademarks, Italian courts allow drug companies to trademark names that are similar to the generic name of a drug; these marks are considered "expressive" and do not need to acquire secondary meaning to be registered.⁴⁴ When evaluating "strong" pharmaceutical trademarks, Italian courts depart from other EU member states by measuring likelihood of confusion from the perspective of physicians.⁴⁵ Thus, competing drug companies can register fanciful trademarks with similar invented names in Italy so long as the court determines that qualified professionals would not be confused as to the source of each drug.⁴⁶

The French Code of Public Health provides that pharmaceutical trade names, which are typically registered as trademarks, must not be confusingly similar to INNs. Similarly, the French Trademark Office will reject applications for trademarks that are confusingly similar to INNs. The French Trademark Office evaluates the risk of confusion from the viewpoint of an average consumer, not a specialist.

To distribute pharmaceuticals in the UK, drug companies must acquire marketing authorization from the Medicines and Healthcare Products Regulatory Agency ("MHRA"). The MHRA will not allow a pharmaceutical product to be marketed under a trade name consisting of the product's INN and the name of the manufacturer; however, the inclusion of an INN or its stem in an invented name will not preclude authorization. The stem in an invented name will not preclude authorization.

To receive trade mark protection in the UK, which is separate from marketing authorization, the manufacturer must apply to the Intellectual Property Office ("IPO").⁵³ The IPO puts the onus on trade

⁴³ See DANIELE CANEVA, ITALY, in WORLD TRADEMARK REVIEW, PHARMACEUTICAL TRADEMARKS 2009 – A GLOBAL GUIDE, 43, 43 (2009), available at http://www.worldtrademarkreview.com/issues/Article.ashx?g=8ea6d7b6-94ec-4d8b-afcd-d92b84567d20.

⁴⁴ *Id.* at 43-44.

⁴⁵ *Id.* at 44.

⁴⁶ See id.

⁴⁷ See MARIE, supra note 39, at 20.

⁴⁸ See id.

⁴⁹ See id.

⁵⁰ ARTY RAJENDRA & EWEN MITCHELL, UNITED KINGDOM, *in* WORLD TRADEMARK REVIEW, PHARMACEUTICAL TRADEMARKS 2009 – A GLOBAL GUIDE, 71, 72 (2009), *available at* http://www.worldtrademarkreview.com/issues/Article.ashx?g=26e48584-7381-4517-afa4-c347677cf21b.

⁵¹ *Id.* at 72.

⁵² *Id*.

⁵³ See id. at 71.

mark owners to object where confusion is likely.⁵⁴ In evaluating an opposition to a trademark application, the IPO judges the likelihood of confusion to both healthcare professionals and end consumers.⁵⁵ In doing so, the IPO assumes consumers have a higher level of attentiveness when purchasing pharmaceutical products than when purchasing other goods.⁵⁶ Once a trademark application has been approved, its registration

> may be revoked [if] . . . in consequence of the use made of it by the proprietor or with his consent in relation to the goods or services for which it is registered, it is liable to mislead the public, particularly as to the nature, quality or geographical origin of [the] goods or services.⁵⁷

Before a drug can be marketed for human use in Ireland, its invented name must be reviewed by the Irish Medicines Board to determine whether it is likely to confuse or mislead the public. ⁵⁸ Evaluation criteria include compliance with EU Directive 2001/83/EC, and the WHO's advisory to avoid using INNs or INN stems in inventive names. Successful registration of a trademark with the Irish Patents Office is not sufficient grounds for approval of an invented name. 60 Rejected applications can be defended by a proposal justifying approval of the name, which can then be appealed to the board's Management Committee.⁶¹

In the United States, the United States Trademark and Patent Office also recognizes that INNs must be kept generic and will not register a trademark for a pharmaceutical product that contains the stem of an INN.⁶² Additionally, the FDA Division of Medication Errors and Technical Support conducts a premarketing review of all

⁵⁴ *Id*.

⁵⁵ *Id*.

⁵⁶ See id.

⁵⁷ Trade Marks Act 1994, 1994, ch. 28, § 46(1)(d) (Eng.).

 $^{^{58}}$ ALISTAIR PAYNE, IRELAND, in WORLD TRADEMARK REVIEW, PHARMACEUTICAL Trademarks 2009 - A Global Guide, 35, 35 (2009), available at http://www.worldtrademarkreview.com/issues/Article.ashx?g=a50b1007-4ddf-4fc6a341-b681b907193e.

⁵⁹ *Id.* at 35-36.

⁶⁰ *Id.* at 36.

⁶¹ *Id*.

JULIE A. KATZ, UNITED STATES, in WORLD TRADEMARK REVIEW, PHARMACEUTICAL TRADEMARKS 2009 – A GLOBAL GUIDE, 75, 75-76 (2009), available http://www.worldtrademarkreview.com/issues/ Article.ashx?g=7a63f7fb-1344-4950-a1ac-d04db2f4e6ee.

proposed trademarks for pharmaceutical products. 63 In conducting the review, the FDA recognizes that drug labeling may be misleading if the drug or ingredient is designated "by a proprietary name that, because of similarity in spelling or pronunciation, may be confused with the proprietary name or the established name of a different drug or ingredient."64

In nations where marketing authorization is required, the agency with the authority to evaluate applications conducts a likelihood of confusion analysis in determining whether to authorize the marketing of invented names, which may or may not be registered trademarks. In Mexico, invented names can be rejected by the Federal Commission for the Protection Against Sanitary Risks if it is confusingly similar to a previously authorized drug name. 65 Mexican Health Law Regulations define confusing similarity as "when at least three consecutive letters in the proposed name and the prior drug name are identical."66

National likelihood of confusion analysis ranges from broad acceptance, as in the UK where an invented name can be disqualified if consumers would be misled based on the spoken name of the drug being confusingly similar to the spoken name of another drug, to limited acceptance, as in Italy where an invented name is acceptable if a professional with specialized knowledge can distinguish between the two drugs with similar names.⁶⁷ Thus, travelers are exposed to varying levels of risk with respect to likelihood of confusion when refilling prescriptions in different countries.

C. DEVELOPING A GLOBAL FRAMEWORK FOR PHARMACEUTICAL TRADEMARK REGULATION

Due to the lack of a uniform, global pharmaceutical trademark regulatory system, drug manufacturers can market pharmaceutical products with different active substances under identical registered trademarks in different regions of the world. As global commerce and travel continue to grow, tourists and other international travelers face

⁶⁴ 21 C.F.R. § 201.10(c)(5) (2009).

⁶³ See MEDICAL ERRORS, supra note 12, at 105.

 $^{^{65}}$ Victor Ramirez, Mexico, in World Trademark Review, Pharmaceutical Trademarks 2009 - A Global Guide, 51, 51 (2009), available at http://www.worldtrademarkreview.com/issues/Article.ashx?g=20dee8d2-0ae0-48b7-96f9-2974a585548d.

⁶⁶ Id. at 51. Furthermore, a proposed name can be rejected if it is identical to a prior name, even if the prior name's application is pending or its marketing authorization has been cancelled. Id. at 52.

⁶⁷ See RAJENDRA & MITCHELL, supra note 50, at 71; CANEVA, supra note 43, at 34.

increasing risks when filling prescriptions abroad. Nations must work together to create global solutions while the number of identical and confusingly similar branded prescriptions is still manageable.

The ideal solution is a global, uniform marketing authorization process similar to the EMEA's marketing authorization process in the European Union. The WHO should use its constitutional authority to develop a committee of experts who will evaluate proposed invented names, similar to the current committee that evaluates proposed INNs. The committee should review proposed submissions based on guidelines derived from trademark principles, particularly likelihood of confusion. After a public objection period, the committee should have the authority to approve proposed invented names. approval from current marketing authorization agencies, international approval should become a prerequisite for locally registering any trademark that is an invented name for a pharmaceutical product. Local agencies should retain trademark registration authority for all products and the right to reject a proposed pharmaceutical trademark for any reason regardless of its international marketing authorization status.

When evaluating applications, the WHO should consider whether proposed trade names are likely to "create a public-health concern or potential safety risk," particularly for international travelers. Thus, regional restrictions commonly placed upon trademark owners for other types of products and services will no longer apply to pharmaceutical trademark owners. Approval to market and distribute a pharmaceutical product in even just one country will preclude anyone else from marketing and distributing a competing pharmaceutical product anywhere in the world with the same invented name. Coupled with the fact that no one will be permitted to register pharmaceutical trademarks without marketing authorization, these changes effectively create a uniform, global trademark system for pharmaceutical products.

Given that pharmaceutical manufacturers will receive unprecedented broad, world-wide trademark protection, marketing authorization should require minimum drug development standards and good faith intent to enter the stream of commerce within 5 years of the date of authorization. Thus, a company currently searching for a cure for cancer may not receive authorization now to use an invented name for a product it will develop some time in the future. Instead, the committee must develop guidelines for showing that use of the name in commerce is relatively imminent. For example, a nationally

⁶⁸ CHMP Overview, *supra* note 38.

approved patent application may be considered sufficient for the application to move forward.

Since trademark law and health law are primarily intended to protect consumers and the public at large, likelihood of confusion should be analyzed from the standpoint of a consumer at the point of sale, not a physician or pharmacist with specialized training. The committee should only hold consumers of pharmaceutical products to a heightened level of attentiveness if the INN is required to appear anywhere the trade name is displayed. In that case consumers have the option of comparing the INN of their original prescription with the INN found on the prescription they receive while visiting another country. Similarly, the WHO will follow its own guidelines of rejecting proposed invented names that are too similar, or likely to be confused with INNS.

If the INN is not required to appear anywhere the trade name is displayed, the committee should evaluate the attentiveness of consumers of pharmaceutical products the same as they would evaluate the attentiveness of consumers of other goods. Although many drug companies would like consumers to associate trademarked names with their companies and become loyal to their brands and some nations currently charge consumers of pharmaceutical products with a higher level of attentiveness than consumers of commodities, ⁶⁹ many consumers do not understand the differences between brand name and competing generic pharmaceutical products. ⁷⁰

Unlike many consumer goods where trademarks serve as the source identifier and relate tangible information about quality to consumers, pharmaceutical products can be indistinguishable because are typically chosen by the prescribing doctor and contain the same active ingredients that produce the intended effects. Many pharmacies in the U.S. sell generic products at a fraction of the price of brand name products⁷¹ and will fill a brand name prescription with a generic product if the less-expensive substitute is available.⁷² This means, U.S. consumers are accustomed to taking a prescription to the

⁶⁹ See RAJENDRA & MITCHELL, supra note 50, at 71.

⁷⁰ See Rebecca Ruiz, What You Should Know About Generic Drugs, FORBES, Jul. 27, 2009, http://www.forbes.com/2009/07/27/generic-drugs-prescriptions-lifestyle-health-drugs.html (explaining patients' perceptions of generic pharmaceuticals and the actual affectivity of generic pharmaceuticals).

Daniel R. Cahoy, Addressing the North-South Divide in Pharmaceutical Counterfeiting, 8 WAKE FOREST INTELL. PROP. L.J. 407, 409 (2008) (noting generic pharmaceuticals are cheaper than branded pharmaceuticals).

⁷² E.g., Walgreens Mail Service, Frequently Asked Questions about Generic Medications,

https://www.walgreenshealth.com/whc/mpharm/jsp/cob_ms_go_generic_faq.jsp (last visited Apr. 5, 2010).

pharmacy that has the name of one pharmaceutical product on it, and receiving a less-expensive substitute product with a different name. In most instances, consumers ingest the product and it works as intended. The only distinguishing factor at the point of sale is the impact on the consumer's wallet.

While traveling in a foreign country, average consumers of pharmaceutical products could reasonably believe that the name of the drugs used to fill their prescriptions are just the foreign nation's versions of their usual prescription medications. Even skeptical consumers who inquire about dissimilar names could face language barriers, or be incorrectly informed that they have received the correct products. The risk for confusion is significantly increased when pharmaceutical products with very different active ingredients that are used to treat very different conditions have identical trademarked names. Preventing invented names from being identical or confusingly similar will give consumers the chance to realize if the pharmacist has made a mistake when refilling the prescription and allow pharmacists to more easily recognize their mistakes.

When evaluating likelihood of confusion, the committee should not separate permissible names into categories based on chemical compounds intended medical uses, or design of the pill. Although some countries, such as the United Kingdom, allow pill design to serve as a trademark, 73 other nations, including Germany, reject such applications.⁷⁴ Unlike the intended use of most consumer products, like vacuum cleaners, televisions, and refrigerators, the intended use of medications, which typically come in pills of various shapes and sizes, is not facially distinguishable. As a trip to the local drug store will prove, even medications that are all intended to relieve headaches come in various forms, sizes and colors. While many consumers can distinguish an Advil from a Tylenol (typically the drug name is printed on the pill), Tylenol itself comes in many different colors, shapes and sizes. The appearance of a pill containing varying active substances is extremely easy to manipulate; a little blue pill may contain the same ingredients as a large white capsule. Sight alone does not sufficiently notify consumers of the pill's chemical compound. Therefore, likelihood of confusion analysis should apply equally to all pharmaceutical medicines, regardless of form.

Finally, likelihood of confusion should apply to both the written and spoken name. Language barriers and thick accents increase the likelihood that consumers will receive the incorrect products at foreign pharmacies.

 $^{^{73}}$ See, e.g. RAJENDRA & MITCHELL, supra note 50, at 71.

⁷⁴ See, e.g. BEST & PFLEGHAR, supra note 36, at 24.

1. Encouraging Corporate Social Responsibility

Historically, company A could market its product to consumers in region X and company B could market its product to consumers in region Y, and both companies could use the same trade name without infringing so long as neither company marketed its product in the competing company's region.⁷⁵ Today consumers, not companies, are creating the mobile force that causes brand confusion. Responsible companies can remedy the problem without agency interference.

Until global solutions become reality, pharmaceutical manufacturers that own names that are identical or confusingly similar to the names of pharmaceutical products marketed in different regions should be encouraged to meet or work things out through mediation. If the parties reach impasse or simply avail themselves to the jurisdiction of the court, a good default rule is for the court to award the right to market the product to the company with the most widespread commercial use, thus minimizing the total number of consumers impacted by the change. Additionally, the company that gets to retain use of the invented name should be required to compensate the other company for costs associated with losing the rights to use the product's name in local markets, like repackaging and educating consumers about the change. Since geographical separation prevents the parties from actually infringing on each other's rights, neither party is more at fault than the other. Thus, both manufacturers, acting in the best interests of consumers, should share the costs and responsibilities of implementing a safer system.

2. Responding to Criticism

Critics may argue that such a wide-range overhaul of pharmaceutical trademark regulation and delegation to international authorities is unnecessary for a problem that has impacted very few people to date. However, where the impact of a trademarked name means a deadly risk, even one affected consumer is one too many. Also, as the number of global travelers continues to increase and more pharmaceutical companies enter the market and develop new products, the likelihood that invented names will be identical to similar to

⁷⁵ Benjamin Prevas & Xiaoyong Yue, *Digital Turf Wars: Issues and Solutions Relating to Concurrent Use in a Cyberspace Context*, 9 WAKE FOREST INTELL. PROP. L.J. 177, 178-91 (2009) (explaining the development of the concurrent use doctrine in realspace).

existing names or INNs increases, and the risk becomes greater. Proactive action can prevent "disastrous results."⁷⁶

Additionally, critics may argue that consumers should be responsible for protecting themselves by bringing medications along or consulting with their physicians before refilling prescriptions abroad. Websites even encourage travelers to refill prescriptions before travel to avoid running out of medication.⁷⁷ However, there are always unforeseeable events, like lost luggage, theft, or an emergency situation that can expose even the most precautious travelers to risk.

Other critics may argue that an international database is unnecessary because information about drug content and specifically information regarding brand name drugs and their possible active ingredients in different countries is prevalent. However, this is often unreliable and subject to change making it insufficient to protect traveling consumers of pharmaceutical products. A non-profit website designed by the WHO solely for the purpose of provided current and reliable information, and made readily available through emerging technologies, like smart phones, is a much better source of information and protection.

Finally, critics may argue that travelers should have heightened awareness when purchasing medications abroad. However as discussed above, consumers have less information readily available to them when traveling and are more likely to mistake substitute nomenclature for their prescription medications as just another of the many cultural differences they are experiencing between their home countries and foreign nations.

3. Implementation

In current international law, the manufacturers, who gain pecuniary benefits from being able to trademark invented names for their unique combination of active and inactive ingredients, may be immune from liability even though the mix-up would likely not have

⁷⁶ See MEDICATION ERRORS, supra note 12, at 105 (enumerating precautions which can reduce the risk of receiving the wrong drug when traveling abroad).

⁷⁷ See, e.g., Institute for Safe Medication Practices, All Brand Names Are Not the Same Medicine in Different Countries, http://www.consumermedsafety.org/articles.asp?p=i_tnom_AR200507001 (last visited Mar. 27, 2010).

See, e.g., Drugs.com, Dilacor Information, http://www.drugs.com/international/dilacor.html (last visited Mar. 27, 2010) (asserting that Dilacor is not known to be marketed in the United States and failing to warn consumers that Dilacor XR is marketed in the United States); LACY, *supra* note 25, at 452 (noting that Dilacor XR is a brand name in the United States for diltiazem).

occurred if the products had distinguishable names. Even if such remedies existed, they would take years to come to fruition in international courts.

As illustrated above, concerted action among nations is difficult to obtain because most international agreements are voluntary in nature, and sometimes subject to interpretation by national courts. While striving for the ideal solution, intermediary practical solutions should be implemented. Some of the steps taken toward global resolve can be utilized for intermediate relief.

For example, the benefits of an international marketing authorization process include a global database of all registered, proposed and rejected pharmaceutical trade names. This database would at first be difficult to compile, but once created would facilitate an efficient authorization process where pharmaceutical companies and authorities alike could conduct quick searches of trade names to track both their international marketing authorization status and status of all trademark registration applications.

The database would be similar to the online U.S. PTO database ⁷⁹ with a few modifications. First, the database would consist exclusively of pharmaceutical trade names. Second, a designated agent of each participating nation would have internal access to update its nation's information, along with the duty to keep the data current. Third, the information would be publicly available through a link of the WHO's website, although tiered access levels may be developed for consumers, pharmaceutical companies and regulatory agencies. And finally, users would have the option of conducting broad searches using the entire database, searching based on criteria (such as all names registered by a particular manufacturer, all products containing an active ingredient, or all products designed to cure a certain ailment), or conducting a reverse search where users input the proposed name and the database generates a list of all possible conflicting or confusingly similar names and, upon request, uses an algorithm to suggest non-conflicting names.

Even before all nations support the international marketing authorization initiative, having all of this information organized, updated and centrally located would assist consumers in source identification. A consumer-friendly, interactive website, kiosks located at pharmacies, and even an application designed for smart phones would assist consumers in determining whether the products pharmacies distribute match the medicine their doctors prescribed, thus reducing the likelihood of confusion at the point of sale.

⁷⁹ Trademark Electronic Search System (TESS), http://tess2.uspto.gov/ (last visited Mar. 27, 2010).

Regardless of the solutions implemented, pharmaceutical companies and regulatory agencies need to educate consumers, like our hypothetical traveler Tim, 80 about the risks of filling prescriptions abroad and the tools available to make filling prescriptions abroad risk- and hassle-free.

III. DISTINGUISHING ONE'S GOODS FROM ONE'S **OWN GOODS**

A. A New Purpose for Trademarks: PROTECTING THE CONSUMER

The subject of pharmaceuticals shows the need for expanding the existing global trademark regulation to help truly distinguish one's goods from another's. However, a new issue presents with the increasing ease of global travel and with the global marketing of products: distinguishing one's goods from one's own.

It is undisputed that a universal purpose of trademarks is to identify one's goods from those made or sold by others.⁸¹ However, to address the issue of distinguishing one's goods from one's own, the universal purpose of trademarks must be expanded. The goal of trademark law should be not only to distinguish one's goods from those made or sold by others but also to protect the consuming public from confusion (by distinguishing one's goods from one's own).

Imagine the hypothetical traveler Tim from above. excited to go abroad and discover new cultures and customs. However, at some point in his travels Tim will be faced with the dilemma of purchasing some sort of necessity, whether it is food, household goods, personal hygiene or so on. Tim may be persuaded to buy an item that he recognizes from home, expecting the same quality he has become accustomed to, but instead he buys a product that is different. Protecting Tim and travelers like him from confusion in purchasing products and goods is the new goal trademark law should address.

But is the idea of consumer protection really new? In Roman times, it was left to the defrauded purchaser to bring an action against a trademark infringer.⁸² This preferential treatment for the consumer over the owner of a trademark shows the historical presence of the consumer protection concept.

81 See supra Part I.

⁸⁰ See supra page 217.

⁸² RESTATEMENT (THIRD) OF UNFAIR COMPETITION § 9 cmt. b (1995).

Furthermore, the generally accepted purpose of trademarks, distinguishing one's goods from another's, is enforced so as to prevent unfair competition. International businesses are using the familiarity of their mark with foreign travelers, like traveler Tim, but they are not offering the same product. This is a form of unfair competition over non-international, or local, companies who cannot use brand-name recognition to gain business from a foreigner.

Unfair competition exists when a product contains "indications...the use of which in the course of trade is liable to mislead the public as to the...manufacturing process [and] the characteristics...of the goods." This definition, as recognized by the 173 contracting countries of the Convention for the Protection of Industrial Property ("Paris Convention"), 85 prohibits indicators that would mislead the public. Therefore, as one of the first global treaties on trademark regulation, the Paris Convention recognized the need to protect the consuming public from confusion.

While perhaps the purpose of consumer protection has been overshadowed in the very recent by the purpose of protecting the trademark owner, the idea that consumers should be sheltered from confusion is not new. It is evident in the concept of unfair competition and has roots in the common law system of trademarks. To extend trademark regulation to better include the idea of consumer protection, a system must be developed that helps distinguish one's goods from one's own.

B. Two Possible Areas of Concern: Service Marks and Trademarks

When implementing a system that incorporates a concern for consumer protection, two areas of concern are presented: service marks and trademarks. Each can be further broken down into subcategories of industries. Trademarks are used mainly for goods, such as food, drink, soap, toiletries, etc. Service marks are used chiefly by businesses in retail and restaurants. To develop a system

⁸⁴ Paris Convention for the Protection of Industrial Property art. 10^{bis} , ¶ (3)(3), Mar. 20, 1983, 21 U.S.T. 1583, 828 U.N.T.S. 305 (as revised at Stockholm, July 14, 1967).

⁸³ *Id.* § 9 cmt. c (1995).

World Intellectual Prop. Org., Contracting Parties - Paris Convention, http://www.wipo.int/treaties/en/ShowResults.jsp?lang=en&treaty_id=2 (last visited Apr. 5, 2010).

⁸⁶ See 15 U.S.C. § 1052 (2006) ("No trademark by which the goods of the applicant may be distinguished from the goods of others . . .").

⁸⁷ See id. § 1053 (2006) ("[S]ervice marks shall be registrable.").

that effectively addresses consumer protection, each area, service marks and trademarks, must be considered individually.

Beginning with service marks, and the industries of retail and restaurant, it is difficult to find international businesses that offer a same-named product globally that differ depending on the region where it is sold. For retail, most services and products sold do not tend to change in terms of quality, but rather the products available for sale will vary depending on where the store is located. This allows for local taste and preference to dictate what is sold, but still the quality of the products appears to be universal. For example, Adidas apparel and shoes can be found both in the United States and in England. A consumer may find a pair of Adidas shoes in England which are not available in America even in the same week or month.⁸⁸ Either the shoes were never available in one country, or more than likely the shoe have already been available or will be in the future. While the selection of shoes may be different globally, the quality of the materials used to structure the products remains consistent.

Restaurants, like retail businesses, tend to cater to local trends and cultural specifications of a given territory. Restaurants may lower the amount of sugar in their food or may offer meat-alternative dishes in order to appease the local consumer. Although an international restaurant chain may not offer the exact same products, the quality of the food offered appears to remain as consistent as possible when dealing with such a variance of taste preferences. For example, McDonald's has chains all over the globe. In the United States a popular sandwich is the Big Mac, which consists of beef patties. However in India, due to local customs and beliefs, McDonald's serves the Maharajah Mac, which consists of chicken patties. ⁸⁹

Because the success of retail businesses and restaurants depends so much on catering products to local preference, it is unrealistic to ask these industries to offer the exact same products globally, without alterations, so as not to confuse consumers. One possible solution to alleviate consumer confusion would be for the companies to only use the same name for a product when it is exactly the same world-wide. However, as evidenced by the above Big Mac example, most businesses already do that. Pizza Hut offers a Masala

⁸⁸ For example, in March of 2010, Adidas offered six different styles of "outdoor" shoes on its online British store but only six different styles of "outdoor" shoes on its online American store, two of which are different color combinations of the same style. *Compare* Adidas Official Online Store, http://www.shopadidas.com (last visited Apr. 6, 2010), *with* Adidas Online Store, http://shop.adidas.co.uk (last visited Apr. 6, 2010).

Note, Opening for Business in India: Retailers' Options, 31 SUFFOLK TRANSNAT'L L. REV. 165, 167 n. 18 (2007)

Pizza, a spiced-up version of what is offered in the West, ⁹⁰ but the different name serves as a warning to consumers that the product is not the same. Since most service marks already address the issue of consumer confusion by creating different names for their altered products, the potential for consumer confusion is extremely low and a new, global system is not warranted.

The use of trademarks, however, is not as independently regulated and as such is not as easily remedied. An example of the problem with global trademarks is evident when one examines the product of Coca Cola. The soft drink is sold worldwide, adorned with the same famous script trademark, yet the drink does not taste the same. More specifically, Coke made for sale in Mexico uses cane sugar while the same Coke, made for sale in the United States, uses high-fructose corn syrup. Consumers say that there is a sweeter, cleaner flavor with the Mexican version. It is this type of variance that confuses a consumer when one buys a Coke with the expectation that it will taste exactly the same as the identical-looking Coke enjoyed in another part of the world.

To address this problem of consumer confusion within the use of global trademarks, a system that clearly identifies the targeted region for sale and that adequately warns the consumer of product differences is proposed. Instead of developing a new system without any established foundation, a proposal is formed within the confines of the current global trademark regulation scheme, TRIPS.

Article 22 of TRIPS involves the use of geographical indications.⁹⁴ The article is meant to address the permissible use of geographical indicators, stating that "geographical indications are...indications which identify a good as originating in [a] territory...where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin." With this definition, not only must the goods originate in a particular place, but the goods must be (or perceived to be) qualitatively different if they came from some other place. While this article was created so as to restrict the use of geographical indicators (or the misleading use of

 93 Id.

⁹⁰ Ram Ramgopal, The Maharaja Mac: Fast-Food Indian Style, CNN, July 14,2002, http://archives.cnn.com/2002/WORLD/asiapcf/south/07/14/india.spicy.fast.food/ind ex.html.

⁹¹ Louise Chu, *Is Mexican Coke the Real Thing?*, SAN-DIEGO UNION-TRIBUNE, Nov. 9, 2004, http://www.signonsandiego.com/uniontrib/20041109/news_1b9mexcoke.html.

⁹² *Id*.

⁹⁴ TRIPS, *supra* note 10, art. 22.

⁹⁵ *Id*.

such indicators), it can be expanded to contend with the issue of consumer confusion and global trademarks.

Article 22 of TRIPS should be modified to require that all global trademarks use geographical indicators when the product is altered for sale in different parts of the world. The definition of such an indicator would remain relatively the same, reading "geographical indications are...indications which identify a good as *marketed and manufactured for* a territory...where a given quality, reputation or other characteristic of the good is essentially attributable to the *territorial preference*." With this tweaked definition, a geographical indicator would serve as a warning to a potential consumer that, if the indicator is different than the consumer's usual place of consumption, the product will be different based upon territorial preferences.

Practically, a universal indicator is needed so that consumers of any origin, language, and education may understand it. There is room for leeway here in developing a system, with the only requirement that the system be consistent. One possible system would involve the use of pictures. A manufacturer would place on its product a small, representative picture of the geographical region where the product was meant to be sold. For instance, the Mexican Coca Cola would have a picture of the outline of the country of Mexico or a picture of the Mexican flag.

While the picture of a country's flag might be more readily identifiable, it does not allow for the idea that a product can be targeted for a multitude of countries (and that a product is not altered for each and every individual country). The map outline of a geographical region is perhaps the most feasible idea. However, this would require basic geographical knowledge of a territory so as to effectively warn the consumer. One would hope that, at the very least, a consumer will be able to identify that his or her country is *not* a part of the picture, and that knowledge will serve as a warning that the product will be different. The picture need only be big enough for the consumer to find it on the product, so the cost of placing the symbol on an item is not overbearing.

Another possible system would involve the use of colors, which are easily understandable despite language barriers. A manufacturer would put a small representative color on its product to signify an alteration. Each color could represent a desired trait, yet the spectrum of goods and desired traits is so numerous that it seems impractical to assign a color for each. Also, not only would meaning need to be attached to each color, but the global consuming public would have to be educated about the meaning attached to each color. This system appears to require more time and resources than a simple picture representation.

No matter what system is eventually adopted, a global requirement that companies use a universal representative system to identify altered products under the same trademark would alleviate the concern for consumer confusion. Thus consumers would be able to distinguish a manufacturer's goods from its own goods.

C. REMAINING QUESTIONS: ADDRESSING THE CRITICISMS

As with any new proposal, there are criticisms and questions about implementing a global system that distinguishes one's goods from one's own goods. Some possible concerns are that such a system is not needed because the number of international travelers is trivial, because consumers should naturally expect something different in a foreign country, and because the harm is quite minimal.

Beginning with the concern that international travelers are few, the data and statistics show the exact opposite. In 2008, international tourism grew by 2% (or by 18 million) to reach 922 million travelers. These tourists generated 944 billion in U.S. dollars, which comprises 30% of the world's exports of services. And there is no indication of any slowing down for the tourism industry. The forecast for 2020 is that there will be 1.6 billion international tourists. With such an enormous number of international explorers, it seems reasonable that there should be a system in place that protects the consuming traveler from confusion when traveling abroad.

The argument that a consumer should expect something different in a foreign country also falls apart when it is analyzed in terms of global trademark use. Companies use international marketing and global trademarks so as to attract a consumer, no matter where that consumer is located. These companies prey on the traveling consumer's familiarity with the mark to gain a competitive edge over the local, unknown product. While it is accepted and encouraged that a company build goodwill to gain a consumer's loyalty, the users of global trademarks misappropriate their mark by not offering the exact same product the international traveler expects. A system that prevents this type of unfair competition by confusing the international consumer is not only warranted but desired.

Lastly, and perhaps the most compelling, is the argument that the harm presented is quite minimal and does not require a global overhaul of product dress (by requiring a geographical indicator on

WORLD TOURISM ORG., TOURISM HIGHLIGHTS 2 (2009), available at http://www.unwto.org/facts/eng/highlights.htm (last visited Apr. 10, 2010).
Id.

⁹⁸ *Id*.

individual products). If a consumer buys a product and finds that it is different than expected, the consumer knows not to buy the product again or at least can expect the difference at the next point of purchase. The harm, consumer confusion, is minimal and therefore does not warrant global redress.

However, the notion of consumer confusion is exactly the type of harm trademark regulation should protect. Indeed, the concept of confusion is pivotal to the regulation of trademarks in the United States, with most circuits and courts recognizing as their model the *Polaroid* factors for assessing likelihood of confusion. While the eight factors outlined by *Polaroid* are meant to test confusion between two different parties' marks, they can be used to show the need for a global system to distinguish identical trademarks on qualitatively different products.

When applying the *Polaroid* factors to establish a likelihood of confusion, we analyze the confusion, at the very latest, at the point of sale (and arguably before the point of sale with the initial interest). ¹⁰² If the *Polaroid* factors are considered from the view of the international consumer, at the point of sale, a likelihood of confusion appears certain and thus a system to remedy the confusion is warranted.

For some of the factors, degree of similarity, proximity of products, and likelihood of bridging the gap, the marks are identical which leans towards a likelihood of confusion. The strength of the mark is obviously strong, as it has attracted the loyalty of the international consumer. As mentioned above, companies using the identical trademark on different products have an unfair competitive edge, which may resemble bad faith in adopting/using the mark. There is evidence of actual confusion, as international consumers have purchased products and received something they were neither expecting nor wanting. The sophistication of the consumer is perhaps the only factor that does not weigh heavily in favor of likelihood of confusion in that international travelers might be savvy enough to know that products might differ from country to country. However, it is the last factor, the quality of the product, which pushes the scale

¹⁰⁰ Sung Yang, Note, *Staking a Claim in Cyberspace: An Overview of Domain Name Disputes*, 36 WILLAMETTE L. REV. 115, 123 (2000).

⁹⁹ See discussion supra Part III.A.

¹⁰¹ See Polaroid Corp. v. Polarad Elecs. Corp., 287 F.2d 492 (2d Cir. 1961) (considering the likelihood of confusion between Polaroid's POLAROID mark and Polarad Electronics' POLARAD ELECTRONICS mark).

¹⁰² The Second Circuit has recognized initial interest confusion as part of the likelihood of confusion analysis. *See* Mobil Oil Corp. v. Pegasus Petroleum Corp., 818 F.2d 254, 259 (2d Cir. 1987).

unquestionably to a likelihood of confusion. Consumers are expecting a product of a certain, desired quality when they purchase an international trademarked item, yet they receive something different.

By analyzing each of the *Polaroid* factors, it is evident that there is a likelihood confusion for international travelers when global trademarks are used on different products. A system that requires geographical indicators would put an end to this confusion, as consumers would be warned of the existence of dissimilarities and could make an informed decision to purchase. No matter the point at which the confusion is analyzed (at the point of sale or before), the harm of likelihood of confusion is present and should be addressed by a global, unified scheme.

Arguments may exist that contradict the need for expanding global trademark regulation to distinguish one's goods from one's own goods, but either the arguments crumple with logic or are dispelled with practical policy concerns. Trademark law is meant to protect not only the owner of the trademark from infringement but also the consumer from confusion. Regardless of the system implemented, global trademark regulation needs to recognize the harm of consumer confusion and remedy it by providing the consumer with the requisite knowledge for making an informed international purchase.

IV. CONCLUSION

In evaluating whether trademark regulation should be expanded at the global level, we explored three broad categories of trademarks: pharmaceutical trademarks, service marks, and traditional trademarks.

Pharmaceutical trademarks present the strongest argument for global expansion because confusion at the point of sale poses the most severe risks to misled consumers. To prevent disastrous results, manufacturers, nations, and regulatory agencies should lead the push toward a global marketing authorization framework that would serve as a prerequisite to trademark registration in all nations.

Service marks present the weakest argument because recognition of service marks is not closely tied to the point of sale. Retail and restaurant service marks may attract consumers to trademark owners' establishments, but consumers still have the opportunity to inspect the goods, read the menu, or ask customer service personnel clarifying questions before making a purchase decision. Thus, international regulation of service marks is unnecessary.

Traditional trademarks present compelling arguments for global expansion of trademark regulation when the quality of the

product varies by geographic region. Trademark owners should not be able to benefit from consumers' preconceived expectations of quality at the point of sale when the actual quality of the product is noticeably different from a product with the same brand name marketed in a different country. A plausible remedy to this problem is for member nations to ratify a modification to TRIPS requiring companies to place geographic indicators on products when quality varies by region. These indicators would identify every region where the trademarked product is identical to the product contained in the package, so traveling consumers will recognize before purchase whether the quality of the product is identical to or different from the quality of the product sold under the same trademarked name in their native regions.

As commerce and travel become increasingly global, so must the laws and policies that regulate these industries. Authorities must recognize that the scope of trademark law includes protecting traveling consumers. The European Union has paved the way to international consumer protection by expanding trademark policies to encompass an entire region. Now global authorities must continue this trend by designing laws that protect consumers who reside in all regions of the world and travel between them.