

ARTICLE

THE INTERNATIONAL TRADE LAW IMPLICATIONS OF REGULATING E-CIGARETTES: LESSONS FROM TOBACCO LITIGATION

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I. INTRODUCTION

An outbreak of deaths and serious injuries associated with e-cigarette or vaping product use in the United States and Canada starting in 2019 demonstrated that the use of unregulated vaping products can have catastrophic health impacts.¹ These impacts are likely to be particularly severe for young consumers. The increasing evidence that inhaling vaporized liquids containing diverse substances can be harmful to the health of consumers of e-cigarettes, with additional risks if e-liquids contain substances such as nicotine, has resulted in a call to action from the World Health Organization (WHO), who is urging states that “urgent measures are necessary to prevent uptake of e-cigarettes.”²

Many states have responded to these increasing concerns about the health impacts of e-cigarette use with regulatory action. In 2024, Australia passed legislation that will only permit pharmacies to sell e-cigarettes of any kind, prohibit all flavors except mint, menthol, and tobacco, and heavily restrict all e-cigarette advertising.³ In 2020, Denmark adopted legislation for the plain packaging of tobacco products, which was extended by executive order to also apply to e-cigarettes.⁴ The authority of the United States’ (US) Food and Drug Administration (FDA) to regulate “tobacco products” had initially only covered those e-cigarettes which contained nicotine that had actually been derived from tobacco leaf. However, in 2022 the definition of “tobacco products” was widened to include all e-cigarettes that contain

1. Maitri Munsif, Mark Hew & Eli Dabscheck, *E-cigarette or Vaping Product Use-associated Lung Injury (EVALI): A Cautionary Tale*, 213 *MED. J. AUSTRALIA* 109–10 (2020).

2. *Technical Note on Call to Action on Electronic Cigarettes*, WORLD HEALTH ORGANIZATION [WHO] 2–3 (2023), <https://www.who.int/publications/m/item/technical-note-on-call-to-action-on-electronic-cigarettes> [<https://perma.cc/RX2W-FL7P>].

3. See AUSTRALIAN GOVERNMENT DEPARTMENT OF HEALTH AND AGED CARE, THERAPEUTIC GOODS ADMINISTRATION, *Vapes: information for sponsors, importers and manufacturers*, <https://www.tga.gov.au/products/unapproved-therapeutic-goods/vaping-hub/vapes-information-sponsors-importers-and-manufacturers> [<https://perma.cc/7JWN-5ARA>] (last updated July 25, 2024); see also *Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024* (Cth) sch 1 pt 3, sch 4 (Austl.).

4. See WORLD HEALTH ORGANIZATION (WHO) FRAMEWORK CONVENTION ON TOBACCO CONTROL, *Denmark: Plain packaging legislation adopted*, <https://extranet.who.int/ftccapps/ftccapps/ftcc/implementation-database/news/denmark-plain-packaging-legislation-adopted> [<https://perma.cc/SP5V-SN48>] (last updated July 1, 2021); BEK nr. 699 af 19.04.2021 bekendtgørelse om standardisering af elektroniske cigaretter og genopfyldningsbeholdere med og uden nikotin [Executive order on standardization of e-cigarettes and refill containers with and without nicotine] (Den).

nicotine, including synthetic nicotine that is not actually derived from tobacco.⁵ The effect of this is that e-cigarettes containing nicotine will be treated like tobacco products, which includes the requirement that new products entering the market must receive authorization from the FDA.⁶ Like cigarettes sold in the United States, which cannot have a flavor other than tobacco or menthol,⁷ the FDA to date has only authorized tobacco or menthol flavored e-cigarettes.⁸

The regulations enacted in Australia, Denmark, and the United States illustrate how e-cigarette regulations are rapidly evolving in many countries, reflecting the increasing concern about the widespread availability and use of these products, while also demonstrating the diverse range of regulatory approaches countries are adopting. Unsurprisingly, new or novel regulatory approaches have often attracted controversy, and there is an emerging body of litigation relating to the regulation of e-cigarettes and e-cigarette safety issues.⁹ Juul, one of the world's most well-known e-cigarette manufacturers, used domestic courts in Israel to challenge the government's decision to ban import of their e-cigarettes on public health grounds.¹⁰ In the United States, Juul settled litigation arising from investigations by thirty-three states regarding alleged misleading and deceptive conduct in the marketing of their products to young people.¹¹ Litigation relating to e-cigarettes has not been limited to domestic courts, and is also arising in supranational and international forums. The Court of Justice of the European Union (CJEU) has already had to consider a case

5. See Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §387(a).

6. *Id.* § 387(j)(a).

7. *Id.* § 387(g).

8. Jamie Hartmann-Boyce, *FDA authorized the sale of menthol-flavored e-cigarettes – a health policy expert explains how the benefits may outweigh the risks*, THE CONVERSATION, (Jun. 26, 2024), <https://theconversation.com/fda-authorized-the-sale-of-menthol-flavored-e-cigarettes-a-health-policy-expert-explains-how-the-benefits-may-outweigh-the-risks-233057> [<https://perma.cc/TEX7-675C>].

9. A fuller overview of e-cigarette-related litigation can be found in *Litigation Relevant to Regulation of Novel and Emerging Nicotine and Tobacco Products: Case Summaries*, WORLD HEALTH ORGANIZATION [WHO] (2021).

10. HCJ 6665/12 E-Cig Ltd. v. Ministry of Health (2014) (Isr.).

11. *Juul agrees to \$US440 million settlement following probe into marketing vapes to teens*, ABC NEWS, <https://amp.abc.net.au/article/101412686> [<https://perma.cc/P9BR-K557>](last updated Sept. 6, 2022 at 7:27 P.M.).

concerning whether e-cigarettes should be regulated in the same way as were tobacco products.¹²

The growing range of e-cigarette related litigation is reminiscent of the use of litigation by the tobacco industry to challenge stringent public health measures.¹³ One international avenue that tobacco producers have pursued in recent years to challenge novel or strict tobacco regulations has been the dispute settlement mechanisms of international trade agreements. In particular, two prominent disputes were brought in the World Trade Organization (WTO) concerning tobacco regulations that were (at least as alleged by the relevant country) enacted for public health reasons. In 2010, Indonesia challenged a US law which banned characterizing flavors in cigarettes, other than menthol.¹⁴ While the Panel and Appellate Body found that the US law was inconsistent with its WTO obligations,¹⁵ the dispute was eventually settled through a mutually agreed solution.¹⁶ In 2012, several countries challenged Australia's Tobacco Plain Packaging scheme, although Australia successfully defended the measure.¹⁷

12. See Case C-477/14, *Pillbox 38 (UK) Ltd. v. Sec'y of State for Health*, ECLI:EU:C:2016:324, ¶¶ 33–43 (May 4, 2016).

13. See Benjamin Hawkins, Chris Holden & Sophie Mackinder, *A Multi-Level, Multi-Jurisdictional Strategy: Transnational Tobacco Companies' Attempts to Obstruct Tobacco Packaging Restrictions*, 14 *GLOB. PUB. HEALTH* 570, 571 (2019).

14. See Request for Consultations by Indonesia, *United States—Measures Affecting the Production and Sale of Clove Cigarettes*, WTO Doc. WT/DS406/1 (Apr. 14, 2010).

15. See Panel Report, *United States—Measures Affecting the Production and Sale of Clove Cigarettes*, WTO Doc. WT/DS406/R (Sept. 2, 2011) [hereinafter Panel Report, *US – Clove Cigarettes*]; Appellate Body Report, *United States—Measures Affecting the Production and Sale of Clove Cigarettes*, WTO Doc. WT/DS406/AB/R (Apr. 4, 2012) [hereinafter Appellate Body Report, *US – Clove Cigarettes*].

16. See Notification of Mutually Agreed Solution, *United States—Measures Affecting the Production and Sale of Clove Cigarettes*, WTO Doc. WT/DS406/17 (Oct. 9, 2014).

17. See Panel Report, *Australia—Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, WTO Doc. WT/DS458/R (adopted June 28, 2018); Panel Report, *Australia—Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, WTP Doc. WT/DS441/R (adopted June 28, 2018); Panel Report, *Australia—Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, WTO Doc. WT/DS435/R (adopted June 28, 2018); Panel Report, *Australia—Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, WTO Doc. WT/DS467/R (adopted June 28, 2018) [hereinafter Panel Reports, *Australia—Tobacco Plain Packaging*]; Appellate Body Report, *Australia—Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to*

Similar to these cases, e-cigarette regulations may be subject to challenge under international trade rules. Distinctions between similar products such as e-cigarettes and tobacco products, or different flavors of e-cigarettes, create a real potential for claims that the public health regulations violate the non-discrimination rules of international trade law. In addition, any requirements relating to packaging, labelling, and the use of trademarks may engage trade agreements that protect intellectual property rights.

Against this background, this Article considers the lessons for e-cigarette regulation that can be learned from international trade disputes about tobacco regulation. Even if a state is ultimately successful in defending their measure, trade disputes can be expensive and time consuming to defend. In the context of other WTO Dispute Settlement Body decisions, the decisions in the tobacco-related WTO dispute provide useful insights for policymakers working on e-cigarettes and related areas. These insights will help to ensure that states responding to the WHO's call to action by adopting or reforming e-cigarette regulations can minimize the risk of their measures being successfully challenged under international trade rules.

We begin our analysis, in Part II, with an overview of the health impacts and concerns around vaping products, and the lack of international consensus around how to best regulate these products. While several countries treat e-cigarettes similarly to traditional tobacco products, there is a diverse range of regulatory approaches being taken in different countries, which reflects the complexity and uncertainty around their health impacts. As a relatively new product, we lack longitudinal studies on the health impacts of vaping, and unlike tobacco products—which have only negative health impacts—there is a potential for e-cigarettes to have positive health impacts if they are used as an aid for smoking cessation. Part III then sets out some of the WTO agreements and obligations that are most likely to be relevant to e-cigarette regulations, particularly the Agreement on Technical Barriers to Trade (TBT Agreement), the General Agreement on Tariffs

Tobacco Products and Packaging, WTO Doc. WT/DS441/AB/R (adopted June 9, 2020); *Appellate Body Report, Australia—Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, WTO Doc. WT/DS435/AB/R (adopted June 9, 2020) [hereinafter *Appellate Body Reports, Australia—Tobacco Plain Packaging*].

and Trade (GATT), and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).¹⁸

Having provided this overview of the relevant obligations and how they might apply, Part IV draws out three key lessons for the design and justification of e-cigarette policies that can be drawn from the WTO tobacco disputes: first, that a measure must have a clear, precise and sufficient justification; second, that alternative measures that may be less restrictive of trade or of the use of intellectual property rights should be considered when developing e-cigarette regulations; and thirdly, that non-WTO international law, including agreements and decisions under the auspices of the WHO Framework Convention on Tobacco Control (FCTC)¹⁹ and international human rights instruments such as the Convention on the Rights of the Child, can be relevant when applying WTO obligations to e-cigarette regulation. These lessons provide guidance for how e-cigarette regulations can and should be consistent with international trade law.

II. *HEALTH CONCERNS ARISING FROM E-CIGARETTES AND DIVERGENT REGULATORY RESPONSES*

A. *Health Impacts and Concerns About Vaping*

E-cigarettes are battery-operated devices used to inhale aerosols from heated products that developed as an alternative to smoking.²⁰ E-cigarettes are also known as electronic cigarettes, electronic vaporizers or, most commonly, vapes. There have been several generations of e-cigarettes as delivery technology has evolved. They are frequently made from plastic and can take several different forms, including

18. TBT: Agreement on Technical Barriers to Trade, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 1868 U.N.T.S. 120 [hereinafter TBT Agreement]; GATT 1994: General Agreement on Tariffs and Trade 1994, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 1867 U.N.T.S. 187, 33 I.L.M. 1153 (1994) [hereinafter GATT]; TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement].

19. WHO Framework Convention on Tobacco Control, May 21, 2003, 2302 U.N.T.S. 166 [hereinafter FCTC].

20. *Opinion of the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) on Electronic Cigarettes*, 2021 O.J. 17, 20.

disposable e-cigarettes and reusable e-cigarette devices.²¹ Reusable devices can use either vaping liquid (often referred to as e-liquid) or cartridges that contain e-liquid (sometimes called pods).²² E-liquids are heterogenous and contain diverse ingredients,²³ some of which can be used to create different flavors and scents. E-cigarettes can contain nicotine which is the addictive substance found in tobacco products.

To consider the health impacts and concerns arising from e-cigarettes, we need to consider who is using these products and why they are using them. E-cigarettes can be used by tobacco smokers as a tool to aid in smoking cessation. Both Electronic Nicotine Delivery Systems (ENDS) and Electronic Non-Nicotine Delivery Systems (ENNDS) can assist people to give up smoking or prevent relapse by providing an alternative mechanism for managing nicotine addiction and/or replacing behavioral habits associated with smoking. Although there are other electronic products available, such as heated tobacco products, e-cigarettes are used extensively as both ENDS and ENNDS.²⁴ References to ENDS and ENNDS in this Article are specifically to e-cigarettes within those categories. As a smoking cessation tool, e-cigarettes may be useful to prevent and reduce tobacco consumption. Comparisons between the health impacts of e-cigarette use and tobacco use suggest that the harm posed by tobacco use is greater,²⁵ which could result in a net health benefit for smokers who substitute e-cigarettes for tobacco products. However, to date, there is only limited evidence that nicotine-containing e-cigarettes actually constitute an effective cessation tool for current smokers.²⁶

21. *Id.* at 20.

22. Jérémie Pourchez, Clément Mercier & Valérie Forest, *From Smoking to Vaping: A New Environmental Threat?*, 10 *LANCET RESPIRATORY MED.* 63–64 (2022).

23. *Statement on the Potential Toxicological Risks from Electronic Nicotine (and non-nicotine) delivery systems (E(N)NDS – e-cigarettes)*, COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS, AND THE ENVIRONMENT (COT) 3–4 (2020).

24. Regina El Dib et al., *Electronic Nicotine Delivery Systems and/or Electronic Non Nicotine Delivery Systems for Tobacco Smoking Cessation or Reduction: a Systematic Review and Meta-Analysis*, 7 *BMJ OPEN* e012680, at 8 (2017) [<https://bmjopen.bmj.com/content/7/2/e012680.full.pdf>] [<https://perma.cc/6GFF-2U5B>].

25. *See, e.g.*, Colin Mendelsohn, Alex Wodak & Wayne Hall, *How Should Nicotine Vaping be Regulated in Australia?* 42 *DRUG AND ALCOHOL REV.* 1288, 1288 (2023).

26. EMILY BANKS ET AL., *ELECTRONIC CIGARETTES AND HEALTH OUTCOMES: SYSTEMATIC REVIEW OF GLOBAL EVIDENCE* 271 (2022). Banks also finds insufficient evidence that nicotine e-cigarettes are efficacious for smoking cessation, compared to non-nicotine e-cigarettes. Michelle I. Jongenelis et al., *E-cigarette use is associated with susceptibility to tobacco use among Australian young adults*, 74 *INT’L J. OF DRUG POL’Y* 266, 269 (2019).

But e-cigarettes' popularity has increased not only in former and existing smokers but also in never-smokers.²⁷ Worldwide, e-cigarettes have strong popularity among young people, including people under the age of eighteen.²⁸ There are concerns that ENDS and ENNDS use provides a gateway for never-smokers to commence smoking.²⁹ Thus, any potential health benefits of the use of e-cigarettes as a smoking cessation tool need to be considered alongside the potential harms caused to users that may not otherwise have smoked, especially young people.

The health impacts of e-cigarette consumption on users are still being understood but serious concerns are emerging. A range of harms that could arise from e-cigarette use have been identified, including nicotine addiction.³⁰ Diverse ingredients are vaporized and inhaled in e-cigarette use and there are concerns that these substances may harm consumers.³¹ Some harms may be exacerbated by the prevalence of black markets for e-cigarettes.³² In the United States, several deaths have been linked to e-cigarette or vaping product use-associated lung injury (EVALI).³³ Reviews of these cases identified a strong association between EVALI and vaping products containing Vitamin E,³⁴ and were in turn linked to black market products containing tetrahydrocannabinol (THC) that were difficult to distinguish from

Further research is required. *See* NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE, *PUBLIC HEALTH CONSEQUENCES OF E-CIGARETTES* (Kathleen Stratton et al. eds., 2018).

27. Emily Banks et al., *Electronic Cigarettes and Health Outcomes: Umbrella and Systematic Review of the Global Evidence*, 218 *MED. J. OF AUSTRALIA* 267, 273 (2023).

28. *Technical Note on Call to Action on Electronic Cigarettes*, *supra* note 2, at 3; *see also* Mateusz Jankowski, *E-Cigarettes are More Addictive than Traditional Cigarettes: A Study in Highly Educated Young People*, 16 *INT'L J. OF ENV'T RSCH. AND PUB. HEALTH* 1 (2019).

29. *See* Banks et al., *supra* note 26, at 260, 264. *But see* Colin Mendelsohn & Wayne Hall, *Does the gateway theory justify a ban on nicotine vaping in Australia?*, 78 *INT'L J. OF DRUG POL'Y* 1, 4 (2020).

30. *See* Emily Banks, Melonie Martin & Miranda Harris, *Framework for the public health assessment of electronic cigarettes*, 31 *TOBACCO CONTROL* 608, 610–11 (2022).

31. *See* Alexander Larcombe et al., *Chemical analysis of fresh and aged Australian e-cigarette liquids*, 216 *MED. J. OF AUSTRALIA* 27, 27 (2022).

32. *See* Anita Dessaix et al., *Undermining Australian controls on electronic nicotine delivery systems: illicit imports and illegal sales*, 31 *TOBACCO CONTROL* 689, 689–90 (2022).

33. Munsif, Hew & Dabscheck, *supra* note 1.

34. *See* Melissa M. Baker et al., *Vaping-associated lung illness (VALI) in Canada: a descriptive analysis of VALI cases reported from September 2019 to December 2020*, 1 *HEALTH PROMOTION AND CHRONIC DISEASE PREVENTION IN CAN.: RSCH., POL'Y AND PRAC.* 37, 41–42 (2022).

genuine products.³⁵ There were also reports of EVALI injuries in Canada that were not clearly linked to contaminated vaping products.³⁶ Long term use of e-cigarettes can result in pulmonary and respiratory harm in intensive users,³⁷ and in increased risk of cardiovascular disease.³⁸ There are also health concerns that second-hand vapor from e-cigarette consumption will negatively impact the health of others in close proximity to the vapor.³⁹ For the increasing number of recreational e-cigarette smokers who have never previously smoked tobacco, the benefits of smoking cessation do not mitigate the health concerns associated with e-cigarette consumption.⁴⁰

There is particular concern about the increasing numbers of people under the age of eighteen consuming e-cigarettes. As nicotine is addictive, young people who consume e-cigarettes containing nicotine and become addicted are likely to be exposed to health harms for a longer period of time, which may exacerbate the issues. E-cigarettes can permit consumption of significantly larger quantities of nicotine than tobacco products.⁴¹ Research suggests that nicotine exposure can be particularly harmful for developing adolescent brains.⁴² Direct consumption of vaping liquids that contain nicotine has

35. See Eric Schuetz, *Electronic Cigarette and Vaping-Associated Lung Injury: Basic Information for Nurses*, 40 J. of Radiology Nursing 152, 155 (2021).

36. See Melissa M. Baker et. al., *supra* note 34, at 41–42. EVALI has also been reported in a fifteen-year-old girl in Italy: Casamento Tumeo, et al., *E-cigarette or Vaping product use Associated Lung Injury (EVALI) in a 15 year old female patient—case report*, 1 IT. J. OF PEDIATRICS 1, 1 (2022).

37. Ahmed identifies “bronchiectasis, eosinophilic pneumonia, pleural effusion, and suspected hypersensitivity pneumonitis, and diffuse alveolar hemorrhage syndrome” in a systematic review of health impacts from exposure to electronic cigarettes. See Ayesha Ahmed, *A Review of Electronic Cigarettes and Liquid Nicotine Poisoning Exposure Cases in the United States: The health impact of the short-term exposure*, 25 J. OF PHARMACY & PHARM. SCI. 354, 359 (2022).

38. Espinoza-Derout, et. al., *Electronic cigarette use and the risk of cardiovascular diseases*, 9 FRONTIERS IN CARDIOVASCULAR MED. 1, 9 (2022).

39. Wouter F. Visser et al., *The health risks of electronic cigarette use to bystanders*, 16 INT’L J. OF ENV’T RSCH. AND PUB. HEALTH 1, 1 (2019).

40. Banks et al., *supra* note 26, at 269–70.

41. T. G. Cutts and A. M. O’Donnell, ‘*The implications of vaping for the anaesthetist*’, 21(7) BJA EDUC. 243, 246 (2021).

42. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *E-CIGARETTE USE AMONG YOUTH AND YOUNG ADULTS: A REPORT OF THE SURGEON GENERAL 99* (Office of the Surgeon General, 2016).

caused death in children in Australia,⁴³ the United States, and other parts of the world.⁴⁴

Policymakers regulating e-cigarettes should therefore give consideration to the vulnerabilities of youth to harms related to e-cigarettes and, particularly, mechanisms that are being used to entice young people to smoking including the use of flavors that are appealing to children and adolescents and advertising that is directed towards this group. For example, until June 2024 the US FDA had not authorized any e-cigarettes that were not tobacco flavored, creating a “de facto flavor ban” for ENDS in the United States.⁴⁵ Flavor bans had also been imposed by states of the United States, such as New York, which only allows tobacco flavored or unflavored vapes.⁴⁶ These flavor bans directly target youth consumption of vaping.⁴⁷

Children are vulnerable to advertising and the need for specific protections for children in relation to health information has been recognized in international law.⁴⁸ Internationally, e-cigarettes have been promoted in a misleading and deceptive manner. The leading e-cigarette seller in the United States, Juul, recently agreed to a settlement regarding allegations of misleading and deceptive practices in the marketing of cigarettes to young people.⁴⁹ Currently, American packaging requirements are a combination of general restrictions on misleading and deceptive practices and requirements to warn about the

43. Jody Morgan, Andreas K. Breitbarth & Alison L. Jones, *Risk versus regulation: an update on the state of e-cigarette control in Australia*, 49 *INTERNAL MED. J.* 110, 111 (2019).

44. Gerdinique C. Maessen et al., *Nicotine intoxication by e-cigarette liquids: a study of case reports and pathophysiology*, 58 *CLINICAL TOXICOLOGY* 1, 3 (2020).

45. For discussion of the “de facto” flavor ban and the issuance of the first approvals for menthol e-cigarettes in June 2024, see Jamie Hartmann-Boyce, *supra* note 8.

46. N.Y. PUB. HEALTH L. 45 Art. 13-F § 1399-MM-1 (Consol.).

47. See Press Release, U.S. Food & Drug Admin., FDA Denies Marketing of Two Use Menthol E-Cigarette Products Following Determination They Do Not Meet Public Health Standard, <https://www.fda.gov/news-events/press-announcements/fda-denies-marketing-two-use-menthol-e-cigarette-products-following-determination-they-do-not-meet> (Jan. 24, 2023) (noting that the authorization applications did not “present sufficient scientific evidence to show that the potential benefit to adult smokers outweighs the risks of youth initiation and use.”); see also Press Release, N.Y. State Dep’t. of Health, New York State Department of Health Announces Statewide Ban of Flavored Nicotine Vapor Products Takes Effect Today, https://health.ny.gov/press/releases/2020-05-18_fl_nicotine_vapor_products_ban.htm [<https://perma.cc/SWA7-5R7M>] (May 18, 2020) (noting that the flavor ban will “protect our children”).

48. Convention on the Rights of the Child art. 17, Nov. 20, 1989, 1577 U.N.T.S. 3.

49. *Juul agrees to \$US440 million settlement following probe into marketing vapes to teens*, *supra* note 11.

presence of nicotine for nicotine containing vapes.⁵⁰ Yet vaping rates continue to increase and there are concerns about the effectiveness of mechanisms to deter young people from vaping such as flavor bans.⁵¹ In the context of the growing evidence of e-cigarette consumption associated health harms that underpins the WHO Call to Action,⁵² countries with high rates of vaping need to seriously consider whether stricter packaging is needed, as well as other restrictions on advertising such as social media. Stricter regulation of e-cigarette advertising could be targeted particularly at the protection of young people, but, where this restricts the use of trademarks registered in relation to e-cigarettes, special attention needs to be given to minimum intellectual property standards protected by WTO rules.

As outlined in this Section, the harms and benefits associated with consumption of e-cigarettes vary considerably between users and products. The different health impacts of e-cigarettes—both negative and positive—have led to a wide range of different regulatory responses being implemented in different jurisdictions, as outlined in the next Section. These complexities also influence how the justification for e-cigarette regulations will be assessed when considering their consistency with WTO rules, as discussed in Parts III and IV of this Article.

B. Different Domestic Regulatory Approaches

The Global Tobacco Control database of e-cigarette regulations notes that, as of August 2023, 132 countries had been identified that either ban or regulate e-cigarettes.⁵³ These countries take a diverse range of approaches to regulation of e-cigarettes, indicating different

50. See 21 C.F.R. § 1143.3(a)(1)–(2); see also SAMUEL C. HAMPSHER-MONK, JAMES E. PRIEGER & SUDHANSHU PATWARDHAN, *TOBACCO REGULATION, ECONOMICS, AND PUBLIC HEALTH, VOLUME III: CLEARING THE AIR ON E-CIGARETTES AND HARM REDUCTION* 19 (2024).

51. See Liane M. Schneller et al., *Awareness and Perceived Behaviour Changes Following the New York State Vaping Flavour Ban, 2021–2022*, *TOBACCO CONTROL* 1, 6 (2024).

52. See *Technical Note on Call to Action on Electronic Cigarettes*, *supra* note 2.

53. See Institute for Global Tobacco Control, *Country Laws Regulating E-Cigarettes*, JOHNS HOPKINS BLOOMBERG SCH. OF PUB. HEALTH, <https://www.globaltobaccocontrol.org/en/policy-scan/e-cigarettes/countries?country=263> [<https://perma.cc/LU4G-V5F9>].

perspectives on the potential risks and benefits of these products.⁵⁴ It is beyond the scope of this Article to provide a comprehensive overview of the rules that currently apply to e-cigarettes in different countries.⁵⁵ Any effort to summarize or distil current approaches to e-cigarette regulation around the globe is complicated by the variety of different e-cigarettes on the market, as regulating regimes often distinguish between different kinds of e-cigarettes, particularly those that contain nicotine (ENDS) and those that do not (ENNDS), those with characterizing flavors (such as fruit or candy flavors), and whether the vapes are disposable or reusable. In this Section, we provide a general overview of the categories of approaches which countries can take when regulating e-cigarettes, which reflect a spectrum from highly restrictive frameworks such as complete bans, to relatively lenient approaches which treat e-cigarettes as consumer products.

Brooke Campus et al. provide a useful framework for understanding the range of different approaches which countries have taken to e-cigarette regulation, and how these approaches reflect the relevant government's views regarding the purpose of e-cigarette regulation.⁵⁶ At one end of their spectrum is the goal of health protection, which seeks to minimize the number of new users of nicotine and related products, and is reflected in strict regulatory approaches, such as a complete prohibition on e-cigarettes or treating them as medicinal products which can only be legally accessed as part of smoking cessation therapy.⁵⁷ Singapore has taken a strict approach to e-cigarettes since 2018, when it legislated that a person must not "import into Singapore, or distribute, sell, offer for sale or possess for sale in Singapore" any imitation tobacco product. Imitation tobacco products include any device or article "that is capable of being smoked"

54. See Brooke Campus et al., *Comparing the Regulation and Incentivization of E-Cigarettes across 97 Countries*, 291 *SOCIAL SCI. & MEDICINE* 1, 2 (2021).

55. See *Country Laws Regulating E-Cigarettes*, *supra* note 53 (for a comprehensive database of e-cigarette regulations); see also S. Jenkins et al., *International Regulatory Overview*, MELBOURNE CANCER CENTER VICTORIA (2023), <https://www.tobaccoaustralia.org.au/chapter-18-e-cigarettes/18-14-regulatory-overview> [<https://perma.cc/VP6S-Y8H4>] (for studies that provide an overview or synthesis of the different regulatory approaches); Campus et al., *supra* note 54. See generally Ryan David Kennedy et al., *Global Approaches to Regulating Electronic Cigarettes*, 26 *TOBACCO CONTROL* 440, 440.

56. Campus et al., *supra* note 54.

57. *Id.*

or “that may be used in such a way as to mimic the act of smoking.”⁵⁸ Australia is currently reforming its e-cigarette regulatory framework to adopt a strict approach that will, by the end of 2024, mean that the only e-cigarettes that can legally be imported into Australia, domestically manufactured, or offered for sale are therapeutic vapes, which will only be able to be purchased from a pharmacy.⁵⁹ The reforms also include bans on any flavors other than tobacco, mint, or menthol, advertising prohibitions, and packaging regulations.⁶⁰

At the other end of Campus et al.’s spectrum are regulatory approaches with the goal of harm reduction, which seek to minimize the health risks of e-cigarette use by ensuring product safety, and are reflected in more lenient regulatory approaches, such as treating e-cigarettes as tobacco products or as consumer products.⁶¹ The United States classifies ENDS as tobacco products, which are regulated by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act.⁶² Although the FDA’s regulatory authority initially only extended to products which contained tobacco-plant derived nicotine, in 2022 its authority was expanded to cover synthetic nicotine.⁶³ In 2020, New Zealand amended its tobacco control legislation, the Smokefree Environments and Regulated Products Act 1990, to cover all “vaping products,” including both nicotine and non-nicotine products.⁶⁴ Under this statute, vaping products are subject to many of the same restrictions as tobacco products, including smoking in public areas, advertising, and promotion and sale to minors,⁶⁵ although with some differences, such as vaping products may be visible in a store while tobacco products cannot be.⁶⁶ While all vaping products are regulated by this general framework in New Zealand, there are

58. See Tobacco (Control of Advertisements and Sale) Act, 1993 (Act No. 10/1993), *rev’d* 2020 (Sing.).

59. See AUSTRALIAN GOVERNMENT DEPARTMENT OF HEALTH AND AGED CARE, THERAPEUTIC GOODS ADMINISTRATION, *supra* note 3.

60. *Id.*

61. Campus et al., *supra* note 54.

62. See Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 387–387(v) (relating to “tobacco products”).

63. See *id.* § 387(a).

64. Smokefree Environments and Regulated Products Act 1990, s 2(1) (N.Z.) (defining “vaping device,” “vaping product,” and “vaping substance”).

65. See *id.* ss 5–13(B) (discussing smoking in public areas), 23–27 (discussing advertising and promotion), 40–42 (discussing sale to minors).

66. *Id.* s 37.

some specific rules that apply only to nicotine-containing vaping products.⁶⁷

In the middle of Campus et al.'s spectrum—lying somewhere between the health protection and harm reduction goals—are component bans (e.g. banning the nicotine concentrations above a designated level or bans on adding flavors to e-cigarettes) and treating e-cigarettes as a poison or hazardous substance.⁶⁸ In contrast to the United States, where there are no federal limits on nicotine concentration, regulations in the European Union, United Kingdom, and Canada limit the amount of nicotine that can be contained in disposable vapes and vaping liquids.⁶⁹ Since April 2022, when products containing synthetic nicotine were included within the “tobacco products” regulated by the FDA, all new e-cigarettes entering the US market have to be authorized by the FDA.⁷⁰ The FDA did not authorize any e-cigarettes or e-liquids with flavors other than tobacco, until in June 2024, when it authorized some menthol flavored e-cigarettes.⁷¹ In tandem, a number of US states have banned certain e-cigarette flavors.⁷² For example, in the state of New York, e-cigarettes can only be sold in tobacco flavor or unflavored.⁷³ For several years, non-therapeutic ENDS were prohibited under the legislation of each state in Australia on the basis that nicotine is a hazardous poison.⁷⁴ Similarly, until recently, Malaysia prohibited non-therapeutic ENDS under its poisons legislation, although this was controversially changed in 2023 to exempt the use of nicotine in e-cigarettes and vaping products from the ban.⁷⁵ Finland was the first country to ban flavoring as a component

67. See, e.g., *Smokefree Environments and Regulated Products Regulations 2021*, reg 68 (N.Z.) (requiring packaging for ENDS to include messaging about the harmful effects of using the vaping product).

68. Campus et al., *supra* note 54.

69. See HAMPSHER-MONK, PRIEGER & PATWARDHAN, *supra* note 50, at 40.

70. See Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 387(j)(a).

71. Hartmann-Boyce, *supra* note 8.

72. See Yong Yang et al., *The Impact of Flavored E-Cigarette Bans on e-Cigarette Use in Three U.S. States*, MEDRXIV (May 21, 2023) (unpublished manuscript).

73. See N.Y. PUB. HEALTH L. § 1399-MM-1 (Consol. 2020).

74. Each state of Australia enacted its own legislation. See *Standard for the Uniform Scheduling of Medicines and Poisons 2024* (Cth) sch. (7) (Austl.) (listing nicotine as poison except when for therapeutic use or in tobacco products).

75. See Rahmat Khairulrijal, *Health minister sued for removing nicotine from Poisons Act*, NEW STRAITS TIMES (July 3, 2023), <https://www.nst.com.my/news/nation/2023/07/926692/health-minister-sued-removing-nicotine-poisons-act> [<https://perma.cc/FLX2-3AHD>].

of e-cigarettes in 2016,⁷⁶ but, in the past two years, several more countries have also taken this step, including Hungary, the Netherlands, Lithuania, China, Ukraine, Denmark, and Estonia.⁷⁷ Several countries restrict other components in e-cigarettes, either by limiting the nicotine concentration permitted and/or banning additives which are harmful or that could be perceived as having health benefits, such as vitamins or stimulants like caffeine and taurine.⁷⁸

Most of the regulatory approaches on this spectrum situate e-cigarettes within a wider category of products that have an existing regulatory framework (e.g. medicinal products, tobacco products, or consumer products), but, as Campus et al. note, some countries are treating e-cigarettes as an entirely unique product and designing a bespoke regulatory framework.⁷⁹ For example, in Canada e-cigarettes, e-liquids, and other accessories, regardless of whether they contain nicotine, are treated as a unique class of “vaping products” under the Tobacco and Vaping Products Act,⁸⁰ and will also be regulated as a medicinal product if the manufacturer makes therapeutic claims or if not, as a consumer product.⁸¹

Many jurisdictions combine a range of different regulatory approaches to manage the risks and potential benefits of e-cigarettes,⁸² often distinguishing between different vaping products on the basis of ingredients/additives (particularly nicotine or flavorings), whether the vaping product has a therapeutic purpose (and is therefore regulated as a medicine), or whether the vaping device is disposable or reusable. For example, in the United Kingdom, e-cigarettes can be licensed as a

76. See Campus et al., *supra* note 54, at 5.

77. See Jenkins et al., *supra* note 55.

78. See, e.g., Directive 2014/40 of the European Parliament and of the Council of 3 April 2014 on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Concerning the Manufacture, Presentation and Sale of Tobacco and Related Products and Repealing Council Directive 2001/37/EC, 2014 O.J. (L 127) 1, art. 20(3)(a)–(c) [hereinafter Tobacco Products Directive 2014/40].

79. Campus et al., *supra* note 54, at 6 n.56.

80. Tobacco and Vaping Products Act, S.C. 1997, c 13, s 2 (Can.) (defining “vaping product”).

81. For discussion of the applicability of the Food and Drugs Act to vaping products which make a therapeutic claim or the Canada Consumer Products Safety Act for other vaping products, see GOV'T OF CAN., HEALTH CAN., REGULATING TOBACCO AND VAPING PRODUCTS, <https://www.canada.ca/en/health-canada/services/smoking-tobacco/regulating-tobacco-vaping.html> [https://perma.cc/HPJ3-PF7T](2021).

82. Campus et al., *supra* note 54, at 2 n.6.

medicine to be used as a smoking cessation aid, although as of 2022, there were no medicinally licensed vaping products in the United Kingdom.⁸³ In addition, nicotine-containing e-cigarettes can also be sold as a consumer product as regulated under the Tobacco and Related Products Regulations 2016 (United Kingdom), which restricts the inclusion of additives or flavors in e-cigarettes,⁸⁴ regulates nicotine concentration,⁸⁵ bans advertising of e-cigarettes in the media,⁸⁶ and requires e-cigarette packaging to include a health warning.⁸⁷ Vaping products that don't contain nicotine are subject to far less stringent regulation through general product safety standards which are overseen by local authorities.⁸⁸ Applying different regulations to different categories of e-cigarette may have trade law implications, as will be discussed in Part III.A below.

While a country may generally take a health protection or a harm reduction approach to e-cigarette regulation, its specific choice of approach may place greater emphasis on the interests of particular e-cigarette users (or potential users). For example, characterizing flavors are popular with younger consumers, and flavor bans such as the New York State example can correspond with the objective of protecting young people.⁸⁹ Alternatively, if a jurisdiction is particularly concerned about helping existing tobacco smokers to quit, it may prioritize a regulatory approach that supports the use of e-cigarettes as a smoking cessation tool, such as treating these as medicinal/therapeutic products.

Depending on the regulatory approach taken, the manufacturing, importation, distribution, advertising/promotion, packaging, sale, and/or use of e-cigarettes may be restricted or subject to health/safety standards.⁹⁰ The specific aspects of e-cigarette commerce that are restricted will determine which WTO agreement/s might apply to the regulation. As will be discussed further in Part III.A of this Article,

83. See Gov't of U.K., *Nicotine vaping in England: 2022 evidence update summary*, OFF. FOR HEALTH IMPROVEMENT AND DISPARITIES, <https://www.gov.uk/government/publications/nicotine-vaping-in-england-2022-evidence-update> https://perma.cc/9KDP-5FNZ(2022).

84. The Tobacco and Related Products Regulations 2016, SI 2016/507, § 36(5) (U.K.).

85. *Id.* § 36(2)–(4).

86. *Id.* § 42.

87. *Id.* § 37.

88. See General Product Safety Regulations, 2005, SI 2005/1803 (U.K.).

89. Liane M. Schneller et al., *supra* note 51, at 1.

90. On the different regulatory domains through which e-cigarettes may be regulated, see Kennedy et al., *supra* note 55.

regulations that affect the importation or sale of e-cigarettes, including product and safety standards, may raise issues under the WTO's agreements relating to trade in goods. In many jurisdictions where e-cigarettes are treated as tobacco products or consumer products, the relevant regulatory framework includes restrictions on the advertising or promotion of e-cigarettes, or imposes packaging requirements.⁹¹ To the extent that these measures affect the ability of e-cigarette companies to use their intellectual property rights—most notably any trademarks, such as brand names or logos—they may raise issues under the TRIPS Agreement, as will be discussed below in Part III.B.

C. *The Lack of International Consensus or Guidance*

Although the WHO has recently urged its members that “urgent and strong decisive action to prevent uptake of e-cigarettes, which are harmful to health, should be taken to protect children, as well as non-smokers and minimize health harms to the population,”⁹² the diverse approaches to e-cigarette regulation outlined above reflect a lack of international consensus. This contrasts to traditional tobacco products. The need for multilateral consensus on tobacco control was recognized by parties to the FCTC, which was agreed in 2003 and applies to tobacco products.⁹³ This agreement ensures core principles which provide the basis for evolving consensus on tobacco control measures through the FCTC Conference of Parties (COP). The COP meets regularly and agrees protocols with detailed guidance on the principles agreed in the convention, including protocols regarding marketing, advertising, and packaging. Tobacco products are defined as “products entirely or partly made of the leaf tobacco as raw material which are manufactured to be used for smoking, sucking, chewing or snuffing.”⁹⁴ Although some e-cigarettes contain nicotine which is derived from tobacco plants, some contain synthetic nicotine or no nicotine at all. Even if nicotine in ENDS is derived from tobacco, it may not mean that the products constitute tobacco products. Gruszczynski argues that the

91. See *infra* Part III.B.1 for a discussion on examples of these measures.

92. WORLD HEALTH ORGANIZATION, ELECTRONIC CIGARETTES: CALL TO ACTION (Dec. 14, 2023) https://cdn.who.int/media/docs/default-source/tobacco-hq/regulating-tobacco-products/ends-call-to-action.pdf?sfvrsn=ea4c4fdb_12&download=true [https://perma.cc/XMQ8-JU2M].

93. See FCTC, *supra* note 19.

94. *Id.* art. 1.

most appropriate legal basis for dealing with ENDS under the FCTC is the general obligation in Article 5.2, for states to “adopt and implement effective legislative, executive, administrative and/or other measures and cooperate, as appropriate, with other Parties in developing appropriate policies for preventing and reducing tobacco consumption, nicotine addiction and exposure to tobacco smoke.”⁹⁵ However, Article 5.3 may be relevant to both ENDS and ENNDS as it provides that:

In setting and implementing their public health policies with respect to tobacco control, Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law.

Arguably tobacco industry investment in ENDS and ENNDS and the potential for these products to be a gateway for tobacco consumption engage this obligation.⁹⁶ The FCTC preamble also recognizes “the need to be alert to any efforts by the tobacco industry to undermine or subvert tobacco control efforts.”⁹⁷ E-cigarettes were originally developed and marketed as a tool for smoking cessation but there is increasing concern that e-cigarette use in young people is a gateway to initiating tobacco use.⁹⁸ Although this is contested,⁹⁹ the tobacco industry has made significant investments in the e-cigarette industry.¹⁰⁰ Any marketing activities for e-cigarettes that may be part of a strategy by trademark owners with vested interests in the tobacco industry to continue tobacco consumption engage FCTC Article 5.3. The extent to which the FCTC can shape interventions remains uncertain and the way that the FCTC can and should be interpreted in regulation of e-cigarettes remains unresolved.¹⁰¹

In the absence of multilateral consensus, domestic policymakers need to pay close attention to the way that they frame regulation of e-cigarettes to ensure that an individual approach is not challenged for

95. Lukasz Gruszczynski, *Taming Schrödinger’s Cat: E-Cigarettes under the Framework Convention on Tobacco Control*, in *THE REGULATION OF E-CIGARETTES: INTERNATIONAL, EUROPEAN AND NATIONAL CHALLENGES* 76, 86 (Lukasz Gruszczynski ed., 2019).

96. *See id.* at 93.

97. FCTC, *supra* note 19, pmbl.

98. *See* Explanatory Statement, *Customs (Prohibited Imports) Amendment (Vapouriser Nicotine) Regulations 2020* (Cth) 14 (Austl.).

99. *See* Mendelsohn & Hall, *supra* note 29, at 1.

100. *See E-Cigarettes*, TOBACCO TACTICS: UNIVERSITY OF BATH <https://tobaccotactics.org/article/e-cigarettes/> [<https://perma.cc/K93Z-A78P>].

101. For references to novel and emerging tobacco products, see Conference of the Parties to the World Health Organization Framework Convention on Tobacco Control, Tenth Session, *Panama Declaration*, WHO Doc. FCTC/COP/10/11, ¶ 4 (Feb. 10, 2024).

non-compliance with trade and investment law, particularly through the dispute mechanisms of the WTO.

III. WTO AGREEMENTS AND OBLIGATIONS RELEVANT TO E-CIGARETTE REGULATIONS

In this Section, we consider some of the key WTO agreements and obligations that are likely to be relevant to e-cigarette regulations. Given the diverse range of approaches countries are taking, we provide a general overview of the obligations and how they have been interpreted, rather than considering whether any specific approach or policy will be consistent with each WTO provision. We begin, in Part A, with two key agreements relating to trade in goods—the TBT Agreement and the GATT—and their core obligations relating to non-discrimination and the trade-restrictiveness of regulations. Part B then considers the TRIPS Agreement, with a focus on rights of trademark owners to use their trade-marks and how encumbrances can be justified on public health grounds.

A. Agreements Relating to Trade in Goods: the TBT Agreement and the GATT

1. The Application of the TBT Agreement and the GATT to E-Cigarette Regulations

The GATT sets out general obligations that apply to any measures affecting trade in goods, including measures that are obviously trade-related such as bans on importation of certain products, as well as any domestic regulations that may affect the “internal sale, offering for sale, purchase, transportation, distribution or use” of an imported product.¹⁰² This broad category of measures would likely encompass most e-cigarette regulations.

In contrast, the TBT Agreement contains more specialized rules applying to technical regulations, standards and conformity assessment procedures. A “technical regulation” is defined as a “[d]ocument which lays down product characteristics . . . with which compliance is mandatory.”¹⁰³ A product characteristic can be either positive (e.g. the

102. See GATT, *supra* note 18, art. 3, ¶ 4, art. I, ¶ 1.

103. See TBT Agreement, *supra* note 18, Annex 1.1.

product must contain X) or negative (e.g. a product must not contain Y).¹⁰⁴ Component bans (such as prohibitions on the inclusion of nicotine, characterizing flavors, or additives in e-cigarettes) or any other product safety standards would likely be considered technical regulations which are subject to the TBT Agreement. For example, in *US – Clove Cigarettes* it was held that a ban on characterizing flavors other than menthol being added to cigarettes was a technical regulation.¹⁰⁵ Similarly, regulatory frameworks which ban the sale of ENDS or which ban vaping liquids/cartridges containing nicotine may be considered to impose a negative product characteristic. An absolute ban on all e-cigarettes may not constitute a technical regulation, because it would not prescribe any characteristics for a particular group of products.¹⁰⁶ However, a measure which generally banned e-cigarettes but which allowed certain exceptions (e.g. for approved e-cigarettes to be used for smoking cessation) could potentially be considered a technical regulation—this would need to be considered on a case by case basis,¹⁰⁷ and would likely turn on whether the permitted e-cigarettes were defined by product characteristics (as opposed to the purpose of their use).¹⁰⁸

The TBT Agreement itself specifies that the product characteristics that are imposed by a technical regulation may “include or deal exclusively with terminology, symbols, packaging, marking or

104. See Elizabeth Sheargold, *Article 1 and Annex 1 TBT: General Provisions and Terms and Their Definitions*, in COMMENTARIES ON WORLD TRADE LAW 306, 323–26 (Markus Wagner ed., 2023).

105. Panel Report, *US – Clove Cigarettes*, *supra* note 15, ¶¶ 7.32, 7.40. This finding was not challenged on appeal. See Appellate Body Report, *US – Clove Cigarettes*, *supra* note 15, ¶ 76.

106. For discussion of whether an absolute product ban is a technical regulation, see Appellate Body Report, *European Communities – Measures Affecting Asbestos and Asbestos-Containing Products*, ¶ 71, WT/DS135/AB/R (Mar. 12 2001) [hereinafter Appellate Body Report, *EC – Asbestos*].

107. Marina Foltea & Bryan Mercurio, *A Ban on Electronic Nicotine Delivery Systems: Step One in the WTO Discrimination Analysis*, in THE REGULATION OF E-CIGARETTES 126, 126 (2019) [hereinafter *A Ban on Electronic Nicotine Delivery Systems*].

108. In *EC – Seal Products*, an EU ban on the sale of seal products which contained significant exceptions for products produced by indigenous communities and for marine research was not considered a technical regulation because the exceptions were defined by the identity of the hunters and the purpose of the hunt, rather than characteristics of the end product. See Appellate Body Reports, *European Communities – Measures Prohibiting the Importation and Marketing of Seal Products*, ¶¶ 5.39, 5.41–42, 5.53–54, 5.58, WTO Docs. WT/DS400/AB/R, WT/DS401/AB/R (May 22, 2014) [hereinafter Appellate Body Reports, *EC – Seal Products*]; Sheargold, *supra* note 104, at 324–26.

labelling requirements.”¹⁰⁹ Given this definition, any labelling or packaging requirements imposed on e-cigarettes—including plain packaging rules or the imposition of health warning requirements—would likely be considered a technical regulation.¹¹⁰

The preceding paragraphs have shown that most of the regulatory approaches that countries are applying to e-cigarettes—including bans with exceptions for therapeutic use, component bans, or restrictions on additives such as nicotine content and flavors, product safety standards, and packaging requirements like health warnings—could arguably be considered technical regulations that are subject to the TBT Agreement. If a measure is a technical regulation, this does not exclude the application of the relevant GATT obligations. Instead, the obligations contained in the GATT and the TBT Agreement are cumulative, meaning that a measure must comply with both agreements.¹¹¹

The only regulatory approach identified by Campus et al. that is unlikely to be considered a technical regulation is the strictest approach on their spectrum¹¹²—an absolute prohibition on all e-cigarettes. This is the conclusion reached by Foltea and Markitanova, who analyze the WTO compatibility of a complete prohibition of e-cigarettes under GATT obligations only.¹¹³

As will be discussed in Part II below, e-cigarette regulations will need to comply with the non-discrimination obligation under TBT Article 2.1 and/or GATT Articles I and III. For those e-cigarette regulations that constitute a technical regulation, then the measure must also comply with other aspects of Article 2 of the TBT Agreement,¹¹⁴

109. See TBT Agreement, *supra* note 18, Annex 1.1.

110. This was the finding reached by the Panel in *Australia — Tobacco Plain Packaging*, despite Australia arguing that the TBT Agreement could not apply to elements of the regime that constrained the use of trademarks. See Panel Reports, *Australia — Tobacco Plain Packaging*, *supra* note 17, ¶¶ 7.146–7.158. This finding was not challenged on appeal.

111. See Appellate Body Report, *EC—Asbestos*, *supra* note 106, ¶¶ 80–82, applying the general approach to Annex 1A agreements taken in Appellate Body Report, *Korea – Definitive Safeguard Measure on Imports of Certain Dairy Products*, ¶¶ 74–75, WTO Doc. WT/DS98/AB/R (adopted Dec. 14, 1999).

112. See Campus et al., *supra* note 54.

113. See Marina Foltea & Anna Markitanova, *The Likeness of E-Vapour Products and Cigarettes in the World Trade Organization*, 8 EUR. J. OF RISK REGUL. 342, 343 (2017).

114. Other aspects of TBT Article 2 include: that technical regulations must not be maintained if the circumstances leading to their creation change (Article 2.3), that technical regulations should be based on relevant international standards (Article 2.4), that Members could

most notably the requirement that technical regulations not create unnecessary obstacles to trade under TBT Article 2.2, an obligation which was central in the *Australia – Tobacco Plain Packaging* dispute.

2. Discrimination Between “Like Products”: TBT Agreement Article 2.1 and GATT Articles I and III

Article 2.1 of the TBT Agreement, and Articles I and III of the GATT, require that measures not discriminate against imported products, *vis-à-vis* local products (national treatment) or imports from a third country (most-favored nation treatment).¹¹⁵ These anti-discrimination provisions are a core aspect of international trade law, as they are intended to ensure a level playing field for imported goods. In essence, non-discrimination obligations seek to prevent similar or equivalent products being treated differently in a way that would disadvantage imported goods. Thus, these obligations assess the relative treatment of the relevant imported products, and it is therefore central to establishing discrimination that another category of comparable products is identified (known as “like products”) that receives more favorable treatment.

A non-discrimination claim involving e-cigarette regulations could arise in one of two ways. First, a WTO Member which exports e-cigarettes could challenge strict regulatory measures imposed on e-cigarettes or on a certain category of e-cigarettes (such as those that contain nicotine or flavored e-cigarettes) on the basis that the regulations discriminate relative to other products that are regulated more leniently (such as ENNDS, tobacco flavored e-cigarettes or tobacco products). While e-cigarette production is concentrated in China and it would therefore be the country most likely to be significantly affected by restrictions on e-cigarettes in other countries,¹¹⁶ any WTO Member with even a small e-cigarette industry

contribute to harmonization of regulations and mutual recognition (Articles 2.6 and 2.7) and notification and publication requirements (Articles 2.9 – 2.12). *See* TBT Agreement, *supra* note 18, arts. 2.3, 2.4, 2.6, 2.7, 2.9–2.12.

115. TBT Agreement Article 2.1 covers both national treatment and most favored nation treatment, while GATT Article 1 prescribes most favored nation treatment, and GATT Article III requires national treatment. *See* TBT Agreement, *supra* note 18, art. 2.1; GATT, *supra* note 18, arts. 1, 3.

116. As of 2019, it was reported that ninety percent of global e-cigarette production came from the city of Shenzhen in China. *See* Michael Standaert, *Shenzhen, vaping capital of the world, holds its breath as health concerns spiral*, THE GUARDIAN (Dec. 1, 2019, 7:00 PM),

could launch such a challenge. There is no minimum threshold for volume or value of affected trade in order for a WTO Member to bring a dispute; instead claims under the GATT or the TBT Agreement are brought on the basis of any “nullification or impairment” of benefits that should accrue under the agreements and any measures which are found to be inconsistent with an obligation imposed by either agreement is rebuttably presumed to cause nullification or impairment.¹¹⁷ Second, if a WTO Member takes a permissive approach to e-cigarette regulation, a WTO Member that produces potentially “like” products—most likely tobacco products—which are subject to more stringent restrictions could argue that the differences in the regulations constitutes discrimination. Tobacco-producing WTO Members have already demonstrated a willingness to bring WTO claims challenging public health regulations in the *US – Clove Cigarettes* and *Australia – Tobacco Plain Packaging* disputes, sometimes with “legal and financial support” from tobacco companies themselves.¹¹⁸

The first stage in identifying whether any discrimination has occurred is to identify the relevant “like” products,¹¹⁹ an analysis which is likely to be crucial in the evaluation of e-cigarette regulation given the distinctions that are made in many jurisdictions between different kinds of e-cigarettes or differences in the treatment of e-cigarettes and tobacco products.¹²⁰ The second stage in the discrimination analysis is to examine whether there has been less favorable treatment of an

<https://www.theguardian.com/world/2019/dec/01/shenzhen-vaping-capital-of-the-world-holds-its-breath-as-health-concerns-spiral> [https://perma.cc/FU5E-57VS].

117. Understanding on Rules and Procedures Governing the Settlement of Disputes art. 3.8, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, 1869 U.N.T.S. 401 [hereinafter DSU].

118. Eric Crosbie, Robert Eckford & Stella Bialous, *Containing diffusion: the tobacco Industry’s Multipronged Trade Strategy to Block Tobacco Standardised Packaging*, 28 *TOBACCO CONTROL* 195, 199 (2019).

119. Appellate Body Report, *Korea – Measures Affecting Imports of Fresh, Chilled and Frozen Beef*, ¶ 133, WTO Docs. WT/DS161/AB/R, WT/DS169/AB/R (Dec. 11, 2000) [hereinafter Appellate Body Report, *Korea – Various Measures on Beef*] (discussing GATT Article III:4); see Appellate Body Report, *United States – Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products – Recourse to Article 21.5 of the DSU by Mexico*, ¶ 7.25, WTO Doc. WT/DS381/AB/RW (Nov. 20, 2015) [hereinafter Appellate Body Report, *US – Tuna II (Mexico) (Article 21.5 – Mexico)*] (discussing TBT Article 2.1).

120. See *supra* Section II.B.

imported product.¹²¹ If there has been differential treatment between “like” products, then it must be considered whether this discrimination can be justified by the public purpose of the measure at issue. In respect of technical regulations being scrutinized under Article 2.1 of the TBT Agreement, whether the differential treatment can be justified is examined in the application of the article itself, while for the GATT non-discrimination obligations the purpose of the differential treatment will only be considered if the relevant WTO Member invokes the general exceptions under Article XX as a defense.

a. “Like” Products

With respect to the regulation of e-cigarettes, there are a range of possibilities for what could constitute “like” products. The limited literature to date on the WTO consistency of e-cigarette regulation has focused on whether ENDS are like cigarettes or other traditional tobacco products.¹²² But, depending on the approach taken in the e-cigarette regulatory regime, any distinction drawn between different kinds of e-cigarettes or related products could potentially be seen as distinguishing between “like” products, for example: ENDS v. ENNDS; disposable vapes v. reusable vapes; e-cigarettes which are tobacco flavored and those which have other characterizing flavors.

The test for determining whether products are “like” under both the GATT and TBT non-discrimination obligations is focused on establishing the nature and extent of any competitive relationship between two groups of products.¹²³ There are four criteria which the Appellate Body has traditionally considered when assessing likeness and the extent of a competitive relationship between groups of products: (i) physical characteristics of the products; (ii) end-uses of the products; (iii) consumer tastes and habits; and (iv) tariff

121. Appellate Body Report, *Korea – Various Measures on Beef*, *supra* note 119 (with respect to GATT Article III.4); *see* Appellate Body Report, *US – Tuna II (Mexico) (Article 21.5 – Mexico)*, *supra* note 119 (with respect to TBT Article 2.1). Note that for the GATT obligations there is an additional step of establishing that the measure is a “law, regulation, or requirement affecting their internal sale, offering for sale, purchase, transportation, distribution, or use.” As noted above in Part III.A.1, most of the e-cigarette regulations discussed in this Article would be likely to fulfil this requirement.

122. Foltea & Mercurio, *supra* note 107; Foltea & Markitanova, *supra* note 113.

123. Appellate Body Report, *EC – Asbestos*, *supra* note 106, ¶¶ 98–99; *see* Appellate Body Report, *US – Clove Cigarettes*, *supra* note 15, ¶¶ 111–12.

classification.¹²⁴ These criteria are not closed and need to be assessed holistically, in light of all relevant evidence.¹²⁵ While the Appellate Body has been clear that regulatory purpose is not a separate criteria to be assessed in the likeness analysis, the regulatory concerns underlying a measure are relevant to the criteria outlined above. For example, in *EC – Asbestos*, where the measure at issue was a ban on products containing asbestos fibers, the carcinogenic properties of asbestos were considered in the assessment the physical characteristics of the products and in relation to consumer tastes.¹²⁶ In the following sections, we consider how these criteria might apply in the assessment of whether: (i) e-cigarettes containing nicotine and tobacco products are “like”; and (ii) different categories of e-cigarettes are “like.”

i. Nicotine-Containing E-Cigarettes vs. Tobacco Products

There are many physical differences between e-cigarettes and tobacco products. These include, but are not limited to, differences in the composition, appearance, and operation of the products—for example, that e-cigarettes are usually made of plastic and/or metal and consume liquid or cartridges, while cigarettes are made out of tobacco leaf and paper. The physical differences are greatest when comparing reusable e-cigarettes with cigarettes, although there are still many differences between disposable vapes and cigarettes. This is not to say that there are no similarities, such as both products contain nicotine. However, such small physical commonalities would generally not be sufficient for products to be considered “like.” For example, in the many WTO disputes concerning alcoholic beverages there has been debate about whether different kinds of spirits are “like,”¹²⁷ but it is

124. These criteria were first set out by the GATT Working Party in *Border Tax Adjustments*, but have since been adopted and developed by the Appellate Body several disputes, including: Appellate Body Report, *EC—Asbestos*, *supra* note 106, ¶ 101.

125. *Id.* ¶ 102.

126. *Id.* ¶¶ 113, 114, 122. *See also* Panel Report, *Indonesia – Measures Concerning the Importation of Chicken Meat and Chicken Products*, ¶¶ 7.313–7.318, WTO Doc. WT/DS484/R and Add.1 (Oct. 17, 2017) [hereinafter Panel Report, *Indonesia – Chicken*].

127. *See generally* Appellate Body Report, *Philippines – Taxes on Distilled Spirits*, WTO Docs. WT/DS396/AB/R, WT/DS403/AB/R (Dec. 2, 2011) [hereinafter Appellate Body Report, *Philippines – Distilled Spirits*]. Note that these cases concern GATT Article III:2 first sentence, which refers to “like products” but which may have a different scope to the concept of like products under GATT Article III:4. *See, e.g.*, Appellate Body Report, *Japan – Taxes on Alcoholic Beverages*, WTO Docs. WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R (Oct. 4, 1996) [hereinafter Appellate Body Report, *Japan – Alcoholic Beverages II*].

broadly accepted that drinks such as wine and beer are not “like” even though both contain alcohol. The category of tobacco products that is most physically similar to e-cigarettes are electronic heated tobacco products.

The different health risks of e-cigarettes as compared to cigarettes and traditional tobacco products would also be relevant to their likeness.¹²⁸ This could be argued in two ways: a WTO Member seeking to show that e-cigarettes and tobacco are “like” products may argue that they pose some similar or overlapping health risks, e.g. from the inhalation of certain chemicals and the addictive properties of nicotine.¹²⁹ On the other hand, a WTO Member who was seeking to show that e-cigarettes and tobacco cigarettes were not “like” could point to possible differences in the potential health risks posed by these products as factors which suggest that e-cigarettes and tobacco cigarettes are not “like.” This may include identifying risks that are unique to e-cigarettes (e.g. EVALI or other impacts that can be tied to ingredients found in e-cigarettes but not in tobacco products), the uncertainty in the health impacts of vaping (in contrast to clearer longitudinal evidence of the health impacts of tobacco smoking), or evidence that e-cigarettes pose less of a health risk than tobacco.

Following the approach taken by the Appellate Body in *EC – Asbestos*, where there are so many physical differences between allegedly “like” categories of products there is a “higher burden” on the claimant to establish, on the basis of other criteria such as consumer tastes and habits, that there is still a competitive relationship between the products.¹³⁰ Differences in the composition, appearance, operation and health risks posed by e-cigarettes and tobacco cigarettes suggests that these two categories of products are probably not “like”. Although not a case applying WTO rules, it is notable that in 2016 the CJEU reached this conclusion when considering whether the principle of equal treatment meant that e-cigarettes should be regulated consistently with tobacco products.¹³¹ In that decision, the CJEU emphasized the different composition of the products (e.g. that e-cigarettes generally

128. See *supra* notes 125–126 and accompanying text (discussing “like” products).

129. See *supra* Section II.A for a more detailed discussion of these health risks.

130. See Appellate Body Report, *EC – Asbestos*, *supra* note 106, ¶¶ 118–21; see also Panel Report, *Indonesia – Chicken*, *supra* note 127, ¶¶ 7.317–18.

131. See Case C-477/14, *Pillbox 38 (UK) Ltd. v. Sec’y of State for Health*, ECLI:EU:C:2016:324, ¶¶ 33–43 (May 4, 2016).

do not contain tobacco, that tobacco products are consumable while e-cigarettes are often refillable and are never fully consumed), different patterns of consumption (that e-cigarettes use electromechanical vaporization rather than combustion) and that the health impacts of e-cigarettes were unclear due to the novelty of the product.¹³²

Establishing a competitive relationship despite the different physical characteristics of the products will depend on the three remaining criteria the Appellate Body uses to assess likeness: end-uses of the products (focused on the uses which a product is capable of), consumer tastes and habits (consumers' actual use and preferences), and tariff classification.¹³³ The critical issue when considering end uses of the products are how the "end use" of e-cigarettes and tobacco products are conceived or framed, as the end uses must be "comprehensive and specific enough to provide meaningful guidance as to whether the products in question are "like" products."¹³⁴ In *US – Clove Cigarettes* the Appellate Body held that simply saying that the end use of cigarettes is "to be smoked" did not provide sufficient guidance for determining if clove cigarettes and menthol cigarettes were "like."¹³⁵ When making this point the Appellate Body noted that "cigars, loose tobacco, and herbs share the same end-use of being 'smoked', although this does not say much as to whether all these products are like", and drew a comparison to how the end use of alcoholic beverages is not framed simply as "to be drunk."¹³⁶ In *Clove Cigarettes*, the more specific end uses put forward by the US and accepted by the Appellate Body were (i) satisfying an addiction to nicotine and (ii) "creating a pleasurable experience associated with the taste of the cigarette and the aroma of the smoke."¹³⁷

Foltea and Mercurio argue that it is likely that nicotine containing e-cigarettes and traditional tobacco products would be treated as "like" under WTO rules because they both are "capable of performing the same function and in essence served to deliver nicotine and contribute to the 'ritual' of smoking."¹³⁸ While we agree that both products are

132. *See id.*

133. *See supra* text accompanying note 125 (discussing likeness criteria).

134. *See* Appellate Body Report, *US – Clove Cigarettes*, *supra* note 15, ¶ 129.

135. *See id.*

136. *See id.* ¶ 129 n.305.

137. *Id.* at 127–30.

138. Foltea & Mercurio, *supra* note 107, at 134–35.

capable of delivering nicotine, we would suggest that there are potentially differences in how the products may be used as part of a “ritual” of smoking, the sensation created by the taste and aroma of the smoke (while both products involve inhalation, vaping does not involve combustion) and the social features of the products. In addition, as Foltea and Mercurio also note,¹³⁹ e-cigarettes containing nicotine are arguably capable of an end use of acting as an aid in smoking cessation which may distinguish them from tobacco products.¹⁴⁰

The criterion of consumer tastes and habits essentially considers the extent to which consumers treat e-cigarettes containing nicotine and tobacco products as interchangeable or substitutable. As noted above, given the significant physical differences between these products, an argument that e-cigarettes and cigarettes are “like” would require significant evidence of a competitive relationship based on consumer tastes and habits. In their analyses of this question, Foltea, Mercurio, and Markitanova note that the evidence to date on consumer tastes and preferences is mixed.¹⁴¹ In favor of likeness are studies which suggest that a significant proportion of e-cigarette users are also using tobacco products in tandem, with one recent UK study suggesting that 56% of e-cigarette users are ex-smokers and 37% continue to use tobacco products, and the proportion of ex-smokers among e-cigarette users has grown considerably over the past decade, relative to users that continue smoking tobacco products.¹⁴² Of the ex-tobacco smokers using e-cigarettes, the study found that 31% used them as a smoking cessation aid, and 22% used them to prevent relapse into tobacco smoking.¹⁴³

It is important to note that the consumer tastes and habits analysis would be specific to the WTO Member whose regulatory measure is under challenge, and may therefore vary between different countries/markets. Within this criterion it may also be important to consider the preferences of specific groups of consumers, such as youth consumption.¹⁴⁴ The analysis cannot be limited to only one such subset

139. *See id.* at 135.

140. *See supra* Section II.A.

141. *See* Foltea & Mercurio, *supra* note 107, at 135; Foltea & Markitanova, *supra* note 113, at 350–51.

142. *Use of e-cigarettes (vapes) among adults in Great Britain*, ACTION ON SMOKING AND HEALTH (Aug. 2023), <https://ash.org.uk/uploads/Use-of-e-cigarettes-among-adults-in-Great-Britain-2023.pdf?v=1691058248> [<https://perma.cc/DTG4-5TRF>].

143. *Id.*

144. *See* Appellate Body Report, *US – Clove Cigarettes*, *supra* note 15, ¶ 137.

of users,¹⁴⁵ but the preferences of key consumer groups are an important part of the consumer taste and habits analysis. For example, if vaping is becoming very common among young people who have never smoked tobacco products, this may suggest that e-cigarettes are unlike tobacco products. Similarly, use of e-cigarettes by former smokers as a smoking cessation tool or as a long-term replacement for tobacco may also suggest that the products are unlike—while in these cases consumers have substituted one product for the other, this is not because they view the products as interchangeable, but is in fact because of the differences between the products, such as the different health impacts.

The final criterion, of tariff classification, is typically a straightforward consideration. However, the tariff classification of e-cigarettes was initially unclear and new categories have had to be created for these products. When e-cigarettes first hit the market there was no appropriate tariff classification, but they were initially put within Chapter 85 of the World Customs Organization (WCO)'s harmonized system (HS) of tariff classification. Chapter 85 relates to electrical machinery, and a specific sub-category now exists in 8543 40 for e-cigarettes and similar personal electric vaporizing devices. This category covers reusable e-cigarettes (i.e. the device itself), and where that device is sold with cartridges these combination packages are also often classified within HS code 8543 40.¹⁴⁶

In 2022, the WCO amended its harmonized system of tariff classification to incorporate some categories of e-cigarettes and related consumables within Chapter 24, which is the chapter for “[t]obacco and manufactured tobacco substitutes; products, whether or not containing nicotine, intended for inhalation without combustion; other nicotine containing products intended for the intake of nicotine into the human body.”¹⁴⁷ While the inclusion of disposable e-cigarettes and e-cigarettes consumables (e.g. cartridges and liquids) within the same

145. *See id.*

146. *See, e.g.*, U.K. Gov't, Guidance: Classifying tobacco for import and export (Aug. 7, 2023), <https://www.gov.uk/guidance/classifying-tobacco#:~:text=An%20electronic%20cigarette%20with%20a,intended%20for%20inhalation%20without%20combustion> [https://perma.cc/MJV4-SXNG] (last visited Jun. 18, 2024).

147. *See* World Customs Org. [WCO], *Harmonised System Nomenclature* (2022), <https://www.wcoomd.org/en/topics/nomenclature/instrument-and-tools/hs-nomenclature-2022-edition/hs-nomenclature-2022-edition.aspx> [https://perma.cc/F2P9-P88R](showing the relevant chapter at 0424-2022E).

chapter as cigarettes may suggest some general degree of likeness,¹⁴⁸ typically in a likeness analysis Panels and the Appellate Body focus on the classification of products at the six-digit, or at least the four-digit, level rather than looking broadly at the HS chapter the goods are classified in (the two-digit level).¹⁴⁹ In an early report concerning tariff classification, the Appellate Body noted that, to be a useful part of the likeness analysis, the HS classification under consideration needs to be “sufficiently detailed.”¹⁵⁰ In *Philippines – Taxes on Distilled Products*, a dispute concerning the tax treatment of spirits such as brandy and whisky, the Appellate Body noted that the four-digit HS classification 2208 was not sufficiently detailed to be useful for a likeness analysis because that code included “all distilled spirits, as well as other liquors and unflavored neutral spirits for human consumption or for industrial purposes.”¹⁵¹ Instead, the Appellate Body found that at the six-digit level it became clear that brandies and whiskies made domestically would fall into a different classification to many imported products, as they were made by distilling different ingredients, and that this would suggest the different spirits are not “like.”¹⁵²

With respect to disposable e-cigarettes, e-cigarette consumables and tobacco products, while these products all sit within Chapter 24 of the HS, they fall into different four-digit classifications: cigarettes typically fall into the 2402 20 category for “cigars, cheroots, cigarillos and cigarettes, of tobacco or of tobacco substitutes,” while disposable ENDS and e-cigarette consumables that contain nicotine will usually fall into the 2404 12 category for “products intended for inhalation without combustion.”¹⁵³ It is particularly notable that the HS classifications distinguish, even at the six-digit level, between products containing tobacco and those which do not—such as products intended for inhalation without combustion that contain tobacco being put into 2404 11, while other (i.e. non-tobacco) products containing nicotine intended for inhalation without combustion are put into category 2404

148. See Foltea & Markitanova, *supra* note 113, at 137–38.

149. See, e.g., Appellate Body Report, *US – Clove Cigarettes*, *supra* note 15, ¶ 7.236 (noting that the products were in the same six-digit level); Panel Report, *Indonesia – Chicken*, *supra* note 126, ¶¶ 7.308, 7.319 (focusing on six-digit classification); Appellate Body Report, *Philippines – Distilled Spirits*, *supra* note 127, ¶¶ 160–63.

150. Appellate Body Report, *Japan – Alcoholic Beverages II*, *supra* note 127, at 21.

151. Appellate Body Report, *Philippines – Distilled Spirits*, *supra* note 127, ¶ 161.

152. *Id.* (noting that, based on a holistic assessment and findings under the other criteria, the relevant products were still found to be “like”).

153. U.K. Gov’t, *supra* note 146.

12. Given that reusable e-cigarette devices are classified in an entirely different chapter of the HS to tobacco products, and that disposable e-cigarettes and e-cigarette consumables are within the same HS chapter as tobacco products but are clearly distinguished at the four-digit HS code level, the tariff classification of the products suggest that e-cigarettes and tobacco products are not “like.”

Ultimately, whether nicotine-containing e-cigarettes and tobacco products are considered “like” will depend upon the specific regulatory measures, market and evidence available at the time of a WTO dispute. However, the physical differences between these products would give rise to a strong argument that they are not “like.” Overcoming this inference would require compelling evidence of consumers treating the products as interchangeable/substitutable.

ii. Different categories of e-cigarettes

As outlined above in Part II.B, many of the regulatory frameworks that countries have currently put in place for e-cigarettes distinguish between different kinds of e-cigarettes, with the distinctions often focused on the presence of a specific additive in the e-cigarette or vaping product (nicotine or the characterizing flavor). Two of the most common distinctions that are made in the rules which apply to e-cigarettes are: (i) applying more stringent rules to e-cigarettes or vaping products which contain nicotine (or ENDS), compared to those which do not contain nicotine (or ENDDS); or (ii) banning e-cigarettes with characterizing flavors, such as candy or fruit flavors, while “unflavored” or tobacco flavored e-cigarettes remain legal. The US ban of characterizing flavors in tobacco products other than menthol—which was the subject of the *US – Clove Cigarettes* dispute—has in effect been extended to e-cigarettes, as the FDA has only authorized unflavored, menthol or tobacco flavor e-cigarettes.

When considering the likeness of different types of e-cigarettes, one of the first issues to be noted is that it is not always possible to draw a bright line between different categories of product. While many regulatory regimes apply more stringent rules to vaping products that contain nicotine, such as the US regime which treats them as tobacco products,¹⁵⁴ a reusable e-cigarette device may be capable of being used with e-liquids or cartridges that contain nicotine or those which do not,

154. See *supra* text accompanying note 62–63 (discussing likeness criteria).

or with flavored or unflavored products, and some are “open systems” that allow further user customization.¹⁵⁵

Where distinctions are drawn between different kinds of vaping products, the presence of nicotine or flavor as an additive in the product is a physical characteristic that differentiates the two product categories. However, some differences in ingredients or additives do not prevent products being found to be alike, and a WTO panel will have to engage in a specific and detailed analysis of the physical characteristics of the products to make a holistic assessment of whether they are alike in physical characteristics or properties. In *US – Clove Cigarettes* the United States made extensive arguments about different additives and composition of clove cigarettes and menthol cigarettes, but the Panel ultimately focused on three general physical similarities: that both were made of tobacco with additives and wrapped in paper; that both were predominantly made of tobacco but were distinguished from regular cigarettes by the addition of a flavor; and that while there are some unique components of clove cigarettes (described by the parties as a “sauce”), that each brand of cigarettes (whether clove or menthol) “has its own specific composition of ingredients and additives that is generally considered proprietary information.”¹⁵⁶ The Panel’s ultimate conclusion was that while there were some physical differences between clove cigarettes and menthol cigarettes, such as clove cigarettes containing Java tobacco, eugenol and coumarin, that these differences were “minor or secondary”, with both products sharing the main trait of “contain[ing] additives that produce characterizing flavors to the cigarette and reduce the harshness of the tobacco.”¹⁵⁷ These conclusions were not appealed by the United States.

In light of the reasoning in *Clove Cigarettes*, different categories of e-cigarettes may be viewed as having similar physical properties, despite differences in additives such as nicotine or flavors. However, the health risks of the products must also be considered.¹⁵⁸ If a WTO Member that had regulated one category of e-cigarettes more stringently could show that that category of product posed a greater health risk, this may be enough for the physical properties of the

155. See generally *Technical Note on Call to Action on Electronic Cigarettes*, *supra* note 2, at 4–5.

156. Appellate Body Report, *US – Clove Cigarettes*, *supra* note 15, ¶¶ 7.176–7.180.

157. *Id.* ¶¶ 7.180–7.182.

158. See *supra* notes 125–126.

different e-cigarettes to be considered dissimilar.¹⁵⁹ Given the highly addictive nature of nicotine, there may be a relatively strong case to argue that e-cigarettes that contain nicotine or which contain nicotine in high concentrations are significantly physically different from those which do not contain nicotine.

While e-cigarettes may pose health risks such as EVALI regardless of their nicotine content, the addictive properties of nicotine and associated increase in use of e-cigarettes or tobacco products should be considered a notable physical difference between the products. It is notable that the fact that both clove and menthol cigarettes contained nicotine and were therefore addictive was a similarity identified between those products in *Clove Cigarettes*.¹⁶⁰ The presence of characterizing flavors may also give rise to different levels of health risk, with some studies suggesting that flavorings themselves may increase the toxicity of e-cigarette aerosols and thus raise additional health concerns.¹⁶¹ Whether these health risks will be enough to distinguish between different categories of e-cigarettes will depend on the extent of the health risk posed. In *US – Clove Cigarettes* the Panel noted that both clove and menthol cigarettes had similar levels of “toxicity,” because “the principal reason why cigarettes create health risks is the inhalation of combusted substances,” and that this risk was similar for either product, even if some additives in clove cigarettes may, as the US alleged, cause “further health problems.”¹⁶²

159. For example, a WTO panel held that frozen and thawed chicken pieces were not “like” fresh (i.e. never frozen) chicken pieces, because of the increased health risks associated with the freezing and thawing of the meat. Panel Report, *Indonesia – Chicken*, *supra* note 126, ¶¶ 7.313–7.318.

160. See Appellate Body Report, *US – Clove Cigarettes*, *supra* note 15, ¶¶ 7.185 – 7.186; see also *infra* note 309. There was some conflicting evidence between the parties about whether clove cigarettes delivered high levels of nicotine and were therefore more harmful to health, but this was not considered decisive by the Panel. See Appellate Body Report, *US – Clove Cigarettes*, *supra* note 15, ¶ 7.185.

161. See *Technical Note on Call to Action on Electronic Cigarettes*, *supra* note 2, at 5 (citing Report on the Scientific Basis of Tobacco Product Regulation: Seventh Report of a WHO Study Group, WORLD HEALTH ORGANIZATION [WHO], WHO Technical Report Series, No. 1015 (2019) <https://www.who.int/publications/i/item/who-study-group-on-tobacco-productregulation-report-on-the-scientific-basis-of-tobacco-productregulation-seventh-report-of-a-who-study-group> [<https://perma.cc/7FS2-HDWT>]); WHO Study Group on Tobacco Product Regulation, *Report on the Scientific Basis of Tobacco Product Regulation: Eighth Report of a WHO Study Group*, WHO Technical Report Series No. 1029 (2021) <https://www.who.int/publications/i/item/9789240022720> [<https://perma.cc/8DLT-FJYG>].

162. See Appellate Body Report, *US – Clove Cigarettes*, *supra* note 15, ¶¶ 7.183–7.187.

Aside from physical properties, there may be some distinctions between different categories of e-cigarettes under the remaining likeness criteria. With respect to end-uses, these need to be considered more specifically than simply that any kind of e-cigarette is capable of being inhaled/“smoked”. Most categories of e-cigarette may be capable of performing the end use of creating a “pleasurable experience” from its inhalation and may be used in a social setting for experimentation, similar to the clove and menthol cigarettes considered in *Clove Cigarettes*.¹⁶³ However, only e-cigarettes that contain nicotine would be capable of fulfilling the end of use of delivering nicotine or satisfying an addiction to nicotine.¹⁶⁴ This is an important distinction, particularly in those countries where e-cigarettes are treated as a therapeutic good for use in smoking cessation, which could be raised by a WTO Member seeking to defend allowing the use of ENDS for medical purposes while banning other e-cigarettes.¹⁶⁵

For a WTO Member seeking to defend differentiating between different categories of e-cigarettes, and particularly only trying to defend a ban on characterizing flavors, a key criterion to focus on will be consumer tastes and habits. While the United States failed to defend its ban on characterizing flavors in cigarettes in the *Clove Cigarettes* dispute, it is important to remember that the discrimination analysis in that case focused solely on whether clove cigarettes were like menthol cigarettes, because menthol flavoring was excluded from the US ban. A ban which applies to all characterizing flavors being added to e-cigarettes, including menthol, will have a greater likelihood of being able to be defended.¹⁶⁶

Flavor bans are typically implemented to protect the interests of young people, as flavored e-cigarettes (like flavored tobacco products) are often designed to attract young people to smoking.¹⁶⁷ Even if the measure is motivated by a desire to protect young people, evidence of

163. See Appellate Body Report, *US – Clove Cigarettes*, *supra* note 15, ¶ 132.

164. *Cf. id.*

165. For example, the new regulatory regime being implemented in Australia. See *supra* text accompanying note 59.

166. See generally Andrew Mitchell & Tania Voon, *Regulating Tobacco Flavors: Implications of WTO Law*, 29 B.U. INT’L L.J. 383 (2011).

167. On the use of flavoring to attract young consumers, see *Technical Note on Call to Action on Electronic Cigarettes*, *supra* note 2. We note that some authors suggest these flavor bans may not achieve their aims. See, e.g., Mendelsohn et al., *supra* note 25, at 1289.

use by all consumer groups will be relevant in this likeness analysis,¹⁶⁸ although even one group of consumers treating the products as highly substitutable may be sufficient to support a finding of likeness.¹⁶⁹ The inquiry into consumer tastes and habits is specific to the market of the WTO Member, so general conclusions cannot be made in the abstract, but if a WTO Member can provide sufficient evidence that consumers do not treat flavored e-cigarettes as interchangeable with other e-cigarettes, then the products may not be in a competitive relationship that would make them “like.” Similar arguments could also be made about consumer tastes and preferences with respect to nicotine content, but again the strength of the argument will depend on the evidence as it relates to the market of the relevant WTO Member.

Finally, with respect to tariff classification, at the six-digit level there are different categories for tobacco products or substitutes that are intended for inhalation without combustion that contain nicotine (HS 2404 12), and those that do not (HS 2404 19).¹⁷⁰

While it is impossible to make definitive conclusions about whether different categories of e-cigarettes are “like,” because these findings would depend on the competitive relationship of the products in a specific market of a WTO Member, it would *prima facie* seem that there is a reasonable case that nicotine containing e-cigarettes can be distinguished from other e-cigarettes, on the basis of physical properties (specifically health risk), end uses, and potentially consumer tastes and tariff classification. In light of the findings of the *US – Clove Cigarettes* dispute it may be harder to establish differences in physical properties or end uses between flavored and unflavored e-cigarettes, but evidence of consumer preferences could have a significant impact in this “like” products analysis.

168. Appellate Body Report, *US – Clove Cigarettes*, *supra* note 15, ¶ 138.

169. *Id.* ¶ 145.

170. See World Customs Organization [WCO], *Harmonised System Nomenclature 2022*, § 24.04, 0424-2022E, https://www.wcoomd.org/-/media/wco/public/global/pdf/topics/nomenclature/instruments-and-tools/hs-nomenclature-2022/2022/0424_2022e.pdf?la=en [https://perma.cc/KT28-S5UT]. Specific tariff classifications for e-cigarettes were only included in the Harmonized System (HS) in 2022, and it is unclear if e-cigarettes which do not contain nicotine would be categorized as a “tobacco or nicotine substitute” and thus fall within HS 2404, or if they would in fact be regulated under another chapter of the HS.

b. Differential Treatment of the “Like” Products

If it is established that the relevant products are “like,” there must then be a consideration of whether the imported products have received less favorable treatment, which depends on whether the measure causes a detrimental impact by “modif[ying] the conditions of competition in the relevant market to the detriment of the imported products.”¹⁷¹ The phrasing of this requirement is slightly different under the GATT Article I:1 most-favored nation treatment requirement, which specifies that “any advantage, favor, privilege or immunity granted” to products from one WTO Member must be immediately and unconditionally granted to “like” products from any other WTO Member. Where obvious regulatory distinctions are made between different products categories—such as banning one category of products while allowing another—a finding of differential treatment is usually not heavily contested and is the “obvious conclusion” to be reached.¹⁷² For the purposes of our analysis, we assume that a regulatory regime which imposes stricter requirements on e-cigarettes than tobacco products, or on a particular sub-category of e-cigarettes, would be likely to modify the condition of competition in the market or constitute a failure to grant the same advantage.

In a real WTO dispute concerning e-cigarettes, one issue that would likely arise is that countries which produce some of the “like” products (e.g. nicotine-containing e-cigarettes) might also produce the other “like” products (e.g. tobacco products). For example, China is by far the world’s largest producer of e-cigarettes,¹⁷³ but also produces and exports a range of tobacco products.¹⁷⁴ However, the fact that the complainant or respondent WTO Member produces more than one of the “like” products does not necessarily prevent a claim of discrimination. To determine whether there is differential treatment that unfairly disadvantages imports from the complaining WTO Member, a Panel will examine whether the group of all imported “like”

171. Appellate Body Report, *US – Clove Cigarettes*, *supra* note 15, ¶ 166 (referring to TBT Article 2.1). Appellate Body Report, *Korea – Various Measures on Beef*, *supra* note 119, ¶ 135.

172. Appellate Body Report, *US – Clove Cigarettes*, *supra* note 15, ¶¶ 7.279, 7.280.

173. *See supra* note 116.

174. For example, China’s exports of products to the world categorized in HS Codes 2401, 2402, and 2403 (all relating to tobacco products) was valued at over US\$839 million in 2023. *See* UN COMRADE DATABASE, <https://comtradeplus.un.org/> [<https://perma.cc/4ZXR-6AL8>](last visited June 18, 2024).

products receives less favorable treatment than the group of domestic or third-country “like” products.¹⁷⁵ For the purposes of comparing how the groups of products are treated, if the “vast majority” of a WTO Member’s production / export is of one kind of “like” product (even if they also produce or export small quantities of another “like” product), discrimination will likely be found if the majority product is treated less favorably.¹⁷⁶ If one WTO Member only produces product A (which is the product that receives less favorable treatment), while the respondent WTO Member produces product A as well as product B and C (the “like” products which are regulated more favorably), then this is likely to be found discriminatory.¹⁷⁷

c. Justifying Any Differential Treatment

If it is found that “like” products have received differential treatment, then *prima facie* there has been discrimination. However, both the GATT and the TBT Agreement provide scope for this differential treatment to be justified through different avenues.

Under TBT Article 2.1, the third stage of analyzing whether the technical regulation is discriminatory is to consider whether “the detrimental impact on imports stems exclusively from a legitimate regulatory distinction.”¹⁷⁸ This latter requirement was read into Article 2.1 to ensure that the non-discrimination obligation is balanced against WTO Members’ right to regulate.¹⁷⁹ Determining whether a measure makes a legitimate regulatory distinction for the purposes of Article 2.1 requires examination of “the design, architecture, revealing structure, operation, and application of the technical regulation at issue, and, in particular, whether that technical regulation is even-handed.”¹⁸⁰ The subjective intent of the state (or its relevant decision-makers) is not at

175. Appellate Body Report, *US – Clove Cigarettes*, *supra* note 15, ¶ 180; Appellate Body Report, *United States – Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products*, ¶ 215, WTO Doc. WT/DS381/AB/R (May 16, 2012) [hereinafter Appellate Body Report, *US – Tuna II (Mexico)*] (discussing TBT Article 2.1); Appellate Body Report, *EC – Asbestos*, *supra* note 106, ¶ 100 (discussing GATT Article 3.4).

176. *See, e.g.*, Appellate Body Report, *US – Clove Cigarettes*, *supra* note 15, ¶¶ 195–198.

177. *See, e.g.*, Panel Report, *European Union and Certain Member States – Measures Concerning Palm Oil and Oil Palm Crop-Based Biofuels*, ¶ 7.487, WTO Doc. WT/DS600/R (Mar. 5, 2024) [hereinafter Panel Report, *EU – Palm Oil (Malaysia)*].

178. Appellate Body Report, *US – Clove Cigarettes*, *supra* note 15, ¶ 182.

179. *Id.* ¶ 174.

180. *Id.* ¶ 182.

issue. Rather, whether the purpose of the measure is legitimate is determined objectively, by comparing its design and implementation with its rationale. The burden of proof falls upon the complainant to establish that their goods have been subject to “less favorable treatment” by the measure. If, however, they can make a *prima facie* case that Article 2.1 has been violated, the burden then shifts to the respondent to demonstrate that the detrimental impact stems exclusively from a legitimate regulatory distinction.¹⁸¹

The key issue in evaluating whether any detrimental impact stems exclusively from a legitimate regulatory distinction under TBT Article 2.1 is whether the treatment of different products by the measure is “even-handed,” which is “a relational concept, and must be tested through a comparative analysis.”¹⁸² The most detailed elaboration of this test by the Appellate Body was in the *US – Tuna II (Mexico)* dispute, where the United States argued that even-handedness required that the regulatory requirements applied to different groups of products must be properly “calibrated” to the risk/s being addressed.¹⁸³ *US – Tuna II (Mexico)* was part of a long-running dispute between Mexico and the United States regarding access to the “dolphin safe” label for tuna. A US measure effectively denied tuna caught by the Mexican fleet access to the “dolphin safe” label. The Appellate Body held that this measure violated Article 2.1 of the TBT Agreement not because denying Mexican tuna products access to the dolphin safe label was disproportionate to the risk that its fishing methods posed to dolphins; rather, the discrimination arose because the measure “fully address[ed]” risks posed to dolphins by the Mexican fleet but did not at all address the risks to dolphins from other fishing methods, such as those used by the US fleet.¹⁸⁴ The United States’ first effort to amend the measure was held not to have properly calibrated the regulatory regime to the relative risks of different fishing methods,¹⁸⁵ but a second revision to the measure raising the eligibility criteria for tuna caught by

181. Appellate Body Report, *US – Tuna II (Mexico)*, *supra* note 175, ¶ 216.

182. Appellate Body Report, *US – Tuna II (Mexico) (Article 21.5 – Mexico)*, *supra* note 119, ¶ 7.125.

183. Appellate Body Report, *US – Tuna II (Mexico)*, *supra* note 175, ¶ 297; Appellate Body Report, *US – Tuna II (Mexico) (Article 21.5 – Mexico)*, *supra* note 119, ¶¶ 7.98–7.101.

184. Appellate Body Report, *US – Tuna II (Mexico)*, *supra* note 175, ¶¶ 297–98.

185. Appellate Body Report, *US – Tuna II (Mexico) (Article 21.5 – Mexico)*, *supra* note 119, ¶¶ 7.98–7.101.

the United States and other fleets was found to bring it into compliance with the TBT Agreement.¹⁸⁶

To be consistent with Article 2.1, a measure must ensure “even-handedness” in the treatment of products which pose similar risks to legitimate public interests. By analogy with the reasoning in *US – Tuna II (Mexico)*, the regulatory standards applied to different categories of “like” products must reflect or be “calibrated” to the relative level of risk posed by each product group. Strict regulation of a category of e-cigarettes would not be discriminatory if other categories of “like” products were regulated in a way that was consistent or even-handed given their relative risk profiles.

An added complication when applying these tests in relation to e-cigarettes would be how health risk should be evaluated in light of uncertainty or lack of evidence,¹⁸⁷ and whether it is permissible for a state to take a precautionary approach in light of this uncertainty. Where the assessment of the relative risks of “like” product categories depends on scientific analysis which uses data that may change with new circumstances or as new studies come to light, it is critical that the regulations are applied in a way that takes account of the new data. In a recent report, a WTO Panel assessing the European Union’s regulatory framework for biofuels, which included a cap and phase-out for biofuels that caused a high-risk of greenhouse gas emissions from indirect land use change (ILUC), was inconsistent with Article 2.1 of the TBT Agreement.¹⁸⁸ The Panel found that the objective of minimizing the risk of ILUC-related greenhouse gas emissions was legitimate and that in principle the distinction between biofuels which caused a high ILUC risk and low ILUC risk fuels could potentially be justified,¹⁸⁹ but that the application of the measure violated Article 2.1 because of a “fail[ure] to conduct a timely review of the data used to determine which biofuels are high ILUC risk, as this results in arbitrary or unjustifiable discrimination.”¹⁹⁰

Whether a measure is consistent with Articles I and III of the GATT does not take account of whether the measure has a legitimate reason or purpose for distinguishing between different categories of

186. *Id.* ¶¶ 6.12–6.13.

187. See *supra* Section II.A.

188. Panel Report, *EU – Palm Oil (Malaysia)*, *supra* note 177.

189. *Id.* ¶ 7.545.

190. *Id.* ¶ 7.572.

“like” products.¹⁹¹ However, the GATT contains general exceptions in Article XX(b) which allow a WTO Member to defend a measure that might otherwise be consistent with the Agreement, if it is necessary for the protection of human, plant or animal life or health. There are two main stages to the analysis of the GATT Article XX(b) exception. The first is determining whether the measure is provisionally justified on the basis that it is “necessary” to protect human, plant or animal life or health.¹⁹² The necessity test is a relatively demanding one, which includes a consideration of the extent to which the regulatory measure contributes to its objective, the relative importance of that objective, the extent to which it restricts trade, and whether there were any less trade restrictive alternatives available.¹⁹³ This analysis is substantially similar to the analysis applied under TBT Agreement Article 2.2,¹⁹⁴

191. See generally Andrew Mitchell, David Heaton & Caroline Henckels, *NON-DISCRIMINATION AND THE ROLE OF REGULATORY PURPOSE IN INTERNATIONAL TRADE AND INVESTMENT LAW* (2016); Donald H. Regan, *Further Thoughts on the Role of Regulatory Purpose under Article III of the GATT*, 37 J. OF WORLD TRADE 737 (2003); Robert E Hudec, *GATT/WTO Constraints on National Regulation: Requiem for an Aim and Effects Test*, 32 INT’L LAWYER 619 (1998) [hereinafter *GATT/WTO Constraints on National Regulation*]; Amelia Porges & Joel P. Trachtman, *Robert Hudec and Domestic Regulation: The Resurrection of Aim and Effects*, 37 J. OF WORLD TRADE 783, 798 (2003) [hereinafter *Robert Hudec and Domestic Regulation*].

192. On the two-tiered approach to GATT Article XX(b), see Appellate Body Report, *Brazil—Measures Affecting Imports of Retreaded Tyres*, ¶ 139, WTO Doc. WT/DS332/AB/R (adopted Dec. 3, 2007) [hereinafter Appellate Body Report, *Brazil—Retreaded Tyres*]. On the two-tiered approach to the GATT Article XX exceptions in general, see Appellate Body Report, *Colombia—Measures Relating to the Importation of Textiles, Apparel and Footwear*, ¶ 5.67, WTO Doc. WT/DS461/AB/R (adopted June 7, 2016) [hereinafter Appellate Body Report, *Colombia—Textiles*]; Appellate Body Report, *United States—Standards for Reformulated and Conventional Gasoline*, ¶ 22, WTO Doc. WT/DS2/AB/R (adopted Apr. 29, 1996) [hereinafter Appellate Body Report, *US – Gasoline*]; Appellate Body Report, *United States—Import Prohibition of Certain Shrimp and Shrimp Products*, ¶¶ 118–20, WTO Doc. WT/DS58/AB/R (adopted Oct. 12, 1998) [hereinafter Appellate Body Report, *US – Shrimp*].

193. See Appellate Body Report, *India—Certain Measures Relating to Solar Cells and Solar Modules*, ¶ 5.59, WTO Doc. WT/DS456/AB/R (adopted Sept. 16, 2016); Appellate Body Report, *Colombia—Textiles*, *supra* note 192, ¶¶ 5.71–5.73, 5.77; Appellate Body Reports, *EC – Seal Products*, *supra* note 108, ¶ 5.169; Appellate Body Report, *United States—Measures Affecting the Cross-Border Supply of Gambling and Betting Services*, ¶¶ 306–07, WTO Doc. WT/DS285/AB/R (adopted Apr. 7, 2005) [hereinafter Appellate Body Report, *US – Gambling*]; Appellate Body Report, *China—Measures Affecting Trading Rights and Distribution Services for Certain Publications and Audiovisual Entertainment Products*, ¶¶ 239–42, WTO Doc. WT/DS363/AB/R (adopted Dec. 12, 2009); Appellate Body Report, *Korea—Various Measures on Beef*, *supra* note 119, ¶¶ 162–64.

194. The necessity test, as applied under TBT Article 2.2, uses the same elements as the GATT Article XX approach, with the additional consideration of “the risks non-fulfillment would create,” which comes from the text of TBT Article 2.2. See Appellate Body Reports,

discussed below in Part 3, and both tests rely heavily on the consideration of potential alternative measures.¹⁹⁵ The second stage of the GATT Article XX(b) analysis is to consider the “chapeau” of Article XX, which requires that the measures are not applied in a manner arbitrarily or unjustifiably discriminates.¹⁹⁶ This “chapeau” analysis is similar (but not identical) to the examination of whether any differential treatment was “even-handed” and stemmed from a legitimate regulatory distinction under TBT Article 2.1, and it is probable that similar conclusions would be reached.¹⁹⁷

3. Technical Regulations Must Not Create Unnecessary Obstacles to Trade: TBT Agreement Art 2.2

Article 2.2 of the TBT Agreement requires that “technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade,” which requires that they “shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create.” An important difference between this obligation and TBT Article 2.1 is that this is an absolute standard, rather than a relative standard. In other words, there is no need to identify “like” products or to argue that another product group is receiving comparatively better treatment—Article 2.2 is purely an assessment of whether the extent of the trade restriction can be justified.

The Appellate Body’s approach to interpreting Article 2.2 focuses on the second sentence of the text, and requires a determination of what the objective of the measure is, followed by a “relational analysis” of (i) the trade-restrictiveness of the regulation; (ii) the degree of contribution that the regulation makes toward the achievement of its objective; and (iii) the risks of non-fulfilment.¹⁹⁸ A comparative

Australia—Tobacco Plain Packaging, *supra* note 17, ¶ 6.3; Appellate Body Reports, *United States—Certain Country of Origin Labelling (COOL) Requirements*, ¶¶ 374–76, 471, WTO Doc. WT/DS384/AB/R (adopted June 29, 2012) [hereinafter Appellate Body Reports, *US – COOL*]; Appellate Body Report, *US – Tuna II (Mexico)*, *supra* note 175, ¶¶ 318–22.

195. *See infra* Part IV.B.

196. *See supra* note 192.

197. *See* Appellate Body Report, *US – Tuna II (Mexico) (Article 21.5—US)*, *supra* note 119, ¶¶ 6.272–6.273, 6.277–6.281.

198. *See* Appellate Body Reports, *Australia—Tobacco Plain Packaging*, *supra* note 17, ¶ 6.3.

analysis with possible less-trade restrictive alternative measures may then be required.¹⁹⁹ This is similar to the approach to necessity analysis that is used in relation to the GATT Article XX general exceptions, and whether less trade restrictive alternatives are available usually becomes a key aspect of the analysis.²⁰⁰

Any “limiting effect” on trade will be enough for a measure to be considered trade restrictive for the purposes of Article 2.2.²⁰¹ Where a measure has been found to be discriminatory under Article 2.1, this will qualify it as trade restrictive.²⁰² If a measure is not discriminatory, such as Australia’s tobacco plain packaging regime, it may still be found to have a limiting effect on trade if, by reducing consumption of a product it reduces the volume of trade in that product.²⁰³ Thus, an e-cigarette regulation which reduced the consumption of e-cigarettes would be likely to be considered trade restrictive, even if it was non-discriminatory.

Assuming that an e-cigarette regulation was found to be trade restrictive, its degree of contribution to its legitimate public objective would then have to be examined. In *Australia – Tobacco Plain Packaging* the analysis of the contribution to the public health objective was related to its restriction of trade—the contribution to the public health objective was in reducing the use of tobacco products, and it was this reduced usage which caused the trade restriction. If a measure is found to contribute to its purpose, then the necessity analysis under Article 2.2 typically turns on whether the complainants can demonstrate that any alternative measures would have made an

199. *See id.* ¶ 6.4.

200. *See infra* Part IV.B.

201. Panel Report, *Australia – Tobacco Plain Packaging*, *supra* note 17, ¶ 7.1072; Appellate Body Reports, *Australia—Tobacco Plain Packaging*, *supra* note 17, ¶ 6.380 n.1085.

202. *See* Panel Report, *United States – Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products*, ¶ 7.455, WTO Doc. WT/DS381/R (adopted Sept. 15, 2011) (noting agreement between the disputing parties that a measure which was discriminatory would be trade restrictive); Appellate Body Report, *US – COOL*, *supra* note 195, ¶ 381 (noting that the US conceded on appeal that if it was unsuccessful in challenging the finding under article 2.1 that the measure was discriminatory, that it would also be unsuccessful in challenging the finding that the measure was trade-restrictive under article 2.2.); Appellate Body Report, *United States – Certain Country of Origin Labelling (COOL) Requirements – Recourse to Article 21.5 of the DSU by Canada and Mexico*, ¶ 5.221, WTO Docs. WT/DS384/AB/RW, WT/DS386/AB/RW (adopted May 18, 2015) (noting that the parties do not contest that the measure was trade-restrictive).

203. *See* Panel Report, *Australia – Tobacco Plain Packaging*, *supra* note 17, ¶¶ 7.1207–7.1208, 6.416–6.417. *See also* Panel Report, *EU – Palm Oil (Malaysia)*, *supra* note 177, ¶ 7.322.

equivalent contribution to the objective.²⁰⁴ Earlier WTO jurisprudence suggested that “alternative” measures would not include different or complementary regulatory approaches that could be adopted as part of a comprehensive regulatory framework for a complex social problem.²⁰⁵ However, in *Australia – Tobacco Plain Packaging* the Appellate Body accepted that increases in the legal age for smoking or increases in taxes applied to tobacco products could be analyzed as “alternatives” to the plain packaging rules.²⁰⁶ If an e-cigarette labelling rule were to be challenged, a complainant WTO Member could therefore seek to argue that a range of other regulatory approaches could be considered “alternatives”, including the use of taxes, minimum age rules, advertising bans, education campaigns, or other policies aimed at reducing smoking.

The assessment of the contribution of a measure to its purpose is usually done on a qualitative, not quantitative basis. For example, in *Australia – Tobacco Plain Packaging* the contribution of the measures to the purpose was held to be a “rather modest” but still “meaningful” reduction in smoking prevalence and consumption of tobacco products.²⁰⁷ Where a measure is not discriminatory but is trade restrictive simply on the basis that it reduces consumption of a product, as was the case in *Australia – Tobacco Plain Packaging*, the identification of less trade restrictive alternatives that achieve an equivalent contribution to the public objective becomes circular. This is because any measure which makes a similar contribution to the purpose—e.g. reducing smoking—will be similarly trade restrictive, because it will cause a similar reduction in the volume of the product which is imported.²⁰⁸

204. Appellate Body Report, *Australia – Tobacco Plain Packaging*, *supra* note 17, 6.34–6.35.

205. See Appellate Body Report, *Brazil – Retreaded Tyres*, *supra* note 192, ¶ 172; Panel Report, *US – Clove Cigarettes*, *supra* note 15, ¶ 7.425.

206. Appellate Body Report, *Australia – Tobacco Plain Packaging*, *supra* note 17, ¶ 6.462; *cf.* Panel Report, *Australia – Tobacco Plain Packaging*, *supra* note 17, ¶ 7.1528 (where the panel followed the approach of earlier WTO cases, citing *Brazil – Retreaded Tyres*, and did not view the different tobacco control policies as alternatives or substitutes to one another).

207. Appellate Body Report, *Australia – Tobacco Plain Packaging*, *supra* note 17, ¶ 6.493.

208. *Id.* ¶ 6.477.

4. Summary

Two of the key WTO agreements relating to trade in goods—the TBT Agreement and the GATT—are likely to apply to most e-cigarette regulations. Most of the regulatory approaches being adopted by states are likely to fall within the category of “technical regulations” that are subject to the TBT Agreement. Any measures that do not qualify as a technical regulation, such as an absolute ban on all e-cigarettes, would still be covered by the GATT.

One of the key obligations under both the TBT Agreement and the GATT is that regulations cannot discriminate between “like” products. These non-discrimination obligations are particularly relevant to e-cigarette regulations, because of the distinctions that many countries are creating in their regulatory frameworks between different kinds of e-cigarettes, such as flavored and unflavored e-cigarettes, or distinctions between how ENDS and tobacco are regulated. Whether these different categories of e-cigarettes and tobacco products will be considered “like” depends upon an analysis of their physical characteristics, end uses, consumer preferences, and tariff classification. Most attention to date has focused on whether e-cigarettes are “like” tobacco products, but we have argued that there is a strong argument that these two groups of products are not “like” because of their physical differences (among other factors)—although the analysis will depend on the particular circumstances of the regulating WTO Member and the specific products involved. Different kinds of e-cigarettes, such as flavored and unflavored e-cigarettes, are more likely to be considered “like.” Differentiating in the regulation of “like” products creates the potential for claims that the regulations are discriminatory.

In addition, any e-cigarette regulations that are technical regulations and therefore subject to the TBT Agreement must not be more “trade restrictive” than necessary to achieve their public health objective/s. E-cigarette regulations may be considered trade restrictive even if they are non-discriminatory, as was held in the *Australia – Tobacco Plain Packaging* dispute, if they reduce consumption (and hence trade) of e-cigarettes.

However, even if an e-cigarette regulation is found *prima facie* to discriminate or to restrict trade, this does not necessarily mean that the measure will violate the TBT Agreement or the GATT. Both of these agreements provide scope for measures to be justified by a legitimate regulatory purpose. In Part IV, below, we consider some of the key

lessons that regulators should keep in mind when designing rules for e-cigarettes, to increase the chances that they are able to be successfully defended against any challenge in the WTO.

B. The TRIPS Agreement

1. The Application of the TRIPS Agreement to E-Cigarette Regulations

Intellectual property protects intangible property rights that can be used in the advertising and promotion of e-cigarettes. Concerns about the health impacts of e-cigarette consumption can prompt restrictions on advertising and promotion, including marketing of products on packaging, that can restrict the exercise of intangible property rights that protect trademarks, design and copyright material. The TRIPS Agreement provides guidance on the way that these rights are protected as it establishes minimum requirements for the protection of intangible property by WTO members. Regulation on e-cigarette marketing and promotion may prompt disputes about whether these minimum requirements are being met and regulation of e-cigarettes needs to be designed with this in mind.

Intellectual property rights generally confer negative rights to prevent others from using protected material rather than absolute rights of use for owners.²⁰⁹ Trademarks benefit social welfare by efficiently signaling the source of a product which a consumer can associate with levels of quality, reducing their search costs and rewarding trademark owners by encouraging them to build goodwill in their brand.²¹⁰ However, a trademark can be used to communicate other advertising messages to consumers and states may attempt to regulate use of trademarks if it is misleading, harmful or targets vulnerable consumers. Widespread concerns about advertising and marketing for e-cigarettes misleading and inappropriately targeting young people include

209. Panel Report, *Australia – Tobacco Plain Packaging*, *supra* note 17, ¶7.2015 (quoting Panel Report, *European Communities – Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs, Complaint by Australia*, ¶7.246, WTO Doc. WT/DS290/R (adopted Mar. 15, 2005)).

210. WILLIAM M. LANDES & RICHARD A. POSNER, *THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW* 173 (2003).

examples of advertising using well-known trademarks like JUUL.²¹¹ Tobacco trademarks have been used to communicate harmful messages, such as that products associated with certain trademarks are healthy or less harmful than others.²¹² These concerns have influenced the development of FCTC Article 11 which requires states to implement measures prohibiting the use of signifiers “[creating] the false impression that a particular tobacco product is less harmful than other tobacco products.” Trademarks registered in relation to e-cigarettes such as OV Organic Vape, Alphagreen and Really Berry may also directly message that a product is healthy by including words like “health” or “organic” in the registration or by associating a product with words or concepts associated with healthy products such as fruit names or the word green.²¹³ Trademark use may target markets that are unlikely to have previously regularly used cigarettes including youth. This is problematic in light of growing evidence that e-cigarettes can harm users’ health.²¹⁴

TRIPS Article 20 could limit the permissible restrictions that WTO members can place on the use of an e-cigarette trademark. It provides that “the use of a trademark in the course of trade must not be unjustifiably encumbered by special requirements” and gives examples of such requirements, including “use with another trademark, use in a special form, or use in a manner detrimental to the trademark’s ability to distinguish the goods or services of one undertaking from those of other undertakings.”²¹⁵ Consequently, when designing e-cigarette regulation that prevents or impacts the use of registered trademarks, it is important to assess whether restrictions encumber the legitimate interests of owners of e-cigarette trademarks, the extent of any restrictions, and whether these restrictions are justified.

211. Kevin Monaghan, *When Lightning Strikes Twice: E-Cigarettes’ Use of Traditional Cigarette Marketing Practices*, 45 SETON HALL LEGIS. J. 449, 452 (2021).

212. Eric Crosbie et al., *Promoting healthier options? Inside the branding of light cigarettes and targeting youth in Brazil*, 17 GLOB. PUB. HEALTH 1913, 1913–14 (2022).

213. See *AU Trade Mark No. 2301044*, filed on 15 September 2022 (registered on 24 April 2023) [hereinafter *OV Organic Vape trade mark*]; *AU Trade Mark No. 2201904*, filed on 17 December 2020 (registered on 6 February 2023) [hereinafter *Alphagreen trade mark*]; *AU Trade Mark No. 1907876*, filed on 26 December 2017 (registered on 26 December 2017) [hereinafter *Really Berry trade mark*].

214. See generally Banks et al., *supra* note 26.

215. TRIPS Agreement, *supra* note 18, art. 20.

Certain measures currently used to regulate e-cigarettes could impact trademark use. Uniform packaging measures that have been adopted in some jurisdictions can both restrict the use of trademarks with a figurative element and prescribe the form of use such as color or font for any word marks that are permitted. For example, Denmark only permits uniform references to word marks and product names on standardized packaging for ENDS and ENNDS products.²¹⁶ In 2023, Finland implemented plain packaging restrictions on e-cigarettes and refill containers, prohibiting use of brand images and logos.²¹⁷ Similar restrictions are in place in Israel.²¹⁸ Even where trademark use is permitted in advertising, certain requirements may accompany that use. In Israel, advertising of e-cigarettes is largely restricted to advertisements in newspapers. Although this may permit trademark use, advertisements must be accompanied by “a textual health warning covering 30% of the print media advertisement” and a counter-advertisement from the Ministry of Health.²¹⁹ E-cigarette producers who wish to use a trademark on packaging of e-cigarettes containing nicotine in New Zealand are able to do so but all packaging must include a warning on packaging that the product contains nicotine and that nicotine is a highly addictive substance.²²⁰ In the European Union extensive advertising restrictions on tobacco products have been extended to e-cigarettes containing nicotine.²²¹ Restrictions on e-cigarettes not containing nicotine are not similarly harmonized but can be extensive.²²² Australia has recently introduced legislation in relation

216. BEK nr 699 af 19/04/2021 Bekendtgørelse om standardisering af elektroniske cigaretter og genopfyldningsbeholdere med og uden nikotin [Executive order on standardization of e-cigarettes and refill containers with and without nicotine], § 2 (Den).

217. *Legislation by Country/Jurisdiction: Finland*, TOBACCO CONTROL LAWS, <https://www.tobaccocontrolaws.org/legislation/finland#:~:text=disposal%20of%20products.-.Act%20No.,of%20stand%2Dalone%20flavoring%20products> [https://perma.cc/2EEN-HHK8] (last updated May 11, 2023). For discussion of amendments, see Ministry of Social Affairs and Health, *Tobacco Act tightened to remove logos from packaging of tobacco products and electronic cigarettes*, FINNISH GOV'T (Apr. 13, 2022), <https://valtioneuvosto.fi/en-/1271139/tobacco-act-tightened-to-remove-logos-from-packaging-of-tobacco-products-and-electronic-cigarettes> [https://perma.cc/E2GN-YVFC].

218. See Yael Bar-Zeev et al., *Tobacco Legislation Reform and Industry Response in Israel*, 30 TOBACCO CONTROL 62–64 (2021).

219. *Id.*

220. *Smokefree Environments and Regulated Products Regulations 2021*, pt 5 (N.Z.).

221. Tobacco Products Directive 2014/40, *supra* note 78, art. 43.

222. For example, Denmark prohibits advertising as part of their unique e-cigarette regulations. Campus et al., *supra* note 54, at 6; BEK nr 65 af 15/01/2021, Bekendtgørelse om

to e-cigarettes, regardless of nicotine content, that creates civil and criminal offences for any unauthorized advertising of vaping goods as part of strict regulation of the availability of e-cigarettes.²²³ Authorized advertising on packaging is likely to be restricted to plain pharmaceutical packaging.²²⁴

Tobacco product packaging measures that restricted the use of trademarks, permitting only the use of word marks in prescribed font, size, and color to indicate origin, were examined in the panel and appellate decisions in *Australia – Tobacco Plain Packaging*. Importantly, the Appellate Body confirmed that the TRIPS Agreement does not confer a positive right to use a trademark.²²⁵ The decisions interpreted TRIPS Article 20 for the first time and provide important guidance as to the way that regulations that might restrict advertising and promotional activities of e-cigarette trademark owners, including the use of trademarks on packaging, could be justified. The plain packaging measures in dispute were considered to be special requirements that encumbered the use of tobacco trademarks in the course of trade.²²⁶ Although these requirements were “far-reaching”²²⁷ they were justified by public health objectives that were explicitly considered and documented by Australia in policy development.²²⁸ Noting differences in justifications for and approaches to the regulation of e-cigarettes and tobacco products, we now consider how the *Australia – Tobacco Plain Packaging* decisions should guide e-cigarette regulation that may impact the use of trademarks.

forbud mod reklame, synlig anbringelse og fremvisning m.v. af elektroniske cigaretter og genopfyldningsbeholdere med og uden nikotin [Order banning advertising, visible placement and display, etc. of electronic cigarettes and refill containers with and without nicotine] (Den.).

223. *Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024* (Cth) sch 1, pt 3 sch 4 (Austl.); *Therapeutic Goods (Vaping Goods—Advertising) Authorisation 2024* (Austl.)

224. *Vapes: information for sponsors, importers and manufacturers*, *supra* note 3.

225. Appellate Body Reports, *Australia – Tobacco Plain Packaging*, *supra* note 17, ¶ 7.7.

226. *Id.* ¶ 6.697.

227. *Id.* ¶ 6.675.

228. Genevieve Wilkinson, *Packaging Domestic Interests into Intellectual Property Law: Lessons from Tobacco Plain Packaging Disputes*, 47 *MONASH U. L. REV.* 142, 164–65, 170 (2021).

2. TRIPS Article 20

a. Protection of Broad Interests of Owners of Trademarks

Owners of registered trademarks for e-cigarettes are entitled to decide how to exploit their trademarks and extract economic value from them unless there is a defensible justification for placing special requirements on this entitlement. This is likely to include exploitation of those marks in commercial, advertising, and promotional activities. Analysis of whether e-cigarette regulation is likely to constitute special requirements is likely to focus on “the implications of the [plain packaging] trademark requirements on a trademark’s ability to distinguish goods and services of undertakings in the course of trade and on the ways in which a trademark owner might wish to use its trademark in the marketplace, as well as how these requirements affect consumers.”²²⁹

Australia – Tobacco Plain Packaging affirmed that TRIPS Article 20 broadly protects owners’ capacity to extract economic value from their trademarks. The Panel recognized “the legitimacy of the trademark owner’s interest in using its trademark for various purposes, including to identify the source of the product and communicate benefits of the product, whether functional or intangible.”²³⁰ The Panel noted that “the ‘use’ of a trademark that is relevant for the acquisition and maintenance of distinctiveness is not limited to use on packaging of a product, but rather extends to a wider range of commercial, advertising and promotion activities.”²³¹ TRIPS Article 20 protects the “legitimate interest of trademark owners in using their trademarks in the marketplace”²³² and “the manner in which the exploitation of . . . trademarks, takes place, and how to extract economic value from it, is essentially a matter for the right holder to decide.”²³³

E-cigarette regulation by WTO members may permit distinctions to be made between products, such as the use of trademarks as indications of the source of origin of the product, but still impose

229. Panel Reports, *Australia – Tobacco Plain Packaging*, *supra* note 17, ¶ 7.2563.

230. *Id.* ¶ 7.2562.

231. *Id.* ¶ 7.2285.

232. *Id.* ¶ 7.2429.

233. *Id.* ¶ 7.2285. Australia’s argument that the right to use a trademark in the course of trade should be construed more narrowly to its use in distinguishing products from one another was rejected. *Id.* ¶ 7.2286.

special requirements that encumber their use. Although Australian plain packaging legislation did permit prescribed use of word marks to indicate product origin, the way it restricted use of a trademark on product packaging constituted special requirements that encumbered the use of a trademark.²³⁴ The extent of this encumbrance varied, depending on the nature of the trademark impacted by the legislation. While word marks could still be used in a heavily prescribed form on packaging,²³⁵ in *Australia – Tobacco Plain Packaging*, the Panel noted “the special requirements are far-reaching in terms of the trademark owners’ possibilities to extract economic value from the use of figurative or stylized features of trademarks.”²³⁶ For any e-cigarette packaging legislation states might consider, its impact on trademark owners’ rights is particularly significant, restrictions such as preventing use of figurative or stylized features should be identified and considered as it will influence an assessment of justification.

b. Encumbrances on the Interests of Trademark Owners Can be Justified if Sufficiently Supported by Societal Interests

If states determine that restrictions on the use of e-cigarettes could constitute special requirements on the use of trademarks in the course of trade, three factors identified in *Australia – Tobacco Plain Packaging* are relevant considerations for policy makers:

- a. the nature and extent of the encumbrance resulting from the special requirements, bearing in mind the legitimate interest of the trademark owner in using its trademark in the course of trade and thereby allowing the trademark to fulfil its intended function;
- b. the reasons for which the special requirements are applied, including any societal interests they are intended to safeguard; and
- c. whether these reasons provide sufficient support for the resulting encumbrance.²³⁷

We now consider the potential applications of these considerations to e-cigarettes.

234. *Id.* ¶ 7.2156. These findings were not appealed. Appellate Body Reports, *Australia – Tobacco Plain Packaging*, *supra* note 17, ¶ 6.623.

235. *Tobacco Plain Packaging Act 2011* (Cth) s 21 (Austl.).

236. Panel Reports, *Australia – Tobacco Plain Packaging*, *supra* note 17, ¶ 7.2285.

237. *Id.* ¶ 7.2430. This interpretation was affirmed in Appellate Body Reports, *Australia – Tobacco Plain Packaging*, *supra* note 17, ¶ 6.719.

i. What is the nature and extent of the encumbrance?

The role of trademarks as a marketing and advertising tool for e-cigarettes is relevant to assessing the nature of any encumbrance regulators place on the use of e-cigarette trademarks. Word trademarks have been found to be commonly used to distinguish tobacco products from each other,²³⁸ and are considered to be highly valuable in marketing and advertising. In *Australia – Tobacco Plain Packaging* it was relevant that the marks had “substantial economic value.”²³⁹ Where the extent of the encumbrance is less great, this will also influence the subsequent assessment of reasons and sufficient support to determine unjustifiableness.²⁴⁰ Trademarks may function differently for e-cigarettes. The nature of e-cigarette supply and their more recent invention may make it more difficult to establish the value of the marks in question although certain marks such as JUUL have strong value.²⁴¹ Tobacco companies hold significant shares in the market and have traditionally invested heavily in trademark protection, yet there are also many small producers in the e-cigarette market²⁴² who may place less value on trademarks in marketing and promotion or have less capacity to invest in them. The role and impact of social media in marketing and advertising has evolved since the WTO disputes.²⁴³ There is extensive evidence of the role of online platforms in advertising e-cigarettes.²⁴⁴ Some types of social media may only reference word marks as opposed to figurative trademarks. Even where advertising of e-cigarettes is restricted on social media, product users tag brand names or incorporate them into hashtags such as #juullife or #doitforjuul.²⁴⁵ Flavor has also

238. See *JT International SA v. Commonwealth* (2012) 250 CLR 1, 96 (Austl.).

239. Panel Reports, *Australia – Tobacco Plain Packaging*, *supra* note 17 ¶¶ 7.2604.

240. *Id.* ¶ 7.2430.

241. See Samantha Emma Sarles et al., *Surveillance of U.S. Corporate Filings Provides a Proactive Approach to Inform Tobacco Regulatory Research Strategy*, 18 INT’L J. ENV’T RSCH. PUBLIC & PUB. HEALTH 1, 1 (2021).

242. See *E-Cigarettes*, *supra* note 100.

243. The disputes only assessed the potential role of social media marketing as an alternative to plain packaging measures to deter tobacco consumption. See Panel Reports, *Australia – Tobacco Plain Packaging*, *supra* note 17, ¶¶ 7.2599–7.2601, 7.1620–7.1624.

244. See Samia Amin et al., *Exposure to E-Cigarette Information and Advertising in Social Media and E-Cigarette Use in Australia: A Mixed Methods Study*, 213 DRUG & ALCOHOL DEPENDENCE 1,1 (2020).

245. Lauren Czaplicki et al., *#toolittletoolate: JUUL-Related Content on Instagram Before and After Self-Regulatory Action*, 15 PLOS ONE 1, 3 (2020).

been identified as a significant influence on e-cigarette consumption²⁴⁶ and these flavor differences may be communicated by plain packaging regulations that permit identification of a product name.

ii. What are the reasons for the encumbrance and do they engage societal interests?

Justifications for restrictions based on health risks are more difficult to assess for e-cigarettes than tobacco products because of the relatively recent introduction of e-cigarettes, disparities in ingredients in e-cigarettes, and diverse market regulation. Yet, justification for any special requirements in the course of trade that encumber the use of trademarks on e-cigarette packaging and other marketing and advertising will be critical if an Article 20 claim is made. Whether special requirements are unjustifiable will depend on the nature of the encumbrance and whether “societal interests” sufficiently support the restrictions. With the preamble, TRIPS Article 7 and 8 set out the object and purpose of the TRIPS Agreement and guide interpretation of which societal interests can be relevant justifications.²⁴⁷ The objectives identified in TRIPS Article 7 provide for “the protection and enforcement of intellectual property rights . . . in a manner conducive to social and economic welfare, and to a balance of rights and obligations.”²⁴⁸ Article 8.1 recognizes that the TRIPS Agreement is not intended to prevent states from taking adopting measures “necessary to protect public health and nutrition and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.”²⁴⁹

For e-cigarettes, the societal interest of protection of public health is clearly relevant. The flexibility available to states in TRIPS Article 8.1 enables them to “adopt measures necessary to protect public health.” For measures that engage complex public health concerns and

246. Michelle Jongenelis, *Challenges and opportunities associated with e-cigarettes in Australia: A qualitative study*, 47 *AUSTL. AND N.Z. J. OF PUB. HEALTH* 1, 5 (2023).

247. Panel Reports, *Australia – Tobacco Plain Packaging*, *supra* note 17, ¶¶ 7.2397–7.2411.

248. TRIPS Agreement, *supra* note 18, art 7.

249. Yu’s approach, using TRIPS article 7 to interpret the requirement for “[consistency] with the provisions of the Agreement” shows that this requirement need not be excessively restrictive. See Peter K. Yu, *The Objectives and Principles of the TRIPS Agreement*, 46 *HOUSTON L. REV.* 979, 1014–15 (2009).

other societal interests, TRIPS Article 7 recognizes the object of “the protection and enforcement of intellectual property rights . . . in a manner conducive to social and economic welfare, and to a balance of rights and obligations.”²⁵⁰ Identifying relevant stakeholders and assessing their interest will be critical to demonstrating that e-cigarette regulations that impact the interests of trademark owners balance rights and obligations.

Key justifications for e-cigarette regulation may differ from the justifications for restricting use of tobacco trademarks. The harmful impacts of tobacco consumption are well established and confirmed by extensive longitudinal studies.²⁵¹ There has been less time to understand the long-term health impacts of e-cigarette consumption but there are overlapping impacts, including on lung health.²⁵² Although evidence of negative health impacts of e-cigarette consumption is emerging, measuring this is complicated by the comparatively short time that e-cigarettes have been available for consumption, the changing nature of e-cigarettes, and the heterogenous content of e-cigarettes. Claims that e-cigarettes are less harmful than tobacco should continue to be scrutinized in light of longitudinal studies. There have been several generations of e-cigarettes which can impact the way that consumption occurs.²⁵³ Ingredients in liquids used to create e-cigarette vapor also differ significantly, partly as a result of the different flavors.²⁵⁴ E-cigarettes can be used by smokers as a smoking cessation tool and dual use of e-cigarettes and tobacco products can also make it difficult to assess the health impacts specific to e-cigarette consumption.²⁵⁵

The role of packaging measures in a broader context of regulation of e-cigarettes will also be relevant to the assessment of justification.²⁵⁶ Australia was a world leader in introducing plain packaging for tobacco products and justified this as part of a comprehensive approach in the

250. TRIPS Agreement, *supra* note 18, art 7.

251. *Id.* ¶ 7.1310.

252. Ahmed, *supra* note 37, at 355–56.

253. Cutts & O’Donnell, *supra* note 41, at 246.

254. Larcombe, *supra* note 31, at 29–31.

255. See Jeffrey Drope et al., *Key Issues Surrounding the Health Impacts of Electronic Nicotine Delivery Systems (ENDS) and Other Sources of Nicotine*, 67 *CA: A CANCER J. FOR CLINICIANS* 449, 464–65 (2017).

256. Panel Reports, *Australia – Tobacco Plain Packaging*, *supra* note 17, ¶ 7.2431.

context of continuing concern about tobacco consumption, particularly in certain vulnerable groups.²⁵⁷ Packaging was viewed as the last vehicle possible for tobacco advertising. The Panel noted that “[tobacco plain packaging] measures, including their trademark restrictions, are an integral part of Australia’s comprehensive tobacco control policies, and designed to complement the pre-existing measures.”²⁵⁸ Similar considerations may not apply for e-cigarettes: informal promotion of products on social media platforms such as Instagram may make a comprehensive approach restricting advertising and promotion more difficult to implement.²⁵⁹

Public health interests are not the only relevant societal interests that should be considered by states in TRIPS Article 20 assessments but they are important interests that are clearly relevant to regulating e-cigarette packaging. As outlined above, regulation of e-cigarettes presents complex public health considerations that may have diverse impacts on different stakeholders. E-cigarette promotion may support long-term smokers who find it effective as a smoking cessation tool. Where there is successful use of e-cigarettes to address addiction to tobacco products and cease tobacco consumption, e-cigarette consumption may result in net health benefits for smokers.²⁶⁰ Cessation can also benefit the public by reducing the burden that the negative impacts of tobacco consumption have on public health systems.²⁶¹ However, the effectiveness of e-cigarettes in promoting smoking cessation remain disputed and may differ, depending on

257. National Preventative Health Taskforce, *Australia: Healthiest Country by 2020. Technical Report 2 – Tobacco Control in Australia: Making Smoking History, including Addendum for October 2008 to June 2009* (2009), at 6–7.

258. Panel Reports, *Australia – Tobacco Plain Packaging*, *supra* note 17, ¶ 7.2604.

259. See Erin Brodwin, *Silicon Valley’s favorite e-cig company shut down its social media accounts—but Juul’s advertising now has a life of its own*, BUSINESS INSIDER (Nov 18, 2018) <https://businessinsider.com/why-juul-shut-down-social-media-facebook-instagram-vaping-2018-11> [<https://perma.cc/A2HE-HP7H>]. Evidence suggesting that e-cigarette consumption is less harmful than tobacco consumption has been used to oppose restrictions on e-cigarette use in Australia. David T. Levy et al., *The Australia smoking and Vaping Model: The potential impact of increasing access to nicotine vaping products*, 25(3) NICOTINE AND TOBACCO RSCH., 486, 486 (2023).

260. *Id.*

261. However, this will depend on the relative health risks of consuming tobacco products and e-cigarettes which remains uncertain. David T. Levy et al., *Public health implications of vaping in the USA: the smoking and vaping simulation model*, 19 POPULATION HEALTH METRICS, 1, 13 (2021).

whether or not nicotine is ingested.²⁶² Where e-cigarettes are not used as a smoking cessation tool that may result in some net health benefit, it is increasingly evident that they present health risks for consumers and the public.²⁶³ Young people can become addicted to nicotine, experience serious health impacts or commence smoking as a result of using e-cigarettes.²⁶⁴ It may be appropriate to consider these distinctions where e-cigarette regulations can restrict the use of a trademark. If e-cigarettes are only available for therapeutic purposes, the approach that is currently being introduced in Australia, use of trademarks may be appropriately regulated in a similar fashion to restrictions on prescription medication.

iii. Are reasons for encumbrances sufficiently supported?

Despite the use of the term “necessary” in TRIPS Article 8, *Australia – Tobacco Plain Packaging* confirmed that the standard required to establish whether measures are unjustifiable differs from the standard of necessity required for TBT Article 2.2 or GATT Article XX. The Panel also rejected Australia’s arguments in *Australia – Tobacco Plain Packaging* that special requirements could be justified by “some rational connection between encumbrances imposed on the use of a trademark and the reason for which they are imposed.”²⁶⁵ The Appellate Body subsequently confirmed the approach proposed by the Panel that justifications for special requirements on the use of a trademark in the course of trade need to be sufficiently supported by societal interests to ensure that they are not unjustifiable and inconsistent with TRIPS Article 20.²⁶⁶

In *Australia – Tobacco Plain Packaging*, the Panel determined that:

the fact that the special requirements, as part of the overall [tobacco plain packaging] measures and in combination with other tobacco-control measures maintained by Australia, are capable of

262. See Catherine M. Pound et al., *Smoking cessation in individuals who use vaping as compared with traditional nicotine replacement therapies: a systematic review and meta-analysis*, 11 *BMJ OPEN*, 1, 2 (2021).

263. See generally Banks et al., *supra* note 26.

264. *Technical Note on Call to Action on Electronic Cigarettes*, *supra* note 2, at 3.

265. Panel Reports, *Australia – Tobacco Plain Packaging*, *supra* note 17, ¶ 7.2422.

266. Appellate Body Reports, *Australia – Tobacco Plain Packaging*, *supra* note 17, ¶ 6.659.

contributing, and do in fact contribute, to Australia's objective of improving public health by reducing the use of, and exposure to, tobacco products, suggests that the reasons for which these special requirements are applied provide sufficient support for the application of the resulting encumbrances on the use of trademarks.²⁶⁷

Local conditions are relevant considerations for determining whether measures are sufficiently supported by societal interests. If there is evidence of no use of e-cigarettes other than as a tool for smoking cessation in a jurisdiction, the type of restrictions on packaging could focus on the related public health objectives of reducing tobacco consumption. For example, in New Zealand, e-cigarette packaging restrictions permit communication about the health benefits of e-cigarette products containing nicotine in comparison to tobacco products.²⁶⁸ However, in markets where there is clear evidence of non-smokers consuming e-cigarettes, that messaging may have unintended consequences, contributing to public attitudes that there are no concerns about the health impact of e-cigarettes.²⁶⁹

3. Summary

States who wish to restrict the advertising and promotion of e-cigarettes need to consider whether this is likely to restrict the use of trademarks, as TRIPS article 20 prohibits special requirements on the use of trademarks that are unjustifiable. Uniform packaging laws may constitute special requirements as trademark owners interests are broader than simply using their marks to identify their products and can include commercial, advertising, and promotional activities. However, these restrictions can be justified on the basis that consumption of e-cigarettes is harmful to health and advertising encourages consumption and targets groups that are particularly vulnerable to the harmful impacts of e-cigarettes, such as children and adolescents. The greater the restriction on the use of the trademarks, the greater the need for justification supporting that restriction. Societal interests are relevant to justification and the object and purpose of TRIPS found in Articles

267. Panel Reports, *Australia – Tobacco Plain Packaging*, *supra* note 17, ¶ 7.2604.

268. Smokefree Environments and Regulated Products Act 1990 (NZ) s. 24(g)(ii); Smokefree Environments and Regulated Products Regulations 2021 (NZ) reg. 73.

269. For evidence of analysis of these attitudes in online messages, see Roy Bara, “*They’re sleek, stylish and sexy:” selling e-cigarettes online*, 47 *AUSTL. AND N.Z. J. OF PUB. HEALTH* 1, 5 (2023).

7 and 8 provides guidance for the type of societal interests that will be relevant in WTO disputes. Societal interests such as the protection of public health are directly relevant. The justifications must provide sufficient support for the encumbrances on the use of trademarks and local conditions will be relevant to understanding whether there is rational connection between the restrictions on trademark use and the justifications the state relies on for imposing them.

The *Australia -Tobacco Plain Packaging* decisions suggest that WTO members can use flexibility mechanisms in the TRIPS Agreement to recognize the interests of other stakeholders if they use a careful approach to developing legislation that transparently identifies their reasons for restricting owner interests. Policymakers seeking to reform regulation of e-cigarettes in ways that impact the use of trademarks in the course of trade should explicitly consider several questions: What is the reason for the regulation? What interests are engaged? Which interests should be restricted? Do TRIPS Articles 7 and 8 support these restrictions?²⁷⁰ Public health protection is likely to be a primary consideration and this justification can be consistent with the object and purpose provisions of the TRIPS Agreement found in Articles 7 and 8 if states can demonstrate that it provides sufficient support for any encumbrances on the use of e-cigarette trademarks. Additional considerations that support restrictions on trademark use, including international obligations in non-WTO agreements and the existence of alternative measures, may also be relevant and these will be considered in Part IV.

IV. CROSS-CUTTING LESSONS FOR THE DESIGN OF E-CIGARETTE REGULATIONS

As the previous section of this Article has shown, many of the e-cigarette regulations being adopted by WTO Members could potentially engage their obligations under GATT, the TBT Agreement, and/or the TRIPS Agreement. Whether the measures are consistent with these WTO agreements will largely depend on the extent to which they can be justified by a legitimate public purpose, such as protecting the interests of young people, the general promotion of public health by reducing use of vaping devices or encouraging the use of e-cigarettes as a smoking cessation tool (and thus improving health outcomes of people that would otherwise smoke tobacco). While there

270. See Wilkinson, *supra* note 228, at 170.

are important textual and contextual differences between the different WTO obligations we have examined, this part identifies common themes that provide useful lessons for policymakers designing e-cigarette regulations.

A. *Lesson One: The Need for a Clear, Precise and Sufficient Justification*

To the extent possible, e-cigarette regulations should include a clear and precise identification of the justifications for the measures. In *Australia – Tobacco Plain Packaging* the Panel held that the purpose of the measure was to “improve public health by reducing the use of, and exposure to, tobacco products,” but did not accept the more “specific objectives” put forward by Australia, such as “reducing the appeal of tobacco products” or “increasing the effectiveness of [graphic health warnings],” as these were instead “mechanisms” by which the measure’s aim could be achieved.²⁷¹ Precision is important in this respect, as the purpose of a regulation applying to tobacco or e-cigarettes may be more specific than simply to promote public health through the reduction of the use of the product: regulations may seek to more narrowly target the health or interests of specific stakeholders, such as young people or existing tobacco smokers seeking to quit. WTO panels and the Appellate Body will consider the interests of these specific groups if it is clear that they were the focus of the purpose of the regulation. For example, in *US – Clove Cigarettes* the Panel and Appellate Body accepted that the purpose of the flavor ban was specifically targeted at reducing youth smoking.²⁷²

In *Australia – Tobacco Plain Packaging*, Australia’s defense of the measure benefitted from extensive evidence in support of its efficacy as a public health measure. The evidence at issue in that dispute included evidence from before the implementation of the plain packaging measure about its anticipated effects (pre-implementation evidence), and evidence of the actual impact of the plain packaging measures (post-implementation evidence).²⁷³ Australian plain

271. See Panel Reports, *Australia – Tobacco Plain Packaging*, *supra* note 17, ¶ 7.227.

272. See, e.g., Appellate Body Report, *US – Clove Cigarettes*, *supra* note 15; Panel Report, *US – Clove Cigarettes*, *supra* note 15, ¶¶ 7.286, 7.289.

273. On the use of this evidence to assess the contribution of the measure to its purpose, see, e.g., Panel Reports, *Australia – Tobacco Plain Packaging*, *supra* note 17, ¶¶ 7.1027–7.1028.

packaging legislation that implemented the policy was developed over many years, based on scientific evidence and involved consultation of a range of stakeholders. The legislative design reflected a consciousness that disputes were likely²⁷⁴ and explicitly set out the reasons for adopting the measures in the object clause of the legislation.²⁷⁵ Related policy documents evidenced recognition of the impact of the legislation on trademark owners and contained explicit assessment that this impact was justifiable and proportionate, citing public interests, public health and implementation of the FCTC.²⁷⁶

However, the level of evidence which Australia was able to provide in that dispute is not essential for a measure to be defended on public health grounds in the WTO. Although evidence about the health impact of e-cigarettes is evolving, this does not mean that regulation of e-cigarettes that is restrictive of trade cannot be justified. WTO panels and the Appellate Body have recognized that it is possible to justify measures even where quantitative empirical evidence that demonstrates the actual efficacy of the measure is unavailable. For example, when assessing whether a measure is “necessary,” panels and the Appellate Body may look to qualitative evidence that supports the likely impact of a measure, considering the hypotheses that would need to be proven to establish that the measure will make a contribution of its objective and the extent of that contribution, even if the evidence does not enable the contribution of the measure to be quantified.²⁷⁷

In *Australia – Tobacco Plain Packaging* itself, the Appellate Body noted that, for the purposes of the TBT Article 2.2 analysis, the contribution of the measure to its purpose did not need to be precisely quantified, and that it was sufficient for it to be described as a “meaningful” contribution to the public health goal.²⁷⁸ The Appellate Body supported the Panel’s conclusion that greater weight should be given to the pre-implementation evidence, which addressed the anticipated impact of the plain packaging measures, given the limitations of the post-implementation evidence, such as the limited

274. Wilkinson, *supra* note 228, at 163.

275. *Tobacco Plain Packaging Act 2011* (Cth) s 3 (Austl.).

276. Wilkinson, *supra* note 228, at 165.

277. See generally Appellate Body Report, *Brazil – Retreaded Tyres*, *supra* note 192 (citing Appellate Body Report, *EC—Asbestos*, *supra* note 106).

278. See Appellate Body Reports, *Australia – Tobacco Plain Packaging*, *supra* note 17, ¶¶ 6.371–6.372, 6.491–6.496; Panel Reports, *Australia – Tobacco Plain Packaging*, *supra* note 17, ¶ 7.1043.

time which had passed in which to study the impact of the measure, and the difficulty in isolating empirically the impact of the measure from other tobacco control measures and market factors on smoking behaviors.²⁷⁹

It is also important, however, not to rely on data once it becomes outdated or when more current data would be available and more accurate. In the Panel's decision in *EU – Palm Oil (Malaysia)* the key basis for the finding that the measure was discriminatory was that the categorization of which biofuel crops posed a high risk of ILUC in 2022 and beyond was based on data from the 2008–2016 period which had not been updated, even though the relevant EU regulatory framework had created a process where the data was meant to be reviewed by June 30, 2021.²⁸⁰

For TRIPS disputes, it is likely that Article 20 would be relevant to the assessment of any packaging measures that limit e-cigarette trademark use. The limitations that states choose may not be as extensive as Australia's tobacco plain packaging measures and this will influence the assessment of unjustifiableness. The nature and extent of any e-cigarette regulation that restricts use of trademarks in the course of trade provides the basis against which sufficient support is assessed and specific consideration should be given to the consistency of these measures with societal interests that are consistent with the object and purposes of the TRIPS agreement.²⁸¹

A final point to note is that public health is not the only grounds on which regulation of e-cigarettes could be justified. Other reasons for regulation such as the environmental implications of waste from disposable vapes may also constitute relevant reasons for restrictions, as relevant WTO agreements treat environmental protection as a public interest that can justify restrictions on trade or interference with intellectual property rights. Under GATT Article XX there are exceptions to justify measures that relate to the conservation of exhaustible natural resources (GATT Article XX(g)), as well as measures that protect plant or animal life or health (Article XX(b)), and

279. See Appellate Body Reports, *Australia – Tobacco Plain Packaging*, *supra* note 17, ¶ 6.358; Panel Reports, *Australia – Tobacco Plain Packaging*, *supra* note 17, ¶¶ 7.1027–7.1040.

280. Panel Report, *EU – Palm Oil (Malaysia)*, *supra* note 177, ¶ 7.570.

281. Appellate Body Reports, *Australia – Tobacco Plain Packaging*, *supra* note 17, ¶¶ 6.658–6.659.

environmental reasons are also recognized under the TBT Agreement.²⁸²

B. Lesson Two: Consider Alternative Less-Restrictive Measures

The availability of alternative less-restrictive measures will be a key aspect of any analysis of an e-cigarette regulation under GATT Article XX or TBT Article 2.2. As discussed above,²⁸³ both of these provisions consider whether the measure was “necessary” to achieve a legitimate purpose, and in most cases a central element of this necessity analysis is the examination of whether there were alternative measures that could have made an equivalent contribution to the objective with less restriction of trade.²⁸⁴

Alternative less-restrictive measures for advertising, promotion or packaging requirements for e-cigarettes can also be relevant to assessing justification under TRIPS Article 20. In *Australia – Tobacco Plain Packaging*, the Appellate Body agreed with the Panel that “it may be possible that, in the circumstances of a particular case, an alternative measure that would lead to at least an equivalent contribution could call into question whether the reasons for the adoption of the special requirements sufficiently support the resulting encumbrances on the use of the trademark.”²⁸⁵ The Appellate Body was careful to note that TRIPS Article 20 does not require a full “necessity” analysis.²⁸⁶ Although the necessity test itself does not need to be applied, the Appellate Body was stated that this does not mean that “the existence of an alternative measure involving a lesser degree of encumbrance on the use of a trademark cannot be used as a consideration in evaluating the justifiability of special requirements and related encumbrances on the use of a trademark.”²⁸⁷ The key distinction between the role of alternative measures under TRIPS Article 20 and the necessity test required in GATT Article XX and the TBT Agreement Article 2.2 is

282. See TBT Agreement, *supra* note 18, prmb, art 2.2.

283. See *supra* Section III.A.

284. See Appellate Body Reports, *Australia – Tobacco Plain Packaging*, *supra* note 17, ¶ 6.4; Appellate Body Reports, *EC – Seal Products*, *supra* note 108, ¶ 5.169; Appellate Body Report, *US – Gambling*, *supra* note 193, ¶ 307; Appellate Body Report, *Korea – Various Measures on Beef*, *supra* note 119, ¶ 166.

285. Appellate Body Reports, *Australia – Tobacco Plain Packaging*, *supra* note 17, ¶ 6.655.

286. *Id.* ¶ 6.653.

287. *Id.*

that consideration of less trade-restrictive alternatives “is not a necessary inquiry under Article 20” of the TRIPS Agreement.²⁸⁸ In *Australia – Plain Packaging* itself no comprehensive consideration of alternative measures was undertaken by the Panel when assessing TRIPS Article 20, and the Appellate Body found that the Panel “did not err” in its approach in that dispute.²⁸⁹

1. Identifying Alternative Measures

Under the Appellate Body’s approach to necessity testing, the burden of identifying any alternative measures that the respondent WTO Member should potentially have taken rests with the complaining WTO Member.²⁹⁰ In complex regulatory areas, such as measures to addressing public health or environmental protection, often countries adopt a comprehensive framework which regulates various aspects of the problem, with measures addressing production, consumption, importation, advertising, and other aspects of trade or commerce in the relevant products.

For example, the plain packaging requirements at issue in *Australia – Tobacco Plain Packaging* were part of a comprehensive strategy for regulating tobacco products. The need for a comprehensive strategy to reduce tobacco consumption was well-established.²⁹¹ Where a comprehensive approach is taken, the question arises as to whether different regulations that are part of the comprehensive scheme should—for the purposes of compatibility with WTO obligations—be treated as possible alternative measures. Australia argued before the Panel in the plain packaging dispute that some of the alternative measures suggested—including an increase in the legal age to purchase tobacco products and an increase in tax—were not truly alternative measures because they were already being implemented (or a similar

288. *Id.* While the Appellate Body has been clear that the consideration of reasonably available less trade restrictive alternatives is a central element of necessity analysis “in most cases,” it has also stated that there will be some situations in which it is not required, such as when it has already been established that the challenged measure does not contribute to its intended purpose. See Appellate Body Reports, *US – COOL*, *supra* note 194, ¶ 376 n.748; Appellate Body Report, *US – Tuna II (Mexico)*, *supra* note 175, ¶ 322 n.647.

289. Appellate Body Reports, *Australia – Tobacco Plain Packaging*, *supra* note 17, ¶ 6.655.

290. See Appellate Body Report, *US – Gambling*, *supra* note 193, ¶¶ 309–11.

291. See Henry Saffer and Frank Chaloupka, *The Effect of Tobacco Advertising Bans on Tobacco Consumption*, 19 J. OF HEALTH ECON. 1117, 1117 (2000).

measure was being implemented) and that they were in fact distinct and complementary elements of a comprehensive tobacco control policy.²⁹² In making this argument, Australia relied on an earlier WTO dispute concerning a Brazilian ban on the importation of retreaded tires. In *Brazil - Retreaded Tyres* the Appellate Body upheld the Panel's view that complementary and distinct aspects of a "comprehensive strategy" for regulating the accumulation of waste tires should not be treated as alternatives for the purposes of GATT Article XX(b).²⁹³ The Appellate Body in *Brazil - Retreaded Tyres* noted that "[s]ubstituting one element of this comprehensive policy for another would weaken the policy by reducing the synergies between its components, as well as its total effect."²⁹⁴ However the Panel in *Australia - Tobacco Plain Packaging* dismissed Australia's arguments, noting that a proposed alternative that is a variation on an existing measure may be considered as an alternative for the purposes of the necessity analysis.²⁹⁵ Australia did not challenge this finding on appeal.²⁹⁶

One reason that it may be difficult to identify an appropriate alternative measure to the use of plain packaging may be the important influence of product packaging on consumption by young people.²⁹⁷ The use of e-cigarette advertising targeted towards young people has been noted with concern.²⁹⁸ Any approach that permits use of trademarks as a form of advertising may not meet policy objectives. In the *Australia - Tobacco Plain Packaging* dispute, Australia argued that, in considering whether a proposed measure was truly an alternative, the Panel should also have regard to "the specific mechanisms or causal pathway" through which the measure makes its

292. See Panel Reports, *Australia - Tobacco Plain Packaging*, *supra* note 17, ¶¶ 7.1353, 7.1377.

293. See Appellate Body Report, *Brazil - Retreaded Tyres*, *supra* note 192, ¶ 172, (upholding Panel Report, *Brazil - Measures Affecting Imports of Retreaded Tyres*, WTO Doc. WT/DS332/R ¶ 7.171 (adopted June 12, 2007)).

294. *Id.*

295. See Panel Reports, *Australia - Tobacco Plain Packaging*, *supra* note 17, ¶ 7.1385; see also Panel Reports, *China - Measures Related to the Exportation of Rare Earths, Tungsten, and Molybdenum*, ¶ 7.186, WTO Docs. WT/DS431/R, WT/DS432/R, WT/DS433/R (adopted Mar. 26, 2014).

296. See Appellate Body Reports, *Australia - Tobacco Plain Packaging*, *supra* note 17, ¶ 6.463.

297. See Jongenelis, *supra* note 246, at 2.

298. See, e.g., *Technical Note on Call to Action on Electronic Cigarettes*, *supra* note 2.

contribution to the objective.²⁹⁹ However, Australia’s argument was unsuccessful, with the Appellate Body noting that an alternative measure did not have to address the “design features” of tobacco products in order to have an equivalent contribution to the measure’s purpose.³⁰⁰

These findings about what measures can be considered alternatives are important when considering the design of e-cigarette regulations. A comprehensive strategy may also be desirable for regulation of e-cigarettes³⁰¹ but this may be harder to demonstrate as e-cigarette products are much newer and approaches to regulation are, on balance, less developed³⁰² and comprehensive restrictions on marketing and advertising are increasingly difficult in the digital environment.³⁰³ In addition, distinctions between vaping products that explicitly contain nicotine and those that do not contain nicotine influence regulation worldwide.³⁰⁴ Where distinctions are drawn between ENDS and ENNDS, this may undermine a respondent WTO Member’s ability to argue that they have taken a comprehensive approach to regulating e-cigarettes, and may open up a wide range of possible “alternative” measures that a complainant could suggest have to be considered.

2. Are There Alternatives That are Less Restrictive of Trade or the Use of Trademarks?

If there are relevant alternative measures, it must be shown that they can make an equivalent contribution to the challenged measure’s purpose, as well as being less trade restrictive (or less restrictive of the use of trademarks) than the challenged measure. Given the range of potential regulatory approaches to e-cigarettes, there is a wide range of potential alternative measures that could be considered. Whether an alternative measure is less trade restrictive requires a consideration of exactly how and to what extent the challenged measure is trade

299. See Panel Reports, *Australia – Tobacco Plain Packaging*, *supra* note 17, ¶ 7.1358.

300. Appellate Body Reports, *Australia – Tobacco Plain Packaging*, *supra* note 17, ¶ 6.514; see also Panel Reports, *Australia – Tobacco Plain Packaging*, *supra* note 17, ¶ 7.227.

301. See generally Yoo Jin Cho et al., *Cross-country comparison of cigarette and vaping product marketing exposure and use: findings from 2016 ITC Four Country Smoking and Vaping Survey*, 29 *TOBACCO CONTROL* 295 (2020) (finding that comprehensive bans on advertising of NVPs are less effective in limiting exposure to online advertising).

302. Campus et al., *supra* note 54, at 9.

303. Czaplicki et al., *supra* note 245.

304. See generally *id.*

restrictive. If the measure has been found to be discriminatory, any alternative measure that has less of a negative impact on the competitive opportunities of the imported products will be less trade restrictive. However, if the measure is not discriminatory and is merely trade restrictive on the basis that it reduces the consumption (and hence importation) of the targeted product, then it is likely that any measure which makes an equivalent contribution to the measure's purpose will be equally trade restrictive. This was the somewhat circular logic upheld by the Appellate Body in the *Australia – Tobacco Plain Packaging* decision.³⁰⁵

For a WTO Member that has taken a health protection approach to e-cigarette regulation that aims to reduce vaping rates/the consumption of vaping products, it is likely that any alternative measure which makes a similar contribution to this aim will be considered to be equivalently trade restrictive when compared with the challenged measure. However, the analysis may be more complex where a state is taking a harm minimization approach, and the aim is not necessarily to reduce the consumption of vaping products, but instead to either ensure that those products are relatively safe and to facilitate their use by tobacco smokers (as a less damaging alternative to tobacco products). The comparison with any alternative measures will have to carefully examine the purpose/s of the measure, the extent to which it contributes to that purpose and whether the purpose could have been achieved with less restriction on trade in vaping products. In undertaking this analysis, the relationship between different measures also needs to be considered—will the contribution of any individual measure “be enhanced (or diminished) in the presence of the other existing measures?”³⁰⁶

Consideration of a range of alternatives in policy development should also include explicit assessment of the rights of e-cigarette trademark owners. The impact of restrictions posed by other measures may vary between trademark owners. Owners of figurative trademarks may alternatively be impacted by measures similar to tobacco plain packaging that only permit the use of word marks as identifiers of source. However, if words are more frequently used to identify brands,

305. Appellate Body Reports, *Australia – Tobacco Plain Packaging*, *supra* note 17, ¶¶ 6.472–6.477.

306. *Id.* ¶ 6.502.

even where devices are associated, this could mitigate the restrictive impact of these measures.³⁰⁷

C. Lesson Three: Non-WTO International Law Provides Relevant Support for Societal Interests

Justifications for any e-cigarette regulations that restrict trade or impose special requirements on the use of a trademark in the course of trade can be “further underscored” by widely adopted international agreements. Where there is fragmentation between WTO agreements and other non-WTO international agreements,³⁰⁸ relevant international law can provide support for restrictions on e-cigarettes.

1. The Relevance of Non-WTO International Law in the Application of the WTO Agreements

The obligations contained in the WTO Agreements should be interpreted in light of other public international law obligations. Article 3.2 of the Dispute Settlement Understanding recognizes that the customary rules of interpretation of public international law, as codified in the Vienna Convention on the Law of Treaties (VCLT), apply in WTO Disputes.³⁰⁹ Article 31(3)(c) of the VCLT provides a mechanism for systemic integration of international law by providing that “relevant rules of international law applicable between the parties” are relevant in treaty interpretation.³¹⁰ There is dispute as to the extent to which rules external to the WTO agreements would be engaged by Article 31(3)(c). It could be interpreted to only include rules of international law applicable to all of the parties to a dispute or it could be limited to agreements which bind all (or a significant number of) WTO Members,³¹¹ or any agreements which are relevant to the issues

307. This was the case in litigation about Australian tobacco plain packaging legislation where it was found that the words in brand names were most commonly used to identify tobacco brands, even where device marks were registered. See *JT International SA v. Commonwealth* (2012) 250 CLR 1, 103 (Austl.).

308. Wilkinson, *supra* note 228, at 182.

309. Appellate Body Report, *US – Gasoline*, *supra* note 193, ¶ 17; Appellate Body Report, *US – Shrimp*, *supra* note 192, ¶ 114.

310. See generally Campbell McLachlan, *The Principle of Systemic Integration and Article 31(3)(C) of the Vienna Convention*, 54 INT’L & COMP. L.Q. 279 (2005).

311. HENNING GROSSE RUSE-KHAN, *THE PROTECTION OF INTELLECTUAL PROPERTY IN INTERNATIONAL LAW* 143 (2016).

in the dispute.³¹² This tension was noted but not resolved in the interpretation of Article 31(3)(c) in *EC and certain member States – Large Civil Aircraft*:

a delicate balance must be struck between, on the one hand, taking due account of an individual WTO Member’s international obligations and, on the other hand, ensuring a consistent and harmonious approach to the interpretation of WTO law among all WTO Members.³¹³

In *Thailand – Cigarettes (Philippines) (Article 21.5 – Philippines II)* the Panel found that the Revised Kyoto Convention was a relevant rule to interpreting the ordinary meaning of terms in dispute, noting that even if the treaty did not meet a minimum threshold for the number of WTO Members which were parties, the relevant rules could still constitute a supplementary means of interpretation consistent with VCLT Article 32 which can be used to confirm interpretations that use Article 31 or determine them when that interpretative process results in “ambiguous or obscure” meanings or “manifestly absurd or unreasonable” results.³¹⁴

Despite the considerable overlap between WTO law and other international obligations, such as environmental obligations, human rights treaties and public health treaties, in practice, there has been limited use of Article 31(3)(c) in interpretation of WTO agreements. More commonly, international obligations found in treaties are used as evidence to support or justify measures. In *Australia – Tobacco Plain Packaging*, the Appellate Body found that the FCTC provided further support for Australia’s justification for its measures, in respect of both the TRIPS Agreement and TBT Agreement obligations. In the appeal, Honduras argued that the Panel had placed undue legal weight on the

312. BENN MCGRADY, *TRADE AND PUBLIC HEALTH: THE WTO, TOBACCO, ALCOHOL AND DIET*, *TRADE AND PUBLIC HEALTH* 45–78 (2011).

313. Appellate Body Report, *European Communities and Certain Member States – Measures Affecting Trade in Large Civil Aircraft*, ¶¶ 844–45, WTO Doc. WT/DS316/AB/R (adopted May 18, 2011) (citing ILC Report on Fragmentation, ¶¶ 410–80, in particular 413, 419 nn.569); see Int’l L. Comm’n, *Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law*, UN Doc A/CN.4/L.682, Add.1 and Corr.1 (Apr. 13, 2006).

314. Panel Report, *Thailand—Cigarettes (Philippines) (Article 21.5—Philippines II)*, ¶ 7.265, WTO Doc. WT/DS371/RW2 (adopted July 12, 2019).

FCTC and its guidelines when considering TRIPS Article 20.³¹⁵ This was rejected.³¹⁶ The Appellate Body did not find that the Panel had interpreted the FCTC to confer a mandatory obligation. The agreement was interpreted to mean that parties to the FCTC should consider adopting plain packaging guidelines³¹⁷ and the Panel correctly determined that the relevant FCTC obligations further underscored Australia's public health reasons for applying the measures.³¹⁸ The Panel had also taken note of the FCTC and its guidelines as evidence when assessing whether the plain packaging scheme would contribute to its health objective, as part of the analysis of TBT Article 2.1.³¹⁹

This characterization of the FCTC as “additional factual support” in the *Australia – Tobacco Plain Packaging* dispute is consistent with previous decisions of Panels and the Appellate Body, which have taken account of a wide range of non-WTO treaties and other international norms as evidence in assessing whether a measure would contribute to its objective. In *US- Shrimp* the Appellate Body noted the Rio Declaration on Environment and Development, Agenda 21, the UN Convention on Biological Diversity and the Convention on the Conservation of Migratory Species of Wild Animals as support for its finding that the conservation of endangered migratory species required cooperation among the relevant states.³²⁰ In *EC – Seal Products*, the Panel noted the ILO Convention concerning Indigenous and Tribal Peoples in Independent Countries and the UN Declaration on the Rights of Indigenous Peoples as “factual evidence” which “demonstrate[d] the recognized interests of Inuit and Indigenous peoples in preserving their traditions and cultures.”³²¹ The Panel specifically noted that “these instruments are not WTO instruments and they do not set out WTO obligations *per se*”, and that they were considering the instruments as “part of the evidence submitted by the

315. Appellate Body Reports, *Australia – Tobacco Plain Packaging*, *supra* note 17, ¶ 6.700.

316. *Id.* ¶ 6.707.

317. *Id.* ¶ 6.704.

318. *Id.* ¶ 6.707. “[T]he Panel referred to Articles 11 and 13 of the FCTC Guidelines as additional factual support to its previous conclusion that the complainants failed to establish that Australia acted inconsistently with Article 20 of the TRIPS Agreement.”

319. *See* Panel Report, *supra* note 314, ¶ 7.800.

320. Appellate Body Report, *supra* note 192, at ¶ 168.

321. Panel Report, *European Communities—Measures Prohibiting the Importation and Marketing of Seal Products*, ¶¶ 7.292–7.295, WTO Docs. WT/DS400/R, WT/DS401/R (adopted Nov. 25, 2013).

European Union to support its position concerning the interests of Inuit and indigenous communities.”³²² In *Turkey – Pharmaceutical Products* the Panel noted various instruments, initiatives and publications by international organizations which recognize the importance of ensuring access to pharmaceutical products. The sources cited by the Panel include a 2009 Resolution of the UN Human Rights Council and a joint publication issued by WIPO and the WHO.³²³ These cases show that it is not just multilateral treaties that may be used as evidence when considering whether a measure contributes to a public objective, and that WTO panels and the Appellate Body have given weight to a wide range of informal sources as well.

2. Relevant Non-WTO International Law That Could Support E-Cigarette Regulation

There are a range of international instruments and decisions that may be relevant to considering the legitimacy of e-cigarette regulations. Although the WHO has not yet recommended a single regulatory approach for states to take to the regulation to e-cigarettes, it has framed its recent call to take “urgent and strong action” to reduce the uptake of electronic cigarette consumption as action that should occur parallel to implementation of the WHO FCTC, noting the requirements for FCTC parties “to adopt policies to prevent and reduce nicotine addiction” and arguing that stronger action on e-cigarettes “should form part of a comprehensive approach to tobacco control and should be implemented in line with national circumstances, including existing tobacco control measures.”³²⁴ The FCTC provided valuable support for Australia’s justification of restriction on trademark use³²⁵ but, as discussed above, its application to support e-cigarette regulation is less clear as the focus of the agreement is on the regulation of tobacco products.

322. *Id.* n.475.

323. Panel Report, *Turkey—Certain Measures Concerning the Production, Importation and Marketing of Pharmaceutical Products*, ¶¶ 7.159–7.160, WTO Docs. WT/DS583/12, WT/DS583/12/Add.1 (adopted Apr. 28, 2022).

324. *Technical Note on Call to Action on Electronic Cigarettes*, *supra* note 2, at 5.

325. See *supra* notes 316–320; see also Suzanne Y. Zhou, Jonathan D. Liberman & Evita Ricafort, *The Impact of the WHO Framework Convention on Tobacco Control in Defending Legal Challenges to Tobacco Control Measures*, 28 *TOBACCO CONTROL* 113 (2019).

The support that the FCTC provided for Australia’s justification of its tobacco plain packaging legislation suggests that other non-WTO agreements can be relevant to justification where they are explicitly recognized.³²⁶ A more detailed consideration of human rights concerns such as the right to health can not only strengthen justification, it can strengthen the development of effective intellectual property policy.³²⁷ The relevance of the right to health obligations found in the International Covenant on Economic, Social and Cultural Rights was recognized in *Turkey – Pharmaceutical Products*, although Turkish restrictions on pharmaceutical products argued to promote access to medicine were found to be inapt to the asserted health objective and inconsistent with national treatment obligations found in GATT 1949.³²⁸ E-cigarette regulation may engage States’ obligations to protect individuals’ right to health, which can be violated through “the failure to discourage production, marketing and consumption of tobacco, narcotics and other harmful substances.”³²⁹ States are obliged to fulfil the right to health through information campaigns regarding “the use of cigarettes, drugs and other harmful substances.”³³⁰ This can support certain types of e-cigarette regulation such as the use of graphic health warnings on packaging where trademarks may be used.

Additionally, the negative health impacts of e-cigarette consumption in young people have been consistently identified as a justification for market regulation. The Convention on the Rights of the Child is one of the most widely ratified international human rights

326. See Wilkinson, *supra* note 228, at 173.

327. *Id.*; see also Christophe Geiger & Luc Desautettes-Barbero, *The Revitalisation of the Object and Purpose of the TRIPS Agreement: The Plain Packaging Reports and the Awakening of the TRIPS Flexibility Clauses*, in *GLOBAL INTELLECTUAL PROPERTY PROTECTION AND NEW CONSTITUTIONALISM* 267, 294 (Jonathan Griffiths & Tuomas Mylly eds., Oxford Univ. Press 2021).

328. Notification of an Appeal by Turkey, *Turkey—Certain Measures Concerning the Production, Importation and Marketing of Pharmaceutical Products*, WTO Doc. WT/DS583/12 (Apr. 28, 2022). The Panel’s decision was upheld on appeal via arbitration conducted pursuant to art. 25 of the DSU. See Decision by the Arbitrators, *Turkey—Certain Measures Concerning the Production, Importation and Marketing of Pharmaceutical Products—Arbitration under Article 25 of the DSU*, WTO Doc. WT/DS583/ARB25 (July 25, 2022).

329. General Comment No. 14 (2000): The Right to the Highest Attainable Standard of Health (Article 12 of the International Covenant on Economic, Social and Cultural Rights), ¶ 51, U.N. Doc. E/C.12/2000/4 (Aug. 11, 2000).

330. *Id.* ¶ 36.

instruments.³³¹ Children’s human rights protect all children under the age of eighteen.³³² There is growing concern about the increasing numbers of people under the age of eighteen consuming e-cigarettes. If there is sufficient evidence of misleading marketing practices for e-cigarettes involving trademarks that are directed towards children, arguments engaging children’s human rights could be particularly relevant to guide restrictions on packaging of e-cigarettes.³³³ Children are vulnerable to advertising and there are specific protections for children in relation to health information.³³⁴ Internationally, there is increasing evidence that e-cigarettes have been promoted in a misleading and deceptive manner.³³⁵

Despite the relevance of these instruments, the recent WHO call to action indicates need for formal multilateral agreement about e-cigarettes.³³⁶ It remains uncertain the extent to which the *FCTC* can shape intervention but leadership from WHO could form the basis for greater multilateral cooperation that can assist states to justify measures that limit intellectual property protection. Further support that could be valuable for states who wish to justify e-cigarette regulations that could impact trademark use includes resolutions from the World Health Assembly, guidance from the Committee on the Rights of the Child, and resolutions in the *FCTC*. Where these are relevant to states they should be explicitly recognized in legislative development documents.³³⁷

331. Status of Treaties: United Nations Convention on the Rights of the Child, UNITED NATIONS TREATY COLLECTION, https://treaties.un.org/pages/ViewDetails.aspx?src=IND&mtdsg_no=IV-11&chapter=4&clang=_en [<https://perma.cc/KJ4E-M5KS>]; Vienna Convention on the Law of Treaties, art. 18, *opened for signature* May 23, 1969, 1155 U.N.T.S. 331 (entered into force Jan. 27, 1980) [hereinafter *VCLT*]. States that have signed but not ratified the agreement, such as the United States, are still obliged “to refrain from acts which would defeat the object and the purpose of a treaty.”

332. Convention on the Rights of the Child, art. 1.

333. See Genevieve Wilkinson, *Using Tobacco Plain Packaging to Protect the Human Rights of Children*, 45 UNIV. NEW S. WALES L.J. 370, 398–99 (2022).

334. Convention on the Rights of the Child, art. 17.

335. See, e.g., *Juul Agrees to \$US440 Million Settlement Following Probe Into Marketing Vapes to Teens*, *supra* note 11; see also Monaghan, *supra* note 211.

336. WORLD HEALTH ORGANIZATION, ELECTRONIC CIGARETTES: CALL TO ACTION, *supra* note 92.

337. Wilkinson, *supra* note 228, at 172.

V. CONCLUSIONS

The WHO's call in December 2023 for states to take urgent action to address emerging health concerns about e-cigarette consumption should prompt states to prioritize reforming their domestic regulation of these products. Despite consistent emerging evidence of health harms, designing e-cigarette regulations is complicated because of the heterogeneity of the liquids that are inhaled and the devices used to inhale them, as well as the limited opportunity for longitudinal studies of the impacts of e-cigarette consumption. The increasing popularity of e-cigarettes among young never-smokers and the uncertain potential for e-cigarettes to be used as a smoking cessation device contributes further complexity to any health assessment. Although the FCTC COP has identified that ENDS and ENNDS are relevant to tobacco control measures, there is limited multilateral consensus on how e-cigarettes should be treated.

Unsurprisingly, significant regulatory differences have emerged as states attempt to grapple with the complex health implications of e-cigarette consumption, ranging from health protection regimes to harm reduction approaches, with a diversity of other measures being used such as flavor bans on restrictions on nicotine content. This lack of consensus increases the likelihood that states could disagree on regulatory approaches. To avoid disputes about consistency with international trade law, states designing e-cigarette regulation should consider the trade law implications and work towards multilateral consensus about the most efficient and appropriate tools to address emerging health concerns.

This Article has focused on three WTO agreements that are likely to govern many approaches to the regulation of e-cigarettes: the TBT Agreement, the GATT, and the TRIPS Agreement. Although the analysis has identified that many WTO rules could apply to the kinds of e-cigarette regulations that states are enacting, this does not mean that e-cigarette regulation that recognizes emerging health concerns and attempts to prevent long-term harm cannot be consistent with trade obligations. E-cigarette regulation can be consistent with WTO rules but particular weight should be given to the lessons identified in Part IV. First, states need to precisely identify the purpose of their measure, and consider what support is available to justify introducing measures that might be characterized as trade-restrictive, discriminatory, or restricting trademark use in the course of trade. This may focus on pre-implementation evidence and is not limited to public health

considerations but can include other societal or public interests. Secondly, states should assess whether alternative regulatory measures are available that would achieve their goals with less interference with international trade or the use of trademarks. Thirdly, non-WTO international law and norms can provide states with valuable support for the measures that they adopt, which WTO panels are likely to accept as persuasive evidence of the efficacy or appropriateness of a regulatory approach.

Despite the WHO's recent call to action, the nature of e-cigarettes makes it uncertain whether the FCTC remains the best vehicle for consensus about a comprehensive approach. States should consider how the FCTC and other widely ratified multilateral agreements that are relevant to the concerns driving e-cigarette regulation, such as the Convention on the Rights of the Child, can provide support for the measures that they adopt. Ultimately, careful and considered justification of e-cigarette regulation is critical but achievable for states who wish to tackle the serious health concerns posed by e-cigarettes worldwide.