Big Tobacco Blows Smoke on Public Health Initiatives: Using Trademark Law to Prevent International Changes to Cigarette Packaging

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I. INTRODUCTION

In June 2009, President Barack Obama signed the Family Smoking Prevention and Tobacco Control Act. This legislation was a bipartisan effort in both houses of Congress, and was hailed by Obama as allowing "the scientists at the FDA to take . . . common-sense steps to reduce the harmful effects of smoking."[1] Among other things that this legislation accomplished, it gave the U.S. Food and Drug Administration ("FDA") authority to regulate the warning labels used by tobacco companies more than ever before. The FDA decided to require nine color graphic warning labels to be attached on a rotating basis to all cigarette packages and advertising.[2] Various aspects of the FDA's regulations have been challenged in the years since 2009, slowing any effective progress. However, progress globally may lend support for a renewed surge to protect public health, despite challenges by tobacco companies in national and international forums.

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1. Press Release, The White House, Office of the Press Secretary, Remarks by the President at the Signing of the Family Smoking Prevention and Tobacco Control Act (June 22, 2009) (noting that the legislation "will not ban all tobacco products, and it will allow adults to make their own choices. But it will also ban tobacco advertising within a thousand feet of schools and playgrounds. It will curb the ability . . . to market to our children by using appealing flavors," and will force tobacco companies "to more clearly and publicly acknowledge the harmful and deadly effects of the products they sell."), https://www.whitehouse.gov/the_press_office/Remarks-by-the-President-at-the-signing-of-the-family-smoking-prevention-and-tobacco-control-act.

2. Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 201(d) (2009).

The United States has been struggling with the tobacco industry for several years over changing the warning labels required on cigarette packages. This fight is indicative of the larger global struggle between countries' governments and tobacco companies on how to promote public health policies by changing the packaging of cigarettes. A large argument that the industry has been clinging to on an international scale is how its intellectual property, specifically its trademarks and branding, is being harmed due to changes to cigarette packaging. How this fight is regulated and resolved globally may provide guidance for how the policymakers in the United States can resolve the issue at home.

The tobacco industry is using trademark law as a legal weapon for brand protection, rather than to protect the principles of consumer confusion and unfair competition that provide foundation for the law in the United States and elsewhere. Moving forward past the legal challenges to the 2010 FDA's proposed rules to implement the Family Smoking Prevention and Tobacco Control Act, the FDA should consider the successes and failures of countries around the world to implement similar legislation in order to anticipate and hopefully avoid most future challenges. By examining Australia's plain packaging laws, case studies of other countries that implement graphic warning legislation, and the United States' specific litigation troubles, recommendations for how the FDA should act going forward become much clearer.

II. AUSTRALIA AND PLAIN PACKAGING

In 2011, the Australian Parliament passed the Tobacco Plain Packaging Act. The first of its kind, this legislation required that all tobacco packaging sold in Australia needed to conform to plain packaging standards, or packaging without any advertisements, branding, or colors.[3] These standards include, among other requirements, that cartons of cigarettes sold be stripped completely of their branding, save the brand name and variant name (i.e. Marlboro Light), though in a standardized font, size, and color.[4] The cigarette packages are also required to be free of a tobacco company's logo or picture trademarks. In lieu of the trademarked brands, the packages must have an olive-brown background color, and contain text and picture health warnings about the hazards of cigarettes that take up 82.5% of the total package area.[5]

3. *See Tobacco Plain Packaging Act 2011* (Cth) § 18 (Austl.).

4. *Id.* §§ 20(2), 21.

5. *Id.* §§ 18-21; *see also* CANADIAN CANCER SOC'Y, CIGARETTE PACKAGE HEALTH WARNINGS: INTERNATIONAL STATUS REPORT 2 (2014).

This landmark legislation provoked strong reactions around the world from those who were for and against its passage.[6] Australia's plain packaging reform was the first of its kind in the world,[7] and as such, there were many differing views to contribute. The main cry of those who were against the implementation of the Act, mostly tobacco companies and their affiliated farmers and distributors, argue that plain packaging is not more likely to prevent adolescents from smoking, persuade current smokers to quit, or promote health warnings more effectively. More effectual alternatives to plain packaging suggested by the industry includes youth smoking prevention programs, tackling the tobacco "black market," and strengthening minimum-purchasing-age laws. Further, they argue that tobacco companies are more likely to be targeted by counterfeiters due to the lack of branding on cigarette packages, that consumers will be confused as to source of origin of the packs, and that there are additional unnamed damages to the cultivated brand of each tobacco company.[8]

On the other side, many plain packaging advocates scoffed at the arguments of the tobacco companies and pointed to the myriad of benefits that would be conferred. Following the World Health Organization ("WHO")'s Framework Convention on Tobacco Control in 2003, many member countries were encouraged to adopt plain packaging in order to "increase the noticeability and effectiveness of health warnings and messages, prevent the package from detracting attention from them, and address industry package design techniques that may suggest that some products are less harmful than others."[9] In addition to the public health policy arguments, proponents of plain packaging also dismissed the tobacco industry's intellectual property arguments. The proponents said that tobacco manufacturers would still be able to distinguish their products from

6. *Compare*, *e.g.*, Enrico Bonadio, *Plain Packaging Does Not Violate Big Tobacco's Intellectual Property Rights*, CONVERSATION (Mar. 16, 2015, 2:22 AM), http://theconversation.com/plain-packaging-does-not-violate-big-tobaccos-intellectual-property-rights-38802, *with Plain Packaging: Stripping Branding Strips Our Rights*, BRIT. AM. TOBACCO, http://www.bat.com/plainpackaging (last visited Apr. 6, 2015) (detailing the pro-plain packaging advocates arguments and the anti-plain packaging advocates arguments on if plain packaging strips tobacco companies of their intellectual property).

7. COMMONWEALTH OF AUSTRALIA, TAKING PREVENTATIVE ACTION – A RESPONSE TO AUSTRALIA: THE HEALTHIEST COUNTRY BY 2020, THE REPORT OF THE NATIONAL PREVENTATIVE HEALTH TASKFORCE 10, 62 (2010).

8. Bonadio, *supra* note 6; *see also Health Warning Labels*, PHILIP MORRIS INT'L, http://www.pmi.com/en_cz/tobacco_regulation/regulating_tobacco_products/health_warning_labels/pages/health_warning_labels.aspx (last visited Apr. 6, 2015).

9. World Health Org. [WHO] Framework Convention on Tobacco Control, *Guidelines for Implementation of Article 11 of the WHO Framework Convention on Tobacco Control (Packaging and Labelling of Tobacco Products)*, FCTC/COP3(10) (Nov. 22, 2008).

competitors as the brand name may still be used, and that trademark registrations merely confer the right to prevent counterfeiters from copying rather than allowing the positive right to use a mark at all (as this comes just from starting a business and using the mark in the course of trade).[10] They also argued that a government that introduces this measure is not acquiring the intellectual property of tobacco companies, but prohibiting the promotional branding on packaging for public health purposes.[11]

These arguments and debates provide a framework for the challenge in the High Court of Australia of the Tobacco Plain Packaging Act brought by British American Tobacco, Imperial Tobacco Australia Limited, Philip Morris, and Japan Tobacco International [hereinafter "the Tobacco Coalition"]. This lawsuit effectively set the stage for what arguments the tobacco industry at large could bring against plain packaging worldwide.

A. Australian High Court Case

In April 2012, the High Court of Australia heard argument for three days from the Tobacco Coalition and Commonwealth's solicitor-general on whether or not the 2011 Tobacco Plain Packaging Act violated Australia's Constitution.[12] The High Court did not release its decision until August 2012, and did not post the reasons for its decision until even later, in October 2012.[13] The oral arguments were packed with lawyers for each side, with members of the public and the media looking on to hear the case that could either jumpstart the promulgation of plain packaging of tobacco products worldwide, or bring it to a screeching halt.

The Tobacco Coalition's arguments followed along the lines of what anti-plain packaging advocates voiced prior to the case, revolving around the central argument that requiring plain packaging amounted to an acquisition of property. This view of property under the Australian Constitution is a broad one, wherein property includes all forms of intellectual property in relation to the Tobacco Coalition's packaging.[14]

10. *See* Bonadio, *supra* note 6.

11. *Id.*

12. Hearing Transcripts 91-93 (Apr. 17-19, 2012), *JT Int'l SA v. Commonwealth*; *British American Tobacco Australasia Ltd. v. Commonwealth* (2012) 250 CLR 1 (Austl.).

13. Dan Taglioli, *Australia High Court Upholds Tobacco Plain-Package Law*, JURIST (Oct. 5, 2012, 10:21 AM), http://jurist.org/paperchase/2012/10/australia-high-court-upholds-tobacco-plain-package-law.php.

14. Matthew Rimmer, *Cigarettes Will Kill You: The High Court of Australia & Plain Packaging of Tobacco Products*, WIPO MAG. (Feb. 2013) (including "trademarks, patents, designs, copyright, and protection against passing-off" as part of the intellectual property at stake), http://www.wipo.int/wipo_magazine/en/2013/01/article_0005.html.

The lawyers arguing for the Tobacco Coalition believed that "the IP rights of tobacco companies had been extinguished, or at least severely impaired."[15] The Coalition also argued that there should be a distinction between graphic health warnings and plain packaging, which was phrased as "excessive regulation," and believed that tobacco companies should be compensated for putting public health advertisements on their products.[16]

There were many who criticized the arguments of the Tobacco Coalition. One commentator even called the arguments "about acquisition of property . . . synthetic and unreal."[17] However, there were also those that supported the views of the Tobacco Coalition, and believe that if this decision were to come down against the Coalition that it would set a dangerous precedent for intellectual property owners on a broader scale about what the government could feasibly take.[18]

On the side of the Commonwealth, the Solicitor-General argued that this was no different from any other information standard for products in the course of trade, and that the legislation was directed to reducing the public health harm that is caused by using tobacco products.[19] Plain packaging was meant only to be the next step in the process of regulating tobacco products, and trademarks should be subject to a prohibition on use to prevent harm to the public health.[20] In fact, the 1994 Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS") recognizes that members may need to regulate in certain ways in order to protect public health.[21] Finally, the Solicitor-General argued that it would go "beyond the requirements of any reasonable notion of fairness" to compensate the tobacco companies for the use of the warnings.[22]

15. *Id.*

16. *Id.*

17. *Id.*; *see also* Matthew Rimmer & Stephen Stern, *Who Won the Argument Over Plain Packaging?*, MANAGING INTELL. PROP., June 2012, at 56, 57.

18. *See* Rimmer & Stern, *supra* note 17, at 58 ("As for intellectual property, software could be taken and argued by the government to be necessary for defence uses, patents for pharmaceuticals could be exploited by the government for the purposes of providing drugs to plague-ridden areas or to soldiers on active duty, designs for the construction of armed vehicles could be used without royalties by the government if the safety of soldiers could be arguably justified.").

19. *See* Rimmer, *supra* note 14.

20. *Id.*

21. Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 8, Apr. 15, 1994, 33 ILM 81, http://www.wipo.int/wipolex/en/other_treaties/text.jsp?file_id=305736 ("Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition . . . provided that such measures are consistent with the provisions of this Agreement.").

22. *See* Rimmer, *supra* note 14.

Several months later, the High Court ruled against the Tobacco Coalition.[23] A few months following that ruling, the High Court issued its reasons for the decision. A majority of six to one rejected that the Tobacco Plain Packaging Act constituted an acquisition of the Tobacco Coalition's property under the Australian Constitution.[24] As one commentator put it, "the majority judges variously described the case of the tobacco companies as 'delusive', 'synthetic', 'unreal', and suffering 'fatal' defects in logic and reasoning."[25] The Justices seemed to break their reasons into three major sources: public health, intellectual property, and constitutional law.

In terms of public policy, one of the majority Justices noted that plain packaging is the latest control measure in a long line of such measures in the tobacco industry, and another Justice recognized that this law gave effect to Australia's obligations as a party to the WHO Framework Convention on Tobacco Control.[26] In terms of intellectual property law, the majority stressed that this kind of law is meant to serve public policy objectives rather than the private interests of the rights holder. Some of the Justices noted that a trademark conferred is not a pass to use that mark free from restraints of other laws, and that trademark legislation in Australia has manifested an accommodation of both commercial and public interests.[27] Justice Crennan said that the aim of trademark law as used by the Tobacco Coalition, and what they strenuously objected to and considered taking of property, was the "advertising or promotional functions of [the Coalition's] registered trademarks or product get-up, which functions were prohibited by the Packaging Act."[28] In terms of constitutional law, the High Court followed its precedents on intellectual property and constitutional law by ruling that the Commonwealth does not acquire any interest in property through the Tobacco Plain Packaging Act. Judge Kiefel pointed out that the point of the Act is to dissuade people from using tobacco products, and that "if that object were to be effective the [Tobacco Coalition's] businesses

23. Order, *JT Int'l SA v. Commonwealth; British American Tobacco Australasia Ltd. v. Commonwealth*, (2012) 250 CLR 1 (Austl.), http://www.hcourt.gov.au/assets/publications/judgment-summaries/2012/projt-2012-08-15.pdf.

24. *JT Int'l SA v. Commonwealth; British American Tobacco Australasia Ltd. v. Commonwealth*, (2012) 250 CLR 1, 133 (Austl.), http://www.austlii.edu.au/au/cases/cth/HCA/2012/43.html.

25. Rimmer, *supra* note 14.

26. *JT Int'l SA*, (2012) 250 CLR at 92, 114-17 (paraphrasing the opinions of Justices Kiefel and Crennan), http://www.austlii.edu.au/au/cases/cth/HCA/2012/43.html.

27. *Id.* at 27, 42 (paraphrasing the opinions of Justices French and Gummow).

28. *Id.* at 102.

may be harmed, but the Commonwealth does not thereby acquire something in the nature of property itself."[29]

This ruling has had a long reach in terms of bringing tobacco packaging reform to the forefront of many countries' public health policy agendas.[30] It may embolden other countries, like Canada and South Africa, which have had similar stances to Australia on tobacco reform, to move forward with plain packaging as well. It can serve as a roadmap for how a country may successfully pass such an act despite pressure from major international tobacco companies. It also shows that the tobacco industry may not be so successful going forward with arguments on intellectual property takings.

B. World Trade Organization Pending Disputes

The tobacco industry is not the only party to be concerned with Australia's Tobacco Plain Packaging Act. There are currently five disputes awaiting final reports from the World Trade Organization ("WTO"): one request from Ukraine in March 2012;[31] one request from Honduras in April 2012,[32] one request from the Dominican Republic in July 2012,[33] one request from Cuba in May 2013,[34] and one request from Indonesia in September 2013.[35] These requests for consultation all challenge Australia's Act, and all allege essentially the same thing: that this law is inconsistent with Australia's obligations under several articles of TRIPS, a few articles of the Technical Barriers to Trade Agreement ("TBT"), and an article of the

29. *Id.* at 132.

30. *See infra* Part II.C.

31. Request for Consultations by Ukraine, *Australia – Certain Measures Concerning Trademarks and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, WTO Doc. WT/DS434/1 (Mar. 15, 2012).

32. Request for Consultations by Honduras, *Australia – Certain Measures Concerning Trademarks and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, WTO Doc. WT/DS435/1 (Apr. 10, 2012).

33. Request for Consultations by the Dominican Republic, *Australia – Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, WTO Doc. WT/DS441/1 (July 23, 2012).

34. Request for Consultations by Cuba, *Australia – Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, WTO Doc. WT/DS458/1 (May 7, 2013).

35. Request for Consultations by Indonesia, *Australia – Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, WTO Doc. WT/DS467/1 (Sept. 25, 2013).

1994 General Agreement on Tariffs and Trade ("GATT 1994").[36] Some of the arguments put forward by these countries for challenging Australia's Act include that it would hurt tobacco farmers in small, vulnerable economies, that counterfeiting of a tobacco company's brand will be much easier, and that the measure will not actually reduce smoking because plain packaging will cause the prices of cigarettes to drop and even out the market, leading to higher consumption by consumers. There are a large number of countries that have reserved their third-party rights in these disputes, representing developed and developing countries, and countries that primarily grow the products in addition to countries that manufacture and sell the products.[37]

These disputes were considered together. A panel was composed on May 5, 2014, and on October 10, 2014, the Chair of the Panel informed the dispute settlement body that it would issue its final reports not before the first half of the year 2016.[38] As such, interested parties have no reports, panel, or appellate body proceedings at the WTO to try and determine how the WTO panel will respond to these disputes. However, the outcome of the major challenge to the law in Australia, in addition to the fact that the tobacco industry pressure has not stopped other countries from considering similar laws, is likely to factor into a decision by the WTO Panel. Until then, it can only be speculated what will happen and how much effect it will have on the momentum already created for plain packaging reform in the past three years.

C. International Movements to Plain Packaging

Prior to Australia implementing the Tobacco Plain Packaging Act in 2011, there were some international attempts to instigate plain packaging regulations. In 1989, New Zealand's Department of Health suggested that

36. *See supra* notes 31-35. The specific articles claimed to be inconsistent with Australia's laws are Articles 2.1, 3.1, 16.1, 16.3, 20, 22.2(b), and 24.3 of TRIPS, Articles 2.1 and 2.2 of the TBT, and Article III:4 of the GATT 1994.

37. Countries that have asserted third party rights include: Brazil, Canada, China, the EU, Guatemala, India, Japan, Korea, Malaysia, Mexico, New Zealand, Nicaragua, Norway, Oman, the Philippines, the Russian Federation, Chinese Taipei, Thailand, Turkey, the United States, Uruguay, Zimbabwe, Peru, Singapore, Argentina, Chile, Malawi, and Nigeria. *See* WORLD TRADE ORG. [WTO], ANNUAL REPORT 2015: DISPUTE SETTLEMENT 96-98, https://www.wto.org/english/res_e/booksp_e/anrep_e/anrep15_chap6_e.pdf (last visited Nov. 22, 2016).

38. *See* WORLD TRADE ORG. [WTO], TIMELINE - WHERE IS THE PLAIN PACKAGING ISSUE IN THE WTO? (Feb. 25, 2015), https://www.wto.org/english/news_e/news14_e/timelinetobacco_e.pdf.

cigarettes be sold in white packs with simple text, and no colors or logos.[39] In 1994, the Canadian House of Commons Standing Committee on Health suggested plain packaging should be including in legislation once further research was done on the effectiveness of the packaging.[40] However, both of these recommendations lost steam and were subsequently dropped from the policy agendas.[41]

Australia opened the floodgate to a host of countries considering plain packaging reform. This consideration can be so little as requesting new studies and evidence on the effectiveness of plain packaging, to so far as actually introducing laws. In February 2014, the European Commission revised the European Union ("EU") Tobacco Products Directive.[42] The Directive mandates more stringent regulations for member states regarding how cigarette packages look. At the minimum, the packs will need to have "picture and text health warnings covering 65% of the front and the back of cigarette packs – to be placed at the top edge."[43] These are typically referred to as "graphic warnings," where there are text and picture warnings covering a good portion of the package, but there is room remaining for a tobacco company's unique brand. While the Directive allows for space to remain available for the tobacco companies to brand their products, it does not stop Member States from going further if they choose:

> The new Directive specifically allows Member States to introduce further measures relating to standardisation of packaging – or plain packaging – where they are justified on grounds of public health, are proportionate, and do not lead to hidden barriers to trade between Member States.[44]

The Directive essentially gives a green light to EU member states to introduce legislation mandating plain packaging of cigarettes, so long as the three conditions quoted above can be justified.

Several EU countries have decided to do just as the Directive allows. In early March 2015, Ireland became the first country in the EU to pass plain packaging legislation.[45] It instituted very similar regulations to Australia, stripping the package of a company's branding save a

39. Andrew D. Mitchell, *Australia's Move to the Plain Packaging of Cigarettes and Its WTO Compatibility*, 5 ASIAN J. WTO & INT'L HEALTH L & POL'Y 405, 411 (2010).

40. *Id.*

41. *Id.*

42. Press Release, European Commission, Questions & Answers: New Rules for Tobacco Products (Feb. 26, 2014), http://europa.eu/rapid/press-release_MEMO-14-134_en.htm.

43. *Id.*

44. *Id.*

45. Henry McDonald, *Ireland Passes Plain Packaging Bill for Cigarettes*, GUARDIAN (Mar. 3, 2015, 2:56 PM), http://www.theguardian.com/world/2015/mar/03/ireland-passes-plain-packaging-bill-cigarettes-smoking-tobacco.

standardized font brand name and variant name, included standardized colors, and had rotating picture and text health warnings. Only a couple of weeks later, the United Kingdom ("UK") joined Ireland and Australia in passing legislation.[46] Both the UK and Irish laws are slated take effect in May 2016.[47] In addition, Norway has publicly announced a consultation on plain packaging, and has reached out to Australia for guidance. Initial discussions are also taking place in South Africa, Panama, France, Burkina Faso, New Zealand, and Turkey.[48] It is obvious that many of the world's developed nations, and even some developing nations, are emboldened by Australia's success thus far, and not all are persuaded or cowed by the tobacco industry's furious and heavy-handed response with increased lobbying and lawsuits.

Japan Tobacco International ("JTI") maintained from a start that there would be a vigorous challenge to the Ireland legislation.[49] It follows that the UK and other countries considering enacting legislation will be up against lawsuits and forceful lobbying efforts from JTI and others heavy hitters in the tobacco industry. Dr. James Reilly, the Irish Minister for Children, stated that even at the EU parliament level that "members . . . complained that the scale of lobbying on this directive was unprecedented," and that once the arena moved back to Ireland that the legislature was "lobbied on a scale that Irish politics had never seen before."[50] The Irish law has since been challenged by JTI, and the case is currently pending in the Commercial Court of Ireland on trade obstacle claims, with other substantive intellectual property and freedom of expression claims being reserved by JTI at this time.[51]

46. World Health Org. [WHO] Framework Convention on Tobacco Control, *Global Domino Effect in Implementing Plain Packaging*, http://www.who.int/fctc/mediacentre/news/2015/ukplainpack/en (last visited Nov. 2, 2015).

47. *Id.*

48. Nick Miller, *As Europe Adopts Australia's Plain Packaging Reforms, Big Tobacco Fights Back*, SYDNEY MORNING HERALD (Mar. 22, 2015), http://www.smh.com.au/world/as-europe-adopts-australias-plain-packaging-reforms-big-tobacco-fights-back-20150319-1m3bwk.html.

49. McDonald, *supra* note 45 ("A spokesperson for JTI said that plain packaging is a disproportionate, unjustified and unlawful measure" and "warned that it will go to court to challenge the new law.").

50. Miller, *supra* note 48.

51. *Plain Cigarette Packaging Case Adjourned in High Court*, IRISH TIMES (Apr. 13, 2015, 2:06 PM) ("JTI contends, because harmonisation of labelling and packaging is a stated objective of the EU directive, a member state cannot adopt national measures which further restrict the free movement of goods on grounds of a high level of protection for human health."), http://www.irishtimes.com/business/plain-cigarette-packaging-case-adjourned-in-high-court-1.2174026.

This is likely only the beginning of the challenges that will come to both Ireland and the UK, and other countries that follow suit in the coming months. However, such movement may create a domino effect that will both put pressure on countries to update their tobacco regulations and laws as well as give them a safer, more established route to follow in doing so.

III. INTERNATIONAL GRAPHIC PICTORIAL WARNING PACKAGING

While plain packaging is the newest kind of tobacco health warning regulation happening on an international scale, many other countries have been implementing other kinds of warnings on packaging for years. The most effective, up until the advent of plain packaging in Australia, are graphic pictorial warnings. As discussed,[52] these warnings typically take up a percentage of the cigarette pack and include text and picture health warnings, with the pictures usually consisting of a graphic representation of the health hazards of smoking. The percentage of the pack taken up varies country to country, with some of the highest covering 85% of the total package.[53] These warnings rotate messages, much like plain packaging warnings do. The main difference is that the rest of the package is left for the tobacco company to include their branding, which usually consists of the brand name and variant name in a stylized font, sometimes a logo, and company-specific color schemes.

Examining some of the countries in the world that require the strictest graphic warnings, and the challenges they have faced from the tobacco industry, is also illustrative of how tobacco companies protect their brand and their products, and what may work for a country attempting to implement this kind of regulation. A 2014 Canadian study reports that by September 2014, seventy-seven countries and jurisdictions have picture warnings (including Australia's plain packaging), an increase from the fifty-five countries and jurisdictions with warnings at the end of 2012.[54] Sixty of these countries or jurisdictions require that the warnings cover at least half of the total package area.[55] Several of the countries that have the largest warnings have also encountered the largest resistance from the tobacco industry, and a country wishing to implement any kind of picture warning

52. *Supra* Section II.B.

53. *See* CANADIAN CANCER SOC'Y, *supra* note 5, at 2 (detailing the top countries in terms of warning size percentages for the combined space on the front and the back of a cigarette package, with Thailand requiring 85% of the package to be covered in warnings).

54. *Id.*

55. *Id.*

regulation on tobacco products would be wise to see how these countries were successful, and where their efforts need improvement.

A. Thailand

As of September 2014, Thailand requires the largest amount of graphic warning labels on tobacco products in the world. The labels must cover an average of 85% of the package, with 85% of the front and of the back covered.[56] Thailand first instituted graphic warnings in 2005, and the size of the warnings has grown in the ten years since as the regulations are updated.[57] The largest jump was from the 2010 regulations, which required 55% of the total package be covered, to the current 2014 regulations that require 85%.[58] The warnings take up the top portion of the package, leaving the bottom for the branding of tobacco companies. Those involved in public health took notice and applauded Thailand's Health Ministry, but they were not the only ones who saw the changes. The tobacco industry also took notice, and subsequently challenged the new regulations.[59]

The regulations were set to go into effect on October 2, 2013, but were stalled in August of that year due to legal action taken by three of the world's largest tobacco companies, headed by Philip Morris.[60] Philip Morris and the other companies sought an injunction in the Administrative Court, leaving the regulation hanging while both parties argued their cases and waited for a judgment. This was especially shocking, given that many Thai legal scholars and professors said this kind of legal action against the Thai Ministry of Public Health is unprecedented, with this being the first time the Ministry has ever had to defend itself in court for its regulations, and the first case in the history of tobacco control in Thailand at all.[61] The tobacco companies argued that the regulations were "not only illegal, but also unnecessary, given that the health risks of smoking are universally known in Thailand."[62] Most of the arguments for illegality are the familiar ones used by the industry: that the Ministry "exceeded its power," that it "failed to consult thousands of retailers and manufacturers" before implementing the legislation, and, of course, that it "impaired the ability of

56. *Id.*

57. *Id.* at 3.

58. *Id.* at 2.

59. Ron Corben, *Tobacco Industry Challenges Thai Government*, DEUTSCHE WELLE – BANGKOK (Oct. 14, 2013), http://www.dw.de/tobacco-industry-challenges-thai-government/a-17156836.

60. *Id.*

61. *Id.*

62. *Id.*

manufacturers and importers to use their trademarks to differentiate their products."[63] The second argument of consultation is especially interesting in the context of relations between the industry and the Thai government, given that the norm for the Ministry of Health is to do just what it did: create regulations, enact them, and expect for the affected industry to comply.[64]

Australia backed the Thai government's move, and voiced concern that countries around the world needed to stand up to the tobacco companies' bullying tactics. Jonathan Liberman, an Australian lawyer and expert on anti-tobacco legislation, said:

> Countries have to defend these measures against these legal claims and legal threats that are brought by the tobacco industry. It tries to intimidate governments and sue them, rather than just allow them to implement the measures that will reduce death and disease and the enormous social and economic costs. The government[]s can't be intimidated [–] there's too much at stake.[65]

Ten months following the preliminary injunction obtained in August 2013, the injunction was overturned.[66] Even as recent as early 2015, the tobacco companies and their supporters cautioned that the restriction on advertising and the placement of the branding on packages in Thailand encroached on the intellectual property rights of the companies.[67]

A draft law was signed on November 24, 2014, by the Thai Ministry of Public Health that is mostly the same as the law passed in 2010, which contains language that says, "the law on intellectual property shall not apply to the display of the Package under this Section."[68] How this law will be

63. *Id.*

64. Ron Corben, *Thailand's Health Ministry Battles Big Tobacco Over Graphic Health Warnings*, VOICE AM. (Oct. 8, 2013, 9:13 AM), http://www.voanews.com/content/thailands-health-ministry-battles-big-tobacco-over-graphic-health-warnings/1765216.html (quoting Pokpong Srisanit, a Thammasat University law professor who said "[w]hen the Ministry of Public Health announce a new regulation normally the big company and the small tobacco company obey the regulation."); *see also* Corben, *supra* note 59 ("Professor Pokpong] said in the past when new regulations were introduced by the ministry, the tobacco companies, after some debate, 'but never in court,' would adopt new measures.").

65. Corben, *supra* note 64.

66. Alan Adcock, *Regulatory Impingement of Intellectual Property Rights in Thailand*, LEXOLOGY (Mar. 26, 2015), http://www.lexology.com/library/detail.aspx?g=67fd1efb-3e76-4cf9-80b8-9e3f6a6951d0; *see also Thailand*, TOBACCO LABELLING RESOURCE CTR., http://www.tobaccolabels.ca/countries/thailand (last visited April 22, 2015) (explaining that in June 2014, the law was approved in a Thailand court, and that retailers were given until September 2014 to comply).

67. *See* Adcock, *supra* note 66.

68. *Id.* (quoting Draft Section 37 of the Thai draft law, the Tobacco Products Control Act).

received is yet to be determined, as it is currently circulating the Ministries of the Thai government for comments.[69] However, it is likely poised to consider following Australia down the plain packaging route should this language remain in the finalized law.

B. Uruguay

Uruguay requires tobacco packages to be 80% covered with graphic warnings, averaging 80% on both the front and the back.[70] Implementation of picture and text warnings began in 2006, but it has been updated six times since then, with the size of the warnings growing until it reached the current size in 2010.[71] In March 2010, Philip Morris International fought this 30% increase in warning label size with a multi-billion dollar lawsuit.[72] This lawsuit differed from those brought in Thailand and Australia because the claim was brought to an international forum, the World Bank's International Center for Settlement of Investment Disputes, and it claimed violations of a bilateral treaty between Uruguay and Switzerland, where Philip Morris is headquartered.[73]

Philip Morris complained about two specific measures implemented by these 2010 regulations: the increase of the warnings from 50% to 80% of the total pack size and that companies would be forced to sell only one variation of cigarettes per brand, essentially forbidding labeling cigarettes as light or mild, or using colors to designate these labels without actually saying it on the pack.[74] The treaty that was alleged to be violated is meant to protect investments that Switzerland has made into Uruguay, including with brands, intellectual property, and ongoing business enterprises.[75] The violation allegedly stems from having to remove seven out of twelve varieties of cigarettes for sale in the country, and because the packages "[leave] virtually no space on the pack for the display of the legally

69. *Id.*

70. *See* CANADIAN CANCER SOC'Y, *supra* note 5, at 2.

71. *See id.* at 3; *see also Uruguay*, TOBACCO LABELLING RESOURCE CTR., http://www.tobaccolabels.ca/countries/Uruguay (last visited April 22, 2015).

72. *See Philip Morris vs the Government of Uruguay*, TOBACCOTACTICS, http://www.tobaccotactics.org/index.php/Philip_Morris_vs_the_Government_of_Uruguay (last visited Apr. 22, 2015).

73. *Id.* (claiming that the Switzerland-Uruguay Bilateral Investment Treaty was violated by Uruguay).

74. *Uruguay Bilateral Investment Treaty (BIT) Litigation*, PHILIP MORRIS INT'L, http://www.pmi.com/eng/media_center/company_statements/pages/uruguay_bit_claim.aspx (last visited April 22, 2015).

75. *Id.*

protected trademarks."[76] The trademark concerns reflect many of the others used in other litigation tactics around the world: basically that there is no room for display of the trademarks, and that it does not address and may actually promote black market cigarettes.[77] The difference between these classic trademark arguments and those brought in Australia and Thailand is that they are viewed in the lens of a bilateral trade agreement, where the focus is kept on investments and capital lost as a direct result of these measures.

Another part of what makes this litigation different from what was done in Australia and Thailand is that it is not being brought in a domestic court, and as such the costs of the suit itself are astronomical. The damages being sought are also extremely high, with Philip Morris asking for $25 million US dollars for actual damages caused by the disregard Uruguay allegedly is giving to investors by not "[keeping] the promises it makes."[78] The idea that a company that makes revenues that almost double the GDP of the country it is taking up litigation against could ask for such a large amount of damages is staggering.[79] However, one commentator speculated that Philip Morris brought this suit as a wider strategy to oppose the plain packaging movement by making "an example of Uruguay, because [Philip Morris] likely believes that [Uruguay] may not have the resources or expertise available to put on the best possible defence, and because Uruguay is an acknowledged world leader in tobacco control."[80]

Currently, the suit is still pending at the World Bank, but despite this, Uruguay continued to implement these and other tobacco control measures.[81] The Pan American Health Organization and the World Health Organization are strongly supporting Uruguay's efforts—as is Michael Bloomberg, strangely enough. While it is unclear what the outcome may be here, it is obvious that the tobacco industry is attempting to make an

76. *Id.*

77. *Id.*

78. *Id.*

79. Claudio Paolillo, *Part III: Uruguay vs. Philip Morris: Tobacco Giant Wages Legal Fight Over South America's Toughest Smoking Controls*, CTR. FOR PUB. INTEGRITY (Nov. 15, 2010, 1:26 AM), http://www.publicintegrity.org/2010/11/15/4036/part-iii-uruguay-vs-philip-morris ("In 2009, Uruguay's GDP was $32 billion, while Philip Morris's revenues that year hit $62 billion.").

80. TODD WEILER, PHYSICIANS FOR A SMOKE FREE CANADA, PHILIP MORRIS VS. URUGUAY: AN ANALYSIS OF TOBACCO CONTROL MEASURES IN THE CONTEXT OF INTERNATIONAL INVESTMENT LAW 17 n.54 (2010), http://www.smoke-free.ca/eng_home/2010/PMIvsUruguay/Opinion-PMI-Uruguay.pdf.

81. *PAHO/WHO Supports Uruguay in Defending Tobacco Control Policies Against Tobacco Industry Challenge*, PAN AM. HEALTH ORG. (Nov. 5, 2014), http://www.paho.org/Hq/index.php?option=com_content&view=article&id=10179%3Apahowho-supports-uruguay-in-defending-tobacco-control-policies-against-tobacco-industry-challenge&Itemid=1926&lang=en.

example out of Uruguay, but it is commendable that the country is not bowing to the pressure despite the financial risk the arbitration poses. This could turn into an avenue of pursuit for the tobacco companies should the World Bank rule that Uruguay violated the bilateral treaty with the Swiss, as many other countries are party to such agreements with Switzerland and the home countries of the other major international tobacco companies.

C. Canada

Canada ties for fourth with Brunei and Nepal for having the fourth-highest total percentage of graphic warnings required on tobacco packages, coming in at 75%.[82] Despite not having the largest percentage of graphic warnings, Canada was the first country in the world to implement picture-based health warnings on cigarette packages, which went into effect in 2001.[83] The regulations required half of the packages to be covered with rotating pictoral and text graphic warnings, leaving the other half for tobacco branding. This was raised to the current 75% total coverage level in 2011, with implementation in 2012.[84]

Canada has had discussions of implementing plain packaging before, and remains a leader on conducting research on the implementation and effectiveness of graphic warnings and plain packaging worldwide.[85] Like other countries that are recognized world leaders in tobacco control, the laws that have been implemented controlling how tobacco companies can advertise and how cigarette packages can look have been challenged by the industry. The 1997 Tobacco Act banned tobacco sponsorship, restricted the way that cigarettes were advertised, and required large warnings on packages.[86] Originally brought to the Quebec Superior Court in 2002 where it was upheld entirely, and reversed in part by the Quebec Court of Appeal in 2005, the law was a sweeping reform at the time.[87] The government argued that they were dealing with a tobacco epidemic and that the legislation was weak compared to laws in countries like Australia, which

82. CANADIAN CANCER SOC'Y, *supra* note 5, at 2.

83. *Canada*, TOBACCO LABELLING RESOURCE CTR., http://www.tobaccolabels.ca/countries/canada (last visited Apr. 22, 2015).

84. *Id.* (noting that Canada also prohibits the terms "light" and "mild" from appearing on packages).

85. *See supra* Part II.C. Take note that many of the sources of the information and reports used here are from Canadian sources, such as the Canadian Cancer Society Report and the Tobacco Labelling Resource Centre facts.

86. *Top Court Upholds Tough Tobacco Ad Laws*, CBC NEWS (Jun. 28, 2007), http://www.cbc.ca/news/canada/top-court-upholds-tough-tobacco-ad-laws-1.654629.

87. *Id.*

had banned tobacco advertising completely at the time. The manufacturers were okay with some prohibitions on promotion, such as youth-targeted advertising, but objected strenuously to being restricted from advertising to of-age adult smokers.[88]

In a unanimous decision by the Supreme Court of Canada, the tobacco companies' argument that the 1997 law violated their right to freedom of expression was dismissed. It was said that the law and corresponding regulations were a reasonable limit that was justifiable under the Canadian Charter of Rights and Freedoms. The Chief Justice even went so far as to say that the key provisions were "constitutional in their entirety," and "nothing less than a matter of life or death for millions of people who could be affected."[89]

This is not the only challenge that Canada has faced however. In 2010, when the proposal to enlarge the graphic warnings from 50% of the total package to 75% was introduced, it was not long before the tobacco industry's lobbyists got to work. A Canadian news outlet revealed that tobacco executives were lobbying against revised labeling for years prior to the announcement, arguing that "the warnings didn't leave them enough room for branding," and that "the government should fight the sale of contraband cigarettes instead."[90] While the lobbying eventually failed, it is yet another example of the same trademark and constitutional arguments being brought by the tobacco companies. In the case of Canada, these arguments remain unpersuasive.

D. Togo

While the previous exploration of countries with picture warnings has showed a significant losing streak for the tobacco companies, there are plenty of instances where the industry has been successful. As chronicled on John Oliver's HBO show *Last Week Tonight* that aired in February 2015,[91] Philip Morris (and most likely other large international tobacco companies) have successfully intimidated countries out of imposing harsher regulations on tobacco packaging.

88. *Id.*

89. *Id.*

90. *New Tobacco Warnings Bigger, More Graphic: Tobacco Companies To Get Transition Period Once Legislation Passes*, CBC NEWS (July 29, 2011), http://www.cbc.ca/news/politics/new-tobacco-warnings-bigger-more-graphic-1.930575.

91. *See Last Week Tonight with John Oliver*, HBO (Feb. 15, 2015), https://www.youtube.com/watch?v=6UsHHOCH4q8 (last visited May 26, 2016).

Togo is tied for seventh in the world, with Turkey and Turkmenistan, for having laws in place that require 65% of the total cigarette package be covered in warnings.[92] However, unlike Turkey and Turkmenistan, these are not graphic pictorial warnings but instead text warnings in the three most common languages in Togo, implemented in September 2014.[93] The government of Togo, recognizing that as one of the world's poorest countries with a high rate of illiteracy that many of its citizens were likely unable to read the warnings, proposed adding graphic images as Australia does.[94] However, Philip Morris sent a letter threatening "an incalculable amount of international trade litigation" against Togo should it go forward with the plan to implement graphic warnings on cigarette packages.[95] Philip Morris also used language from the opinion of the lone dissenting judge in the Australian High Court decision as an apparent precedent to scare Togo into thinking that they would automatically lose any such suit.[96] According to Oliver's report, Togo, "justifiably terrified by the threat of billion dollar settlements, backed down from a public health law that many people wanted."[97]

While Togo may not have implemented the law due apparently to Philip Morris' actions, Oliver's show created a stir of negative activity in the media, forcing a response from the company.[98] The company wrote, "[w]hile we recognize the tobacco industry is an easy target for comedians, we take seriously the responsibility that comes with selling a product that is an adult choice and is harmful to health."[99] Philip Morris also noted that it complies with thousands of regulations in countries around the world, and is investing billions of dollars into finding products that have the potential to be less harmful for smokers to switch to.[100] Finally, the company asserts that "like any other company with a responsibility to its business partners,

92. CANADIAN CANCER SOC'Y, *supra* note 5, at 2, 8.

93. *See id.* at 8; Chuck Idelson, *Trade Deals Should Come With Their Own Warnings for Public Health*, NATIONAL NURSES UNITED BLOG (Feb. 18, 2015), http://www.nationalnursesunited.org/blog/entry/trade-deals-should-come-with-their-own-warnings-for-public-health.

94. *See* Idelson, *supra* note 93.

95. *See Last Week Tonight With John Oliver*, *supra* note 91; *see also* Idelson, *supra* note 93.

96. *See Last Week Tonight With John Oliver*, *supra* note 91.

97. *See id.*; Idelson, *supra* note 93 (noting that Philip Morris made $80 billion in annual revenues in 2014, while Togo's GDP for the same year was $4.3 billion).

98. *See Just the Facts, Taking Comedic License with a Selection of the Facts*, PHILIP MORRIS INT'L (Feb. 16, 2015), http://justthefacts.pmi.com/918.

99. *Id.*

100. *Id.*

shareholders and employees, we ask only that laws protecting investments, including trademarks, be equally applied to us."[101]

Many commentators are still critical of Philip Morris's response, especially of the "balanced . . . facts on the many topics raised by the program,"[102] calling it a classic non-response where Philip Morris does not address Oliver's report point by point, but still claims that the report was misleading.[103] What is apparent from the situation in Togo is that tobacco companies have applied tactics like this before to poor, developing countries, and they will likely continue to do so in the name of protecting their intellectual property and ultimately their profits.

In general, these country case studies show a pattern by the tobacco industry of lobbying, legal threats, and domestic and international suits against countries that attempt to either implement graphic warning label laws, or take regulation a step further to implement plain packaging. They utilize many of the same arguments: threats to trade agreements and investments, violations of permitted and free speech, other constitutional arguments like the "taking" of property, and intellectual property arguments, most prominently centered around trademarks and branding.[104] What is key for a country to remember is that these arguments, while they have not yet been defeated in an international court, have been defeated in numerous domestic courts around the world. It should also be remembered that the tide is moving towards graphic warnings in general.

IV. FDA BATTLES BIG TOBACCO

In 2009, the Family Smoking Prevention and Tobacco Control Act ("the Act") was passed by Congress and signed by President Obama.[105] Congress mandated that the FDA had two years to come up with regulations requiring that tobacco warnings contain color graphics. As such, the FDA put out a Notice of Proposed Rulemaking in 2010 to get public responses to thirty-six proposed warning images and text, along with related

101. *Id.*

102. *Id.*

103. *See, e.g.*, Chris Morran, *Philip Morris Does Horrible Job of Defending Itself After John Oliver Mocking*, CONSUMERIST (Feb. 17, 2015), http://consumerist.com/2015/02/17/philip-morris-does-horrible-job-of-defending-itself-after-john-oliver-mocking.

104. *Countering Tobacco Industry Arguments Against Effective Health Warnings*, WORLD HEALTH ORG., http://www.euro.who.int/en/health-topics/disease-prevention/tobacco/world-no-tobacco-day/2009-tobacco-health-warnings/countering-tobacco-industry-arguments-against-effective-health-warnings (last visited Apr. 22, 2015) (including counter arguments for some of the most typical tobacco company arguments against large, pictorial warnings).

105. *See supra* Part I.

regulations.[106] In 2011, the FDA revealed nine rotating graphic color images that were ultimately selected, which would cover the top half of both the front and the back of the package. These labels were intended to go into effect in September 2012, but the tobacco industry stepped in before regulations were ever implemented.[107]

The FDA was sued in many places, but two of these suits in particular are important.[108] The results of these two lawsuits has effectively set up the United States to make a decision on what, if any, kind of labels or packaging will be mandated upon cigarettes sold. The larger questions are what will the FDA choose to try, and if it should consider the larger international landscape on graphic warnings and plain packaging.

A. D.C. Circuit

In *R.J. Reynolds Tobacco Co. v. FDA*,[109] five tobacco companies obtained a preliminary injunction in the District Court for the District of Columbia and ultimately were granted a motion for summary judgment. The challenge was to the 2009 Act, but it specifically alleged that the nine proposed graphic warnings violated the First Amendment. The FDA appealed this ruling to the Court of Appeals for the District of Columbia Circuit.[110]

Much of what the tobacco companies argued was that the warnings would be cost-prohibitive and would dominate the packaging and damage the promotion of their brands.[111] The FDA argued that communicating the health information about cigarettes effectively would help more people to stop smoking.[112] What was considered "effective," at least from the standpoint of the FDA, was having graphic picture and text warnings.

106. R.J. Reynolds Tobacco Co. v. FDA, 696 F.3d 1205, 1209 (D.C. Cir. 2012); *see* Chris Morran, *Will the FDA Ever Get Around to New Warning Labels For Cigarettes*, CONSUMERIST (Feb. 18, 2015), http://consumerist.com/2015/02/18/will-the-fda-ever-get-around-to-new-warning-labels-for-cigarettes.

107. Morran, *supra* note 106.

108. Another suit, besides the ones discussed at Part IV.A, B, *infra*, came up in the Second Circuit where a provision for graphic advertising wherever tobacco products are sold was struck down.

109. 823 F. Supp. 2d 36 (D.D.C. 2011), *vacated*, 696 F.3d 1205 (D.C. Cir. 2012), *overruled on other grounds by* Am. Meat Inst. v. U.S. Dep't of Agric., 760 F.3d 18 (D.C. Cir. 2014).

110. *R.J. Reynolds*, 696 F.3d at 1208.

111. Bill Mears, *Federal Appeals Court Strikes Down FDA Tobacco Warning Label Law*, CNN (Aug. 25, 2012, 11:38 AM), http://www.cnn.com/2012/08/24/justice/tobacco-warning-label-law.

112. *Id.*

The Court analyzed, under an "intermediate scrutiny" standard, whether or not the interest that the FDA had in these graphic warnings was substantial, and if the regulation directly advanced that interest, and if the regulation was not more extensive than necessary to serve that interest.[113] The Court determined that the "FDA [had] not provided a shred of evidence – much less the 'substantial evidence' required . . . showing that the graphic warnings will 'directly advance' its interest in reducing the number of Americans who smoke."[114] The Court also did not find the argument about why these nine graphic warnings would be more effective convincing either. The majority said:

> [B]oth the statute and the Rule offer a barometer for assessing the effectiveness of the graphic warnings – the degree to which they encourage current smokers to quit and dissuade would-be smokers from taking up the habit. As such, the FDA's interest in "effectively communicating" the health risks of smoking is merely a description of the means by which it plans to accomplish its goal of reducing smoking rates, and not an independent interest capable of sustaining the Rule.[115]

The majority was ultimately not convinced that these nine specific graphic warnings would get current smokers to quit and dissuade those who were thinking about it, or at least it was not convinced enough to take away the tobacco companies' First Amendment right to commercial speech free of restriction. The Court vacated the graphic warning requirements and remanded to the FDA, also vacating the injunction issued by the District Court to allow the FDA to reformulate regulations.[116]

Judge Rogers in his dissent believed that the majority applied the wrong level of First-Amendment scrutiny to the commercial speech of the tobacco companies, and that even if the intermediate level of scrutiny was correct, that the FDA should still have been able to go forward with this regulation.[117] He believed that the goal of the FDA was to effectively convey the negative health consequences of smoking on cigarette packages

113. *R.J. Reynolds*, 696 F.3d at 1217-18.

114. *Id.* at 1219 (italics omitted) (reasoning that the studies provided by the FDA showing that Canadian and Australian youth smokers thought about quitting based on cigarette pack warnings, there was no evidence that such warnings "directly caused a material decrease in smoking rates in any of the countries that now require them.").

115. *Id.* at 1221 (citations omitted) ("The government's attempt to reformulate its interest as purely informational is unconvincing, as an interest in 'effective' communication is too vague to stand on its own. Indeed, the government's chosen buzzwords, which it reiterates through the rulemaking, prompt an obvious question: 'effective' in what sense?").

116. *Id.* at 1222.

117. *Id.* at 1222-23 (Rogers, J., dissenting).

and in advertising, and that the majority disregarded that the tobacco companies have a history of deceptive advertising with their products.[118]

Interestingly enough, the FDA chose not to appeal this ruling with a petition of certiorari to the Supreme Court. Ultimately, this case did not rule that the entire 2009 Act would have to be thrown out, but that the nine warnings specifically chosen by the FDA during its Rulemaking violated the tobacco companies' commercial free speech. This meant that the FDA could still regulate, but could not use the nine graphic warnings it originally planned to use.

B. 6th Circuit

In *Discount Tobacco City & Lottery, Inc. v. U.S.*, several tobacco companies brought suit to a Kentucky District Court challenging the 2009 Act, seeking a preliminary injunction and a judgment declaring the provisions of the law unconstitutional.[119] The tobacco companies challenged five provisions of the Act, including that a significant portion of the display would go to the health warnings.[120] The companies claimed that these provisions "violate[d] their free speech rights under the First Amendment, constitute[d] an unlawful taking under the Fifth Amendment, and [were] an infringement on their Fifth Amendment due process rights."[121] Both parties filed motions for summary judgment with the District Court, and the court mostly granted the motion for the

118. *Id.* (internal quotations, citations, and markings omitted) ("[T]his court has recognized that the government's interest in preventing consumer fraud/confusion may well take on added importance in the context of a product that can affect the public's health. Tobacco products necessarily affect the public health, and to a significant degree. Unlike other consumer products, tobacco products are dangerous to health when used in the manner prescribed. . . . Thus, the government's informational interest takes on added importance, and merits independent consideration.").

119. Commonwealth Brands, Inc. v. United States, 678 F. Supp. 2d 512 (W.D. Ky. 2009), *aff'd in part, rev'd in part sub. nom.* Discount Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509, 522 (6th Cir. 2012).

120. *Discount Tobacco*, 674 F.3d at 520 (listing the other five challenges to the act, which includes: restrictions on the commercial marketing of modified risk tobacco products, ban on statements that at all convey that tobacco products are approved or safer due to regulation by the FDA, restricting most advertising of tobacco products to black text on white background for most media, and bar on the distribution of free samples of tobacco products in most locations, sponsorship of athletic or social events, branded merchandising of any non-tobacco product, and distributions of free items in consideration of a tobacco purchase).

121. *Id.* at 521.

government.[122] The tobacco companies then appealed the decision up to the Sixth Circuit Court of Appeals.[123]

Many of the arguments made by each side in front of the Sixth Circuit were similar to the arguments made in front of the D.C. Circuit.[124] The tobacco companies argued that the "scale and intrusiveness" of the warning proposed by the Act would far outweigh any legitimate interest in conveying information to prevent the confusion of consumers, as most consumers "already overestimate these health risks."[125] They also argued that the warnings are unduly burdensome because the companies' speech is dominated by the warnings, and that the requirement for graphic images extends beyond mere factual warnings to the point of forcing the companies to market "that tobacco use is socially unacceptable."[126] In essence, the tobacco companies believe that the new warnings are far beyond necessary to convey facts that the existing warnings already convey and that consumers already know, so they are unconstitutional.[127]

The government counters these arguments that consumers are not universally aware of the dangers of tobacco use, especially adolescents.[128] The point of the warning labels is not to force the industry to market a message that stigmatizes its own product for the government on its own dime, but merely making sure that the consumers see the health risk warnings right away.[129] Finally, the government argued that these warnings would not be burdensome on the speech of the tobacco companies because they still get half of cigarette packs for their own branding.[130]

The court ultimately concludes that, like the D.C. Circuit, strict scrutiny is not the correct analysis here, but that the same intermediate scrutiny standard should be used to judge the regulation of commercial speech.[131] Where the court differs from the D.C. Circuit is that it considers

122. *Id.* (granting summary judgment to the tobacco companies on the provisions that "the ban on color and graphics in advertising and the ban on statements implying that tobacco products are safer due to FDA regulation violated their First Amendment speech rights.").

123. *Id.* at 553-54.

124. *See supra* Part IV.A-B.

125. *Discount Tobacco*, 674 F.3d at 524.

126. *Id.* at 524-25.

127. *Id.* at 525.

128. *Id.*

129. *Id.*

130. *Id.* (pointing out also that 70% of smokeless tobacco packages and 80% of advertisements remain open for the tobacco companies' "speech," or branding and advertising).

131. Commercial speech that is non-misleading and deserves an intermediate level of scrutiny is governed by Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of NY, 447 U.S. 557 (1980), as was used in the D.C. Circuit case, *supra* Part IV.A.

two kinds of commercial speech: non-misleading commercial speech and commercial speech that is false, deceptive, or misleading. The test that is applied here determines whether a restriction, or disclosure requirement, is unconstitutional, and this test can apply to commercial speech that is inherently or potentially misleading.[132] In the case of misleading or potentially misleading commercial speech, "an advertiser's rights are adequately protected as long as disclosure requirements are reasonably related to the State's interest in preventing deception of consumers and [are] not unjustified or unduly burdensome."[133] This test provides a lower burden for the government in terms of regulating commercial speech, and the court is persuaded that the tobacco industry's history of misleading advertising and messaging allows for this lower-burden test. Ultimately, the court affirmed most of the decision of the District Court, and held that the Act's requirement that tobacco packaging and advertising include color graphic and some non-graphic warning labels was constitutional under the First Amendment.[134]

The tobacco companies appealed this ruling up to the Supreme Court. In April 2013, the Supreme Court declined to hear the appeal, letting the Sixth Circuit decision stand.[135] What this means, in terms of what actions the FDA can and cannot take based on these major two lawsuits, is that the FDA can move forward with developing new graphic cigarette warnings that comply with the 2009 Act and the judicial rulings.[136] The Sixth Circuit ruling upheld the requirement of the Act for graphic warnings, but the nine specific warnings that were supposed to be enacted were struck down by the D.C. Circuit, meaning that the FDA can go forward with creating new graphic warnings under the existing law.[137]

132. *Discount Tobacco*, 674 F.3d at 523-24.

133. *Id.* at 524 (citing Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 651) (quotations omitted).

134. *Id.* at 531. The conclusion of the case also affirmed all other determinations of the district court, with the exception of the court's granting of summary judgment for the tobacco companies on the unconstitutionality of tobacco companies' claiming FDA regulation somehow makes cigarettes safer. *Id.* at 551.

135. Press Release, Susan M. Liss, Executive Director, Campaign for Tobacco-Free Kids, Supreme Court Lets FDA Move Forward with Graphic Cigarette Warnings and Other Tobacco Regulations (Apr. 22, 2013), http://www.tobaccofreekids.org/press_releases/post/2013_04_22_scotus.

136. *Id.*

137. *Id.*

C. The U.S. Moving Forward – Recommendations

The FDA was clear to create new regulations for graphic warnings based on the 2009 Act and subsequent lawsuit decisions starting in late April 2013. However, three years later there seems to be no movement from the agency in terms of proposing rulemaking or new graphic warnings for the public to examine. In considering the possible options for what the FDA can hope to accomplish, assuming it moves forward anytime soon, it is important to keep the international backdrop in mind of how and what the tobacco industry may challenge and how the FDA may fail or succeed in combating these challenges.

The challenges that can be expected to any new tobacco regulation includes the trademark challenges as discussed, as well as constitutional challenges under the First Amendment and the Takings Clause of the Fifth Amendment. Unlike Australia, the United States does protect commercial speech under the First Amendment more broadly. If a government regulation is curtailing commercial speech, as the FDA would be doing by regulating how much of a tobacco company's trademarked brand is visible on the package, it must be directly advancing its purpose for the regulation and must do so in a way that is not excessive, with the means reasonably fitting the ends being used to promote that purpose.[138] Given how the Supreme Court has expanded protections for commercial speech under the First Amendment, especially in regard to regulations targeting "vices" like alcohol and cigarettes, regulation of percentage of cigarette packages dedicated to branding versus warnings would have to tread very carefully.[139] The regulation could not be too broad, and would have to reasonably fit the purpose of promoting public health and awareness of the danger of cigarettes.

Australia's High Court also considered if plain packaging would constitute a taking under the Constitution. The United States has a similar

138. *See generally* Lorillard Tobacco Co. v. Reilly, 533 U.S. 525 (2001) (using a four-part test to analyze regulations of commercial speech, where the court determines (1) whether the expression is protected by the First Amendment, (2) whether the asserted governmental interest is substantial, (3) whether the regulation directly advances the governmental interest asserted, and (4) whether it is not more extensive than necessary to serve that interest) (*citing Central Hudson Gas & Electric Corp. v. Public Service Commission*, 507 U.S. 761, 770-71 (1980). *See also Florida Bar v. Went For It, Inc.*, 515 U.S. 618, 632 (1995) (explaining that in order to determine the fourth prong of the *Central Hudson* commercial speech test, there must be a reasonable fit between the legislature's ends and the means chosen to accomplish those ends, or a means narrowly tailored to achieve the desired objective).

139. Doug Linder, *Exploring Constitutional Conflicts: Government Regulation of Commercial Speech*, UMKC L. SCH., http://law2.umkc.edu/faculty/projects/ftrials/conlaw/commercial.htm (last visited Feb. 1, 2016).

clause in its Constitution, which has been interpreted to allow the federal government and the states to use the power of eminent domain to take private property for "public use." If this is done, the owner must be paid just compensation for what is taken. However, the Supreme Court and other courts in the United States have not seriously tested the application of the takings clause to intellectual property.[140] This is likely because the analysis for tangible property is already uncertain, and becomes infinitely more complicated when considering intangible property like trademarks.[141] The High Court in Australia did not view plain packaging as a taking of property, however it is unclear whether this sort of constitutional challenge by Big Tobacco, apart from any First Amendment challenges, would have merit in an American courtroom.[142] These trademarks owned by the various tobacco companies are longstanding, and are valuable intangible property, but case law is unclear on whether regulation limiting the space for presenting the trademarks would go so far as to constitute a taking.

In terms of general recommendations, it seems advisable that the United States, via the FDA, continues moving forward with graphic warnings rather than going straight to plain packaging. Given that the United States is one of the countries that currently only has text health warnings covering a portion of cigarette packages, it may be a more natural process for the FDA to continue promulgating regulations that require a certain amount of graphic warnings while leaving a portion of the package for a tobacco company's branding. It is also advisable that the FDA not try and increase the percentage of warnings on the package that was called for the by the Act and upheld by the Sixth Circuit. This way, the tobacco companies would have less of an argument for the general constitutionality of the kind or amount of warnings, nor would they likely be able to bring a successful trademark claim. It would also allow for the United States to have some regulations successfully on the books, should it ever want to follow the world trend for graphic picture warnings taking up a larger percentage of the pack or even plain packaging.

The only challenge with serious merit from tobacco companies, based on the D.C. and Sixth Circuit opinions, would be regarding the content of the warnings themselves. For this, it is instructive to look to how other countries have faired in lawsuits from the tobacco companies, especially those common-law countries with similar legal structures and principles to

140 . *Id.* (explaining that "takings cases present serious interpretive questions," and noting many prominent cases deal with real or personal property).

141. *See* Adam Mossoff, *Patents as Constitutional Private Property: The Historical Protection of Patents Under the Takings Clause*, 87 B.U. L. REV. 689, 690 (2007).

142. *See supra* 7-8, n.29.

the United States. Thailand and Uruguay provide extreme examples of graphic images that have been upheld, but these are considered progressive world leaders on such regulations. It may be helpful for the United States to try and implement images like those used in Canada currently or Australia prior to plain packaging, keeping in mind that the percentage of the package covered by the warnings would be 50% of the total package area.[143]

One caveat to the ideal recommendations above is the likelihood that this will remain on the back burner at the FDA for the foreseeable future. A commentator from Consumerist contacted the FDA to ask about timelines and plans the agency may have to move forward with graphic warnings following the Supreme Court's refusal to hear the Sixth Circuit appeal by the tobacco companies. The spokesperson only said, "[T]he agency will undertake research to support a new rulemaking consistent with [the 2009 Act]."[144] The commentator pointed out that the phrase "undertake research" means that no research has begun yet, and also that when spokesperson was pressed for general timelines for additional rulemakings that he "could not provide any additional information."[145] This does not bode well for expectations that the FDA will act anytime soon. It also is feasible that the tobacco industry is utilizing the full reach of its financial sway to conduct lobbying efforts to put off a rulemaking as long as possible. While lobbying by the industry may have reached new heights for many of the other countries implementing harsher regulations, it is a well-oiled machine in American politics and is likely to attempt to stave off regulation as long as possible.

V. CONCLUSION

It is obvious that the tobacco industry has vast resources and influence, and is unlikely to give up fighting against the constant regulations thrown at it internationally any time soon. As such, the large international tobacco companies hire brilliant legal minds to come up with every possible challenge to these regulations in each country in order to stave off regulation that will hurt their brands and profits. One such challenge that has been a favorite to use against graphic picture warnings and plain

143. *See* TOBACCO LABELLING RESOURCE CTR., http://www.tobaccolabels.ca (last visited Apr. 22, 2015) (making available the dates of when different countries implemented picture warnings around the world on tobacco products, as well as pictures of the specific warning labels approved, so to view each country listed above, merely search them from the main page).

144. Morran, *supra* note 106.

145. *Id.*

packaging worldwide is using trademark law. However, this use of trademark law is more for brand protection, rather than the consumer confusion and unfair competition principles that provide foundation for the law in the United States and elsewhere.

While it may be some time before the United States tobacco market needs to directly confront graphic warning regulation from the FDA, the FDA can learn lessons from legal struggles around the world for crafting new regulations to comply with the 2009 Family Smoking Prevention and Tobacco Control Act. Trademark arguments of the tobacco companies can come in various forms, but may often be seen as either takings of intellectual property by the government (especially in the plain packaging context), or as being harmful to the trademarks directly by creating incentives for counterfeiting and tobacco "black markets," as well as consumer confusion. The FDA can avoid these arguments by following the lead of countries like Australia, and putting forth similar arguments to those used by other governments. The FDA should also stick with the warnings prescribed in the 2009 Act in order to avoid further constitutional challenges, and should consider what other countries like Canada have been successful with as far as specific content for the graphic warnings. If the FDA follows these recommendations when it eventually conducts additional research and proposes a new rulemaking, it is much less likely to fail when fighting the inevitable challenges from the tobacco industry.