Lawrence A. Kogan on

The Philippines Breastmilk Substitute/Supplement Marketing Framework Violates WTO Law (Part 2 of 2)

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I. Introduction

Part 1 of this article discusses how the various non-food-safety-related provisions of the PH BMS Framework violate the WTO Technical Barriers to Trade ("TBT") Agreement.[1] In particular, it focuses on how the advertising and labeling restrictions the PH BMS Framework imposes on follow-on formula and complementary food products marketed and/or intended for use by infants older than 6-12 months of age and young children older than 12 months of age create unnecessary obstacles to trade. It also explains how the PHDOH which bears primary responsibility for implementing the Milk Code that serves as the foundation of said framework failed to identify and consider reasonably available less trade-restrictive alternatives to such measures that are capable of achieving the PH BMS Framework's legitimate policy objectives with little, if any, risk they would be unfulfilled.

Part 2 of this article discusses how the PH BMS Framework's prohibitions and restrictions on the use of trademarks, logos and brand names (word marks and non-word marks) in advertising, labeling and packaging materials violate the WTO Trade Related Aspects of Intellectual Property Rights ("TRIPS") Agreement.[2]

II. The PH BMS Framework Violates the WTO TRIPS Agreement

1. TRIPS Articles 8 and 20 and the Doha Declaration Anticipate Trademark Owners' Legitimate Interests Including Use

Various PH BMS Framework provisions[3] encumber the use of trademarks[4] associated with infant formula, follow-up formula and complementary food product advertising, labeling and packaging in contravention of TRIPS Article 20, because they lack sufficient evidence demonstrating that such provisions are "necessary"/"justifiable" to protect public health via breastfeeding under TRIPS Article 8.1 and/or to prevent the abuse of IP rights via deceptive marketing under TRIPS Article 8.2.

Some international organizations and their legal advisers have claimed that the limited TRIPS Article 20 jurisprudence available[5] strongly suggests that TRIPS Article 8.1 "inherently grants Members

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1 *See* Lawrence A. Kogan, *The Philippines Breastmilk Substitute/Supplement Marketing Framework Violates WTO Law* (Part 1 of 2), LexisNexis 2013 Emerging Issues ("Part 1").

2 See *Agreement on Trade-Related Aspects of Intellectual Property Rights*, (Apr. 15, 1994), Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, The Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS] at http://www.wto.org/english/docs_e/legal_e/27-trips.pdf.

3 *See* discussion in Parts II.2.c.v and II.3.b.iii.D, *supra*.

4 TRIPS Article 15.1 provides that trademarks can potentially consist of "[a]ny sign, or any combination of signs, capable of distinguishing the goods or services of one undertaking from those of other undertakings." TRIPS Art. 15. "[S]igns, in particular words", can include "personal names, letters, numerals, figurative elements and combinations of colours as well as any combination of such signs." *Id*.

5 *See* Panel Report, *Indonesia - Certain Measures Affecting the Automobile Industry*, WT/DS54/R, WT/DS55/R, WT/DS59/R, WT/DS64/R (July 2, 1998), at pars. 14.270-14.279. Allegations of TRIPS Article 20 violations are currently limited to the claims recently raised in connection with the pending WTO dispute over Australia's plain tobacco packaging legislation. *See* Lawrence A. Kogan, *Hong Kong's Draft Infant Formula & Complementary Foods Marketing Code Violates WTO Law (Part 3 of 3)*, LexisNexis Emerging Issues 7049 (Aug. 2013), at Sec. I, fn# 15, available at: http://www.itssd.org/HK%20Infant%20Formula%203.pdf.

freedom to pursue legitimate public policy objectives, especially the protection of public health."[6] They reason that "many measures to attain those public policy objectives lie *outside* the scope of intellectual property rights and [therefore] do not require an exception under the TRIPS Agreement" (emphasis added).[7] These stakeholders argue that such a reading of TRIPS is supported by the Appellate Body's recent determination of the status of paragraph 5.2 of the Doha Ministerial Decision,[8] and by paragraphs 4 and 5(a) of the Doha Declaration on TRIPS and Public Health[9] which emphasize the "object and purpose" of the TRIPS Agreement."[10]

Other legal commentators have determined, however, that the policy space TRIPS Articles 7 and 8 afford to WTO Members to pursue public interest objectives is not unlimited, but rather, is circumscribed by the scope of trademark owners' rights and legitimate interests as defined by other TRIPS provisions and other relevant treaties.[11] These rights and legitimate interests were previously recognized, for example, in paragraph 3 of the Doha Decision of 2003 implementing paragraph 6 of the Doha Declaration.[12] Said document reaffirmed that even though "governments have the right to expropriate patents (and any other property rights, for that matter) whenever they find it necessary to pursue the public good…the TRIPS Agreement…in that context…make[s] it clear that any measure that limits private property rights in intangible goods *must be compensated*" (emphasis added).[13]

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6 *See* Gary Fooks, and Anna B Gilmore, *International Trade Law, Plain Packaging and Tobacco Industry Political Activity: The Trans-Pacific Partnership*, Tobacco Control (June 2013) at p. 4, available at: http://tobaccocontrol.bmj.com/content/early/2013/06/19/tobaccocontrol-2012-050869.full.pdf+html.

7 *See* Panel Report, *European Communities – Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs (United States) ("EC - Trademarks and Geographical Indications (US)")*, WT/DS174/R (March 15, 2005), at par. 7.210. The Panel observed that governmental promotion of the public interest is made possible because the TRIPS Agreement does not generally confer "positive" rights to use or exploit IP, but rather provides only for the grant of "negative" rights to prevent unauthorized third-party use of IP. *Id*.

8 *See* World Trade Organization, *Doha Ministerial Declaration of 14 November 2001*, WT/MIN(01)/DEC/1 (Nov. 20, 2001), at par. 5.2, available at: http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_implementation_e.pdf; Appellate Body Report, *United States - Measures Affecting the Production and Sale of Clove Cigarettes ("US-Clove Cigarettes")* WT/DS406/AB/R (Apr. 4, 2012), at par. 268. Some commentators have seized upon the Appellate Body's recent determination in *Clove Cigarettes* that "paragraph 5.2 of the Doha Ministerial Decision constitutes a subsequent agreement between the parties, within the meaning of Article 31(3)(a) of the *Vienna Convention*, on the interpretation of the term 'reasonable interval' in Article 2.12 of the *TBT Agreement*" (emphasis in original), to argue that "the *Doha Declaration* is [also] a subsequent agreement of WTO Members within the meaning of Article 31(3)(a) of the Vienna Convention on the Law of Treaties (VCLT)" (emphasis added). *See* Gary Fooks, and Anna B Gilmore, *International Trade Law, Plain Packaging and Tobacco Industry Political Activity: The Trans-Pacific Partnership*, Tobacco Control (June 2013) *supra* at p. 4, *citing* Benn McGrady, *Revisiting TRIPS and Trademarks: The Case of Tobacco* (2012), at pp. 2-3, available at: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2144269.

9 *See* World Trade Organization, Doha WTO Ministerial 2001: TRIPS, *Declaration on the TRIPS Agreement and Public Health*, WT/MIN(01)/DEC/2 (Nov. 20, 2001), at par. 5(a), available at: http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf.

10 *See, e.g.*, Christoph Spennemann, *TRIPS Flexibilities: Comparing Access to Medicines and Tobacco Control*, UNCTAD, at p.5, available at: http://www.who.int/fctc/4-3-TRIPS_Flexibilities.pdf ("Guidance also for interpretation of trademark provisions (e.g. Art 20 TRIPS: justification of health regulation"). *Id*.

11 *See* Susie Frankel and Daniel Gervais, *Plain Packaging and the Interpretation of the TRIPS Agreement*, Vanderbilt Journal of Transnational Law (2013), available at: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2234580.

12 *See* World Trade Organization General Council, *Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health of August 30, 2003*, WT/L/540 (Sept. 2, 2003), available at: http://www.who.int/medicines/areas/policy/WT_L_540_e.pdf.

13 *See* Nuno Pires De Carvalho, *The TRIPS Regime of Patents,* Kluwer Law Int'l (2010), at Sec. 8.20, p. 234, available at: http://books.google.com/books?id=M8GkbdvTJWEC&pg=PA234&lpg=PA234&dq=What+the+TRIPS+Agreement+does+in+that+context+is+to+make+it+clear+that+any+measure+that+limits+private+property+rights+in+intangible+goods+must+be+compen

The UNCTAD and its legal advisers claim that Article 8 affords WTO Members "the discretion to adopt internal measures they [subjectively] consider 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".[14] However, contrary to such claim, WTO jurisprudence indicates that the TRIPS Agreement does not only grant "negative" rights to prevent unauthorized third-party use of trademarks, but also anticipates the "positive" use of trademarks in commerce as integral to a trademark owner's legitimate interests.[15] As the WTO Panels in *Canada - Pharmaceutical Patents* and *EC - Trademarks and Geographical Indications*[16] have found (in the context of TRIPS Articles 28 and 30, and 16 and 17, respectively,)[17] the legitimate interests of trademark owners encompass both positive rights to use a registered trademark and to exploit its economic value (i.e., through assignment, licensing, etc.), as well, as negative rights to preserve its distinctiveness or capacity to distinguish.[18] As the Panel in *EC - Trademarks and Geographical Indications* concluded,

"[e]very trademark owner has a legitimate interest in preserving the distinctiveness, or capacity to distinguish, of its trademark so that it can perform that function. This includes *its interest in using its own trademark* in connection with the relevant goods and services of its own and authorized undertakings. Taking account of that legitimate interest will also take account of the trademark owner's *interest in the economic value of its mark* arising from the reputation that it enjoys and the quality that it denotes" (emphasis added).[19]

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sated&source=bl&ots=o3xSkzxelQ&sig=T9b05xWcOuJNw6DX2f2rVJR_aDA&hl=en&sa=X&ei=mbwgUuOmLJSvsASa1ICwDw&ved=0CCkQ6AEwAA#v=onepage&q=What%20the%20TRIPS%20Agreement%20does%20in%20that%20context%20is%20to%20make%20it%20clear%20that%20any%20measure%20that%20limits%20private%20property%20rights%20in%20intangible%20goods%20must%20be%20compensated&f=false. Pursuant to paragraph 3 of that Decision, where an exporting WTO Member issues a compulsory license to secure access to a drug, it must pay to the patent holder adequate remuneration under TRIPS Article 31(h) "taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member." WT/L/540, *supra* at par. 3. This suggests that if TRIPS flexibilities such as compulsory licensing are invoked, the more developed exporting Member will likely be incurring the charge for compensating the IP holder on behalf of the lesser developed country importing Member.

14 *See* UNCTAD-ICTSD, *Resource Book on TRIPS and Development*, Cambridge University Press (2004), at Sec. 6 – *Objectives and Principles*, pp. 126-127, available at: http://www.iprsonline.org/unctadictsd/docs/RB_Part1_Nov_1.5_update.pdf. *See also* Frederick Abbott, *Dispute Settlement World Trade Organization, Module 3.14 TRIPS*, in "Course on Dispute Settlement in International Trade, Investment and Intellectual Property", UNCTAD (2003), at Sec. 2.34, p. 15, available at: http://unctad.org/en/Docs/edmmisc232add18_en.pdf. At least one commentator has voiced doubt concerning whether WTO Panels would be willing to go along. *See* Peter Yu, *The Objectives and Principles of the TRIPS Agreement*, 46 Hous. L. Rev. 979, 1009, fn# 133 (2009), available at: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1398746, *quoting* Carlos Correa, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* (Oxford University Press 2007), at p. 108, available at: http://fds.oup.com/www.oup.co.uk/pdf/0-19-927128-3.pdf; http://ukcatalogue.oup.com/product/9780199271283.do#.Ud2ESGLCaSo.

15 Panel Report, *EC - Trademarks and Geographical Indications (US)*, supra at par. 7.611, fn. 564. Consistent with the Panel's understanding, Professor Carvalho has noted that "the right to use a certain sign in a certain field of commerce, industry or services results from economic freedom, not from industrial property law." *See* Nuno Pires De Carvalho, *The TRIPS Regime of Trademarks and Designs*, 2d. Ed. (Kluwer Law Int'l 2011), at Sec. 16.1, p. 343, available at: http://books.google.com/books?hl=en&lr=&id=h8z73JXP3uIC&oi=fnd&pg=PR15&dq=The+TRIPS+regime+of+trademarks+and+designs+/&ots=2I6V-mDsaA&sig=RE_e3CSKQIqTJ3Z2tG3l-pWNHao.

16 Panel Report, *Canada-Patent Protection of Pharmaceutical Products*, WT/DS114/R (Mar. 17, 2000), at pars. 7.68-7.69; Panel Report, *EC - Trademarks and Geographical Indications (US)*, supra at pars. 7662-7.664.

17 *See* Lawrence A. Kogan, *Hong Kong's Draft Infant Formula & Complementary Foods Marketing Code Violates WTO Law (Part 3 of 3)*, LexisNexis Emerging Issues 7049 (Aug. 2013), *supra* at Sec. II.2.

18 *Id*; *Accord* Nuno Pires De Carvalho, *The TRIPS Regime of Trademarks and Designs*, Sec. 16.6, p. 348.

19 Panel Report, *EC - Trademarks and Geographical Indications (US)*, supra at par. 7.664.

The World Intellectual Property Organization ("WIPO") has similarly described a registered owner's "exclusive right to use [a] trademark" as encompass[ing] two things: the right to use the trademark and the right to exclude others from using it."[20] WIPO notes that the "positive right of use belonging to the trademark owner [,which] is recognized in most trademark laws[,]…means first the right of the owner of the mark to affix it on goods, containers, packaging, labels, etc. or to use it in any other way in relation to the goods for which it is registered. It means also the right to introduce the goods to the market under the trademark."[21] "[A] third right out of the series of rights incorporated in the right to use a trademark is the trademark owner's *right to use his mark in advertising*, *on business papers*, documents, etc." (emphasis added).[22] WIPO's views on trademarks are significant given the mandate of TRIPS Article 2.1 which, through incorporation of "Articles 1 through 12, and Article 19, of the Paris Convention"[23] and the context provided by other TRIPS provisions, reflects an implied right to use trademarks subject to conditions.[24]

2. The PH BMS Framework Violates TRIPS Articles 8 and 20

In order to bring a successful claim under TRIPS Article 20, it is necessary to establish that the PH BMS Framework provisions curtailing the use of word marks and non-word marks in infant formula, follow-up formula and complementary food-related advertising materials and product labels constitute "special requirements" and that they "unjustifiably encumber" such trademark use, within the meaning of TRIPS Articles 8 and 20.

a. Restrictions Must Constitute Special Requirements That Encumber Trademark Use Under TRIPS Article 20

TRIPS Article 20 precludes WTO Members from unjustifiably encumbering (i.e., hampering, hindering, impeding, or burdening"[25]) the use of a trademark in the course of trade by special requirements.[26] The Panel in *United States - Article 110(5) of the Copyright Act*,[27] defined the term

20 *See* World Intellectual Property Organization, *Intellectual Property Handbook: Policy, Law and Use*, (June 2001) at par. 2.444, p. 84, available at: http://www.wipo.int/export/sites/www/freepublications/en/intproperty/489/wipo_pub_489.pdf.
21 *Id.*, at pars. 2.446-2.447, p. 84.
22 *Id*., at par. 2.451, p. 85.
23 TRIPS Art. 2.1.
24 "[S]aying there is no absolute right to use in TRIPS, does not mean one can ignore TRIPS Articles that provide context. Our conclusion on this point is also simple: (a) the purpose of registration is an integral aspect of interpreting the TRIPS Agreement's provisions about trademarks; (b) the purpose and *acquis* of the TRIPS Agreement registration provisions and Paris Convention provisions incorporated into TRIPS is to encourage the orderly use of trademarks in commerce; and (c) the rights of trademark owners are limited, but they make little sense seen as mere rights to exclude." *See* Susie Frankel and Daniel Gervais, *Plain Packaging and the Interpretation of the TRIPS Agreement*, supra at p. 26. *Cf*. Mark A. Davison, *The Legitimacy of Plain Packaging Under International Intellectual Property Law: Why There is No right to Use a Trademark Under Either the Paris Convention or the TRIPS Agreement* in PUBLIC HEALTH AND PLAIN PACKAGING OF CIGARETTES: LEGAL ISSUES 81 (Tania Voon, Andrew Mitchell & Jonathan Liberman Eds. 2012), available at: http://ssrn.com/abstract=2009115. According to Professor Davies, "[t]rademark usage is but one of multiple factors that governments consider in making policy decisions. It is difficult to accept that governments would compromise their ability to protect public health and to pursue other valid policy objectives via the oblique and imprecise means of conferring *an implied right to use trademarks* without so much as a suggestion as to how to limit that right or how to create exceptions to it" (emphasis added). *Id*., at p. 9 (SSRN version).
25 *See* Merriam Webster online, available at: http://www.merriam-webster.com/dictionary/encumber.
26 TRIPS Art. 20.
27 *See* Panel Report, *United States-Article 110(5) of the Copyright Act*, WT/DS160/R (Jun. 15, 2000) (adopted Jul. 27, 2000).

"special" as "'having an individual or limited application or purpose', 'containing details; precise, specific', 'exceptional in quality or degree; unusual; out of the ordinary' or 'distinctive in some way'".[28] Arguably, special requirements are those that "concern the use of trademarks with special or specific purpose."[29]

Special requirements contrast, therefore, with 'general requirements', which would apply to all products."[30] Prima facie examples of special requirements, which are not necessarily unjustified *per se*,[31] include those mandating use with another trademark, use in a special form or use in a manner detrimental to a trademark's capability to distinguish the goods or services of one undertaking from those of other undertakings.[32] "All of these requirements involve activities that may diminish the distinctiveness of the trademarks in question by positive action being required of the trademark owner in the context of the use of its trademarks."[33] Indeed, the requirement that a trademark be used "in a special [specific] form" "may [very well] involve reducing its visual or other impact on consumers and…therefore its distinctiveness in the sense of distinguishing the goods in question from other goods."[34] In addition, special requirements may include requirements that impose "unreasonable size limitations on the display of the mark or unreasonable requirements to include other indicia on the label of a product", which could prevent the recognition of the mark or otherwise inhibit the mark from serving to distinguish a good or service.[35]

Special requirements may also include "those that have a special purpose or effect [such as] *to reduce consumption of tobacco* [or] *to reduce brand loyalty on pharmaceuticals*" (emphasis added).[36] Arguably, prohibitions and restrictions applicable to trademarks, logos and brand names of infant formula, follow-up formula and complementary food products used in advertising materials and product containers and labels for the purpose of reducing brand loyalty to and consumption of such products "would likely fall within any reasonable definition [of the term

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28 *Id*., at par. 6.109.

29 *See* Nuno Pires De Carvalho, *The TRIPS Regime of Trademarks and Designs*, supra at Sec. 20.10, and accompanying fn. 926.

30 *Id.*

31 "The three examples of special requirements given in Article 20 (i.e. 'use with another trademark, use in a special form or use in a manner detrimental to its capability to distinguish the goods or services of one undertaking from those of other undertakings') are not necessarily unjustified. When a named special requirement is imposed, the burden of proving the justification rests on the WTO Member imposing it." *See* Daniel Gervais, *Analysis of the Compatibility of Certain Tobacco Product Packaging Rules with the TRIPS Agreement and the Paris Convention*, Prepared for Japan Tobacco International (Nov. 30, 2010) at par. 48, available at: http://www.smoke-free.ca/trade-and-tobacco/Resources/Gervais.pdf. *Accord*, *See* Tania Voon and Andrew Mitchell, *Face off: Assessing WTO Challenges to Australia's Scheme for Plain Tobacco Packaging*, supra at p. 15.

32 TRIPS Art. 20.

33 *See* Mark A. Davison, *The Legitimacy of Plain Packaging Under International Intellectual Property Law: Why There is No right to Use a Trademark Under Either the Paris Convention or the TRIPS Agreement*, supra at p. 15 (SSRN version).

34 *Id*. The requirement that a trademark be used "in a manner detrimental to its capability to distinguish the goods or services of one undertaking from those of other undertakings" "is a more generic reference to conduct demanded of the trademark owner that may diminish the distinctiveness of its trademark." *Id*., at pp. 15-16.

35 See *Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods*, Meeting of Negotiating Group of 16-19 May 1988, *Note by Secretariat* (MTN.GNG/NG11/7) (June 21, 1988), at par. 18, http://ipmall.info/hosted_resources/lipa/trips/7.pdf.

36 *See* Nuno Pires De Carvalho, *The TRIPS Regime of Trademarks and Designs*, supra at Sec. 20.10, and accompanying fn. 926.

'special' requirement,] because such requirement[s] would have 'limited application or purpose' and be 'containing details; precise, specific.'"[37]

Furthermore, legal commentators have argued that a requirement which partially or totally prohibits the use of a trademark in commerce arguably constitutes the type of encumbrance that falls within the scope TRIPS Article 20 because it can diminish the distinctiveness of trademarks. A partial or total trademark-use prohibition could effectively prevent a trademark owner from distinguishing its product from other products in the marketplace,[38] including unbranded counterfeits[39] and illicitly manufactured branded products.[40] Since "the food and pharmaceutical industries are the most vulnerable to the increasingly sophisticated operations of counterfeiters",[41] including in the Philippines,[42] such restrictions, therefore, could further exacerbate the unintended health risks to unwary East Asian (e.g., Filipino) consumers[43] posed by counterfeit and substandard[44] infant formula and follow-on formula products. A partial or total prohibition of the

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37 *See* Susie Frankel and Daniel Gervais, *Plain Packaging and the Interpretation of the TRIPS Agreement*, supra at pp. 22 and 24; Daniel Gervais, *Analysis of the Compatibility of Certain Tobacco Product Packaging Rules with the TRIPS Agreement and the Paris Convention*, supra at par. 47. *Cf*. Mark A. Davison, *The Legitimacy of Plain Packaging Under International Intellectual Property Law: Why There is No right to Use a Trademark Under Either the Paris Convention or the TRIPS Agreement*, supra at p. 19 (SSRN version). *Contra* Susie Frankel and Daniel Gervais, *Plain Packaging and the Interpretation of the TRIPS Agreement*, supra at p. 21.

38 *See* Susie Frankel and Daniel Gervais, *Plain Packaging and the Interpretation of the TRIPS Agreement*, supra at pp. 19-20.

39 *See* United Nations Office on Drugs and Crime, *Transnational Organized Crime in East Asia and the Pacific – A Threat Assessment* (April 2013), at Executive Summary, p. ix and p. 125, available at: http://www.unodc.org/documents/data-and-analysis/Studies/TOCTA_EAP_web.pdf.

40 *See* China Daily, *Fake Infant Formulas a Big Problem* (May 7, 2013), available at: http://www.chinadaily.com.cn/opinion/2013-05/07/content_16481105.htm; United Nations Office on Drugs and Crime, *Transnational Organized Crime in East Asia and the Pacific – A Threat Assessment* supra at p. 134.

41 *See* PR Web, *Global Anti-Counterfeit Packaging Market to Reach US$82.2 Billion by 2015, According to New Report by Global Industry Analysts*, Inc., Press Release (July 12, 2010), available at: http://www.prweb.com/releases/anti_counterfeit/packaging/prweb4241174.htm.

42 *See, e.g.*, IP Advantage, *From Ice Cream Parlor to Fast Food Empire: Tony Tan Caktiong's Story*, WIPO website, available at: http://www.wipo.int/ipadvantage/en/details.jsp?id=2531 (discussing how the "strong Jollibee brand name and its positive connotations have made it a target for free-riders and counterfeiters: 'We have some cases where people will do other things like garments or shoes and they call it "Jollibee". Overseas, they will open a restaurant or a fast food also called Jollibee, even with the same drawing', Mr. Caktiong reports."). *Id*. *See also* Republic of the Philippines, Intellectual Property Office of the Philippines, *Battle Against Fakes Unyielding, Seizures Reached 5.2 B* (Aug. 12, 2013), available at: http://www.ipophil.gov.ph/index.php/20-what-s-new/192-battle-against-fakes-unyielding-seizures-reached-5-2-b ("BIGGEST HAUL OF COUNTERFEIT PRODUCTS IN THE HISTORY OF NCIPR. The IPOPHL reported that in July alone total seizures reached PHP 1.7Billion. This was a joint effort of the brand owners, BOC, IPOPHL, and NBI"). *Id*.

43 *See, e.g.*, United Nations Office on Drugs and Crime, *Transnational Organized Crime in East Asia and the Pacific – A Threat Assessment* supra at Executive Summary at ix and p.134.

44 Lawrence A. Kogan, *Hong Kong's Draft Infant Formula & Complementary Foods Marketing Code Violates WTO Law (Part 2 of 3)*, LexisNexis Emerging Issues 7048 (Aug. 2013), at Sec. II.6.d.ii.B, available at: http://www.itssd.org/HK%20Infant%20Formula%202.pdf (discussing how unscrupulous small Chinese-owned export-market-only New Zealand-based companies lacking basic supply chain integrity have been shipping substandard infant formula products to mainland China and adversely affecting the positive reputations of New Zealand branded formula companies), *citing* Christopher Adams, *New China Heat on NZ Baby Formula*, New Zealand Herald (July 31, 2013), available at: http://www.nzherald.co.nz/business/news/article.cfm?c_id=3&objectid=10905697; Zhou Wenting, *Complaints Spike Over Subpar Baby Formula Imports*, People's Daily Online/China Daily (July 29, 2013), available at: http://english.peopledaily.com.cn/90778/8343660.html; http://usa.chinadaily.com.cn/business/2013-07/29/content_16848364.htm; Joe Nocera, *The Baby Formula Barometer*, New York Times Op-Ed (July 26, 2013), available at: http://www.nytimes.com/2013/07/27/opinion/nocera-the-baby-formula-barometer.html?_r=0; Abe Sauer, *Infant Formula Marketing Scam Unravels in New Zealand*, Brandchannel (June 3, 2011), available at: http://www.brandchannel.com/home/post/2011/06/03/Intl-Infant-Formula-Marketing-Scam-Unravels-in-New-Zealand.aspx.

use of a trademark may even make it more difficult for a trademark owner to establish or maintain well-known status for a mark,[45] or to prevent against a loss of well-known mark status, which may engender separate violations of TRIPS Articles 16.2 and/or 16.3.[46]

Indeed, legal commentators have construed a total prohibition of the use of a trademark as "the ultimate encumbrance",[47] particularly in Anglo-American common law systems where "trademark law originated as the judicially created tort of passing off" and "[r]egistration is not required to obtain relief under tort law."[48] Since, in such jurisdictions, "the existence of protection depend[s] on use in commerce",[49] "[p]rohibiting use (on products the sale of which is legal) amounts to denying the possibility of obtaining and maintaining protection," and thus, preventing trademarks from performing their functions."[50]

In this regard, at least one Filipino legal commentator has identified how the Philippines has a mixed legal system with common law elements reflecting Anglo-American public law, particularly, constitutional and procedural law, which has significantly influenced private property (including intellectual property), tort and commercial law development under the Philippines Civil Code.[51] "The common law tort…was adopted and adapted in the new Civil Code…such as…violation of constitutional rights…[and]…unfair competition."[52] Apparently, for these reasons, the Philippine Constitution of 1987 protects the sanctity of private property rights in various of its provisions: Article II, Section 5 provides that, "…*the protection of* life, liberty, *and property*…are essential for the enjoyment by all the people of the blessings of democracy;" Article III, Sections 1 and 9 of the Bill of Rights provides that, "*No person shall be deprived of life, liberty, or property without due process of law*, nor shall any person be denied the equal protection of the laws," and that "P*rivate property shall not be taken for public use without just compensation*"; and Article XIV, Section 13 provides that "*The State shall protect and secure the exclusive rights* of scientists, inventors, artists, and other gifted citizens *to* their *intellectual property* and creations, (emphasis added).[53]

See also Christopher Adams, *China Rejects NZ Baby Formula*, The New Zealand Herald (Nov. 13, 2012), available at: http://www.nzherald.co.nz/business/news/article.cfm?c_id=3&objectid=10846912; *Substandard Baby Formula Returned to Australia*, China.org (Aug. 21, 2012), available at: http://www.china.org.cn/china/2012-08/21/content_26293691.htm.

45 *See* Susie Frankel and Daniel Gervais, *Plain Packaging and the Interpretation of the TRIPS Agreement*, Vanderbilt Journal of Transnational Law (2013), *supra*, at pp. 40 and 50.

46 *Id*., at p. 5, fn. 12. In fact, "a ban of the use of certain well-known marks likely to lead to a loss of well-known mark status may [possibly] amount to a separate violation of Article 16.2 and/or 16.3." *Id*. "Intuitively, if a well-known mark ceases to be used (remembering that it became famous not because it was registered but rather because it was used extensively), then it seems fair to surmise that it may lose its well-known status and rights under Article 16.3." *Id*., at p. 36.

47 *See* Nuno Pires De Carvalho, *The TRIPS Regime of Trademarks and Designs*, supra at Sec. 20.1.

48 *See* Susie Frankel and Daniel Gervais, *Plain Packaging and the Interpretation of the TRIPS Agreement*, supra at p. 23.

49 *Id*., at p. 22.

50 *Id*., at p. 23. According to such commentators, "the rights provided in [TRIPS Article] 16 (against unauthorized third party use of a protected mark) make little sense if the trademark owner cannot [affirmatively] use the mark." *Id*., at fn# 79.

51 *See* Soliman M. Santos, *Common Law Elements in the Philippine Mixed Legal System*, 2 Australian Journal of Asian Law (2000), at pp. 40-43, available at: http://digital.federationpress.com.au/3aj4a/8gujl/toc. "The selection of rules from Anglo-American law was justified by the Code Commission…in 1947-48..., firstly, because elements of American culture had been incorporated into Filipino life; secondly, because of the foreseeable continuation of Philippine-American economic relations; and thirdly, because of the desirability of adopting equitable rules developed by the American and English courts (Code Commission, 1948:3). *Id*., at p. 43.

52 *Id*., at p. 45.

53 See *1987 CONSTITUTION of the Republic of the Philippines*, available at: http://www.lawphil.net/consti/cons1987.html.

For these reasons, Sections 138 and 147 of the Philippine Intellectual Property Code[54] recognize that trademarks engender both positive and negative exclusive private property rights which can be quite economically valuable. Section 138 states that a valid certificate of trademark registration constitutes prima facie evidence of ownership of and the exclusive right *to use* said mark in connection with the goods or services and those that are related thereto specified in the certificate.[55] Section 147 states that the owner of a registered trademark shall have the exclusive right to prevent all unauthorized third parties from using signs or containers for goods or services in the course of trade which are identical or confusingly similar to those in respect of which the trademark is registered.[56] Sections 149.1 and 149.5 provide that applications for trademark registration and/or trademark registrations "may be assigned or transferred with or without the transfer of the business using the mark",[57] and shall have "effect against third parties" if properly recorded at the Intellectual Property Office.[58] Section 150.1 recognizes license contracts concerning applications for trademark registration and/or trademark registrations only if the contract ensures the licensor's effective control of the quality of the goods or services of the licensee in connection with which the mark is used.[59] Section 150.2 recognizes a contract of license as legally valid and effective against third parties only if the license contract is properly recorded.[60]

b. Special Requirements Encumbering the Functions of Trademarks Under TRIPS Article 20 Must Be Justifiable

Some legal commentators have argued that special requirements can be deemed to *justifiably* encumber trademark use if they are simply imposed in furtherance of legitimate "public policy goals…such as health, food and security…that are not arbitrary or constitute a disguised restriction on trade."[61] Conversely, where requirements "are taken to pursue goals that are prohibited under a

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54 *See* Republic of the Philippines, Congress of the Philippines 10th Congress, *Republic Act No. 8293, An Act Prescribing the Intellectual Property Code and Establishing the Intellectual Property Office, Providing for its Powers and Functions, and for Other Purposes* (June 6, 1997) available at: http://www.ipophil.gov.ph/images%5Cipenforcement%5CRA8293-Intellectual_Property_Code_of_the_Philippines.pdf

55 *Id*., at Sec. 138. Section 138 replicates Section 20 of the former repealed Trademark Act, RA 166. *See* Republic of the Philippines, Congress of the Philippines, *Republic Act No. 166, An Act to Provide for the Registration and Protection of Trade-marks, Trade-names and Service-Marks, Defining Unfair Competition and False Marking and Providing Remedies Against the Same, and for Other Purposes* (June 20, 1947) repealed, available at: http://www.lawphil.net/statutes/repacts/ra1947/ra_166_1947.html. "Under Section 2 of Republic Act No. 166, as amended (R.A. No. 166), before a trademark can be registered, it must have been actually used in commerce for not less than two months in the Philippines prior to the filing of an application for its registration…[U]nder Section 239.2 of Republic Act No. 8293 (R.A. No. 8293), '[m]arks registered under Republic Act No. 166 shall remain in force but shall be deemed to have been granted under this Act x x x,' which does not require actual prior use of the mark in the Philippines." See *Fredco Manufacturing Corp. v. Presidents and Fellows of Harvard College (Harvard University)*, G.R. No. 185917, Supreme Court of the Philippines (June 1, 2011), available at: http://sc.judiciary.gov.ph/jurisprudence/2011/june2011/185917.html.

56 *Id*., at Sec. 147.

57 *Id*., at Sec. 149.

58 *Id.*, at Sec. 149.5.

59 *Id*., at Sec. 150.1.

60 *Id*., at Sec. 150.2.

61 *See* Nuno Pires De Carvalho, *The TRIPS Regime of Trademarks and Designs*, supra at Sections 20.12 and 20.20. "[T]he mere fact that public health is a legitimate policy objective from the perspective of the WTO (as reflected in Arts 7 and 8 and the Doha Declaration) means that [measures such as] plain packaging [are] justifiable as long as [they are] pursued to achieve that objective." *See* Tania Voon and Andrew Mitchell, *Face off: Assessing WTO Challenges to Australia's Scheme for Plain Tobacco Packaging*, supra at p. 17, paraphrasing Nuno Pires De Carvalho, *The TRIPS Regime of Trademarks and Designs*, supra at Sec. 20.12, p. 424.

GATT rationale…[such as those that are aimed]…at establishing disguised restrictions on trade…or that 'constitute a means of arbitrary […] discrimination between countries'" they would not be deemed 'justifiable'.[62]

In addition, such commentators argue that Article 20 does not require a demonstration of a cause and effect relationship "between the requirement and the 'just' goal pursued", as is required under the "necessary" standard employed in TRIPS Article 8.1.[63] In their view, "Article 20 does not require that the legitimate interests of owners be considered in its application, because it does not formulate any test of proportionality."[64] Consequently, TRIPS Article 20 would permit the imposition of special requirements that refer "to the size and colour of letters and characters", including those that "[r]educ[e] the size of trademarks on [product] packages to a minimum", and "to the inclusion of warnings and notices on the risks of consumption".[65] And, TRIPS Article 20 would also permit special requirements that "prohibit the use of [product]-related marks on different grounds (in order to reduce the goodwill associated to those marks and thus limit their power to induce consumption)…where justifiable (by public policy concerns)…even though it would be seriously detrimental to the (legitimate) interests of the trademark owners."[66]

Other legal commentators, meanwhile, construe TRIPS Article 20 within the broader context of TRIPS Article 8, the key function of which is commonly recognized as interpreting the object and purpose of the TRIPS Agreement.[67] Pursuant to this view, Article 8 "allow[s] WTO Members to take action to protect public health" or to prevent deceptive commercial practices, provided such action is "consistent with the provisions of th[e TRIPS] Agreement."[68] A more contextual approach to statutory interpretation would also be consonant with the *Vienna Convention on the Law of Treaties*.[69] It would read Article 8 consistent with not only the overall object and purpose of the TRIPS Agreement ("to reduce distortions and impediments to international trade…taking into account the need to promote effective and adequate protection of intellectual property rights"),[70] but also the TRIPS Agreement's relationship to other WTO Agreements and to non-WTO law.[71]

For example, TRIPS Article 8 would *not* likely serve as grounds for the application of any new exception available within another WTO Agreement to the extent it is inconsistent with the TRIPS Agreement[72] - e.g., an available GATT Article XX exception for conduct that would otherwise be

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62 *See* Nuno Pires De Carvalho, *The TRIPS Regime of Trademarks and Designs*, supra at Sec. 20.12.
63 *Id.*, at Sec. 20.20; Tania Voon and Andrew Mitchell, *Face off: Assessing WTO Challenges to Australia's Scheme for Plain Tobacco Packaging*, supra at pp. 17-18.
64 Nuno Pires De Carvalho, *The TRIPS Regime of Trademarks and Designs*, supra at Sec. 20.37.
65 *Id*.
66 *Id*.
67 *See* Susie Frankel and Daniel Gervais, *Plain Packaging and the Interpretation of the TRIPS Agreement*, supra at p. 45.
68 *Id*., at pp. 42-43. Thus, Article 8 is relied upon as providing "a clear rationale for exceptions allowed under the Agreement" and as preventing the creation of "broad new exceptions not foreseen under the Agreement." *Id*., at p. 43. According to advocates of this approach, "[i]t would be odd, as a matter of interpretation to read Article 8 as allowing exceptions that do not fit Article 17." *Id*., at p. 44.
69 See *Vienna Convention on the Law of Treaties*, done at Vienna, 23 May 1969, 1155 U.N.T.S. 331; 8 International Legal Materials 679.
70 TRIPS Preamble, par. 1.
71 *See* Susie Frankel and Daniel Gervais, *Plain Packaging and the Interpretation of the TRIPS Agreement*, supra at pp. 44-45.
72 *Id.,* at p. 44.

deemed to contravene the GATT Agreement.[73] "Article 8…[, nevertheless, would] allow[] the adoption of non-intellectual property measures…to promote what a WTO Member reasonably considers to be its public interest in vital sectors…*provided they are compatible with TRIPS*" (emphasis added).[74] In *United States - Section 211 Omnibus Appropriations Act of 1998*, the Appellate Body determined that it may be possible to refer to the jurisprudence underlying the provision of another WTO Agreement (e.g., GATT Article III:4) for purposes of interpreting similar language contained in a TRIPS provision (TRIPS Article 3.1).[75] This same logic should also apply with respect to TRIPS Article 8 and the provisions of other WTO Agreements containing similar language, provided the TRIPS Agreement's object and purpose are not undermined in the process.

Since TBT Article 2.2 and GATT Articles XX(b) and (d) use the term "necessary", as do TRIPS Articles 8.1 and 8.2,[76] TBT and/or GATT jurisprudence interpreting the meaning of that term should arguably inform the interpretation of the term "necessary" for purposes of TRIPS Article 8.[77] Recent TBT jurisprudence, however, reflects that the term "necessary" is construed differently for purposes of TBT Article 2.2 than it is for purposes of GATT Articles XX(b) and (d).[78] For example, in *US - Tuna II (Mexico)*, the Panel determined that, in the context of TBT Article 2.2, "the aspect of the measure to be justified as 'necessary' is its trade restrictiveness",[79] whereas, in the context of GATT Article

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73 The UNCTAD TRIPS Resource Book, for example, acknowledges that "TRIPS does not contain a general safeguard measure comparable to Article XX of the GATT 1994 or Article XIV of the GATS. For those other Multilateral Trade Agreements (MTAs), the necessity to protect human life or health may take priority over the generally applicable rules of the agreement, subject only to general principles of non-discrimination. Yet when it comes to intellectual property, the 'exceptions' are circumscribed with various procedural or compensatory encumbrances, making their use more difficult. Article 8.1 contains language similar to that of GATT Articles XX and GATS Article XIV, yet it demands consistency rather than tolerating inconsistency…A number of developing countries have suggested that Article 8.1 of the TRIPS Agreement might be made consistent with Article XX(b) of the GATT 1994 that permits exceptional measures that are otherwise inconsistent with the agreement. Although it is not clear whether the Council for TRIPS will consider this issue since it was at least partially addressed in the Doha Declaration, it is a potential agenda item." *See* UNCTAD-ICTSD, *Resource Book on TRIPS and Development*, supra at Sec. 7, pp. 132-133; fn. 293.

74 *See* Susie Frankel and Daniel Gervais, *Plain Packaging and the Interpretation of the TRIPS Agreement*, supra at p. 45.

75 *See* Appellate Body Report, *United States - Section 211 Omnibus Appropriations Act of 1998*, WT/DS176/AB/R (Jan. 2, 2002), at par. 242.

76 *See* Susie Frankel and Daniel Gervais, *Plain Packaging and the Interpretation of the TRIPS Agreement*, supra at p. 44 ("It must be borne in mind that both paragraphs require that the measure be necessary (art.8.2 uses 'needed')."). *Accord* Nuno Carvalho, *The TRIPS Regime of Antitrust and Undisclosed Information*, Kluwer Law International (2007) at Sec. 8.5, p. 106, available at: http://books.google.com/books?id=ROC-Ago0WDYC&pg=PA107&lpg=PA107&dq=carvalho+%2B+article+8.2+%2B+deceptive+practices&source=bl&ots=YgX9YFZxaN&sig=woHRNjFgSeKXEVf-fPlOz_-F-Ak&hl=en&sa=X&ei=SqXgUfLUFJSy4APitICYCw&ved=0CC0Q6AEwAQ#v=onepage&q=carvalho%20%2B%20article%208.2%20%2B%20deceptive%20practices&f=false ("[W]hile Article 8.1 uses the expression 'measures necessary', [Article] 8.2 says that 'measures […] may be needed'. The words 'necessary' and 'needed' are synonymous.").

77 "The meaning of 'necessary' under Article XX(d) of the GATT 1947…most likely applies in the context of Paragraphs 1 and 2 of Article 8 as well." *Id*., at p. 107.

78 *See, e.g.,* Appellate Body Report, *Definitive Safeguard Measure on Imports of Certain Dairy Products ("Korea – Various Measures on Beef")*, WT/DS98/AB/R (adopted Jan. 12,), at par. 161and Panel Report, *EC - Trademarks and Geographical Indications (US)*, supra at pars. 7.298-7.300 (discussing "a process of weighing and balancing a series of factors…[to determine] whether a measure which is not 'indispensable' may nevertheless be 'necessary' within the meaning of [GATT] Article[s] XX(b) and (d) – i.e., "whether a WTO-consistent alternative measure which the Member concerned could 'reasonably be expected to employ' is available, or whether a less WTO-inconsistent measure is 'reasonably available'", as employed by the Appellate Body in several cases).

79 Panel Report, *United States – Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products ("US-Tuna II (Mexico)"* WT/DS381/R (Sept. 15, 2011), at par. 7.460.

XX, it is "the necessity of the measure for the achievement of the objective" – i.e., "the necessity…of the measures themselves."[80]

Recent TBT jurisprudence has accorded relatively greater recognition to WTO Members' sovereign right to regulate in furtherance of legitimate policy objectives at their chosen level of protection provided technical regulations are not employed as unnecessary barriers to trade.[81] This would strongly suggest that the interpretation and application of the term "necessary" in such cases should govern the interpretation and application of the term "necessary for purposes of TRIPS Article 8. Therefore, while a WTO tribunal undertaking a TRIPS Article 20 analysis of a measure "would be unlikely to challenge a WTO Member's determination of its public interest," it could nevertheless "consider the adequacy of that measure in terms of its stated objectives and its compatibility with TRIPS"[82]Article 8.[83]

A TRIPS Article 20 analysis would thus arguably engender a WTO tribunal evaluating the legal obligation to justify a special requirement's encumbrance-ness similarly to the way it would evaluate the legal obligation to justify a technical regulation's trade-restrictiveness for purposes of TBT Article 2.2. To this end, the Appellate Body has ruled that, "[i]n the context of Article 2.2, the assessment of 'necessity' involves a relational analysis of the trade-restrictiveness of the technical regulation, the degree of contribution that it makes to the achievement of a legitimate objective, and the risks non-fulfillment would create…[A]ll these factors provide the basis for the determination of what is to be considered 'necessary' in the sense of Article 2.2 in a particular case."[84] It also noted that, "[i]n most cases, this would involve a comparison of the trade-restrictiveness and the degree of achievement of the objective by the measure at issue with that of possible alternative measures that may be reasonably available and less trade-restrictive (trademark-encumbering) than the challenged measure, taking account of the risks non-fulfillment would create."[85] This, in turn, would depend on the supporting evidence proffered.

Moreover, TRIPS Article 8 would best be construed in light of other non-WTO sources of international law. In the case of plain tobacco packaging measures, such sources would include the Framework Convention on Tobacco Control ("FCTC") and supporting guidelines.[86] Meanwhile, in the

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80 *Id*. According to the Appellate Body, "Article 2.2 does not prohibit measures that have any trade-restrictive effect"; rather, "Article 2.2 is…concerned with restrictions on international trade that exceed what is necessary to achieve the degree of contribution that a technical regulation makes to the achievement of a legitimate objective." Appellate Body Report, *United States — Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products ("US - Tuna II (Mexico)")* WT/DS381/AB/R (May 16, 2012), at par. 319.

81 "[T]he object and purpose of the TBT Agreement is to strike a balance between, on the one hand, the objective of trade liberalization and, on the other hand, Members' right to regulate." Appellate Body Report, *United States- Measures Affecting the Production and Sale of Clove Cigarettes ("US-Clove Cigarettes")* WT/DS406/AB/R (Apr. 4, 2012) at par. 174. "The language of the [TBT Agreement's] sixth recital expressly acknowledges that Members may take measures necessary for, inter alia, the protection of human life or health, provided that such measures 'are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination' or a 'disguised restriction on international trade' and are 'otherwise in accordance with the provisions of this Agreement'". *Id*., at par. 173.

82 *See* Susie Frankel and Daniel Gervais, *Plain Packaging and the Interpretation of the TRIPS Agreement*, supra at p. 43.

83 *Id.,* at pp. 43-44. According to Professor Gervais and other commentators, TRIPS Article 8 can be viewed as "part of the object and purpose of TRIPS". *Id*.

84 Appellate Body Report, *US - Tuna II (Mexico)* at par. 318.

85 *Id*., at par. 320.

86 *See* Susie Frankel and Daniel Gervais, *Plain Packaging and the Interpretation of the TRIPS Agreement*, supra at p. 44.

case of breastmilk substitute and breastmilk supplement marketing measures, such sources would include the WHO International Code of Marketing of Breastmilk Substitutes ("WHO Code"), and perhaps, the WHO *Global Strategy for Infant and Young Child Feeding* and other WHO recommendations and supporting resolutions. These non-WTO sources of international law could be referenced for purposes of defining the scope of "public health" risks, identifying the applicable public health standard as determined by international consensus, and assessing the available scientific or other evidence.[87] And, as at least one commentator has noted, these sources of non-WTO law would be employed only to interpret the terms of the TRIPS Agreement (here, Articles 8 and 20), and not to renegotiate them.[88]

Finally, these constraints apply equally to developing country WTO Members. As at least one commentator who favors a more permissive interpretation of TRIPS Article 20 has lamented,

"Although Article 8.1 can be interpreted broadly to promote the development goals of less-developed countries, the provision contains two major constraints. The first constraint concerns the necessity requirement…By limiting the flexibilities available in the TRIPS Agreement, this requirement threatens to impede the public policy goals of many less-developed countries. For example, without taking into account the language in Paragraph 4 of the Doha Declaration, Article 8 of the TRIPS Agreement does not allow member states to adopt any measures they deem useful to protect public health and nutrition. Rather, the provision states explicitly that they can only adopt measures that are necessary for those purposes. In fact, they may not even adopt measures that they *consider* necessary for those purposes…Even worse, the provision requires the measures to be consistent with the provisions of [the TRIPS] Agreement. This second constraint greatly erodes the pro-development aspect of Article 8" (emphasis in original).[89]

c. Applicable Burdens of Proof and Thresholds of Evidence for Establishing TRIPS Article 20 Justifiability

The Appellate Body has determined that the complaining or defending party in a WTO dispute "who asserts the affirmative of a particular claim or defense" bears the burden of proof.[90] "If that party adduces evidence sufficient to raise a presumption that what is claimed is true, the burden then shifts to the other party, who will fail unless it adduces sufficient evidence to rebut the presumption."[91] The WTO recently applied this approach to the multi-factor "necessity" test for evaluating the trade-restrictiveness of technical regulations under TBT Article 2.2.[92]

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87 *Id*., at p. 45.
88 *Id*.
89 *See* Peter Yu, *The Objectives and Principles of the TRIPS Agreement*, supra at pp. 1013-1014, referencing Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis* (Sweet & Maxwell Ltd, 2d ed. 2003), at pp. 121-122.
90 See *United States - Measure Affecting Imports of Woven Wool Shirts and Blouses from India* WT/DS33/AB/R (Apr. 25, 1997), at p. 14.
91 *Id*.
92 Appellate Body Report, *US - Tuna II (Mexico)* at par. 323; Appellate Body Report, *United States - Certain Country of Origin Labeling ('COOL') Requirements ("US-COOL")*, WT/DS384/AB/R, WT/DS386/AB/R (June 29, 2012), at par. 379. "With respect to the burden of proof in showing that a technical regulation is inconsistent with [TBT] Article 2.2, the complainant must prove its claim that the challenged measure creates an unnecessary obstacle to international trade. In order to make a prima facie case, the complainant must present evidence and arguments sufficient to establish that the challenged measure is more trade restrictive than necessary to achieve the contribution it makes to the legitimate objectives, taking account of the risks non-

Legal commentators have advised that this burden of proof framework should also be applied to the analogous multi-factor "necessity" test for evaluating the encumbrance-ness of special requirements under TRIPS Article 20, but in a manner that is consistent with TRIPS Article 8. In their view, while "[TRIPS] Article 8 is relevant in justifying a measure that affects intellectual property rights…(a) consistency with TRIPS must be established and (b) the party asserting the justification has the burden of proof."[93]

To recall, a TBT Article 2.2[94]-type multi-factor analysis must be performed to determine whether the PH BMS Framework's prohibitions and restrictions imposed on the use of trademarks, logos and brand names related to breastmilk substitute and breastmilk supplement products are "necessary" to protect public health consistent with TRIPS Article 8.1, and/or to prevent deceptive or anti-competitive practices consistent with TRIPS Article 8.2.[95] A measure found to be "necessary" for purposes of Article 8 should then be deemed to constitute a "justifiable" encumbrance within the meaning of TRIPS Article 20.

Recent TBT jurisprudence reflects that the burden of proof is on the complainant to show that a technical regulation is inconsistent with TBT Article 2.2. The complainant must make a *prima facie* case showing "that the challenged measure creates an unnecessary obstacle to international trade" by providing "evidence and arguments sufficient to establish that the challenged measure is more trade restrictive than necessary to achieve the contribution it makes to the legitimate objectives, taking account of the risks non-fulfillment would create."[96] "In making its *prima facie* case, a complainant may also seek to identify a possible alternative measure that is less trade restrictive, makes an equivalent contribution to the relevant objective, and is reasonably available."[97] Once the complainant has made a prima facie case, the respondent government must "rebut the complainant's prima facie case, by presenting evidence and arguments [i.e., a 'defense'] showing that the challenged measure is not more trade restrictive than necessary to achieve the contribution it makes toward the objective pursued and by demonstrating, for example, that the alternative measure identified by the complainant is not, in fact, 'reasonably available', is not less

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fulfilment would create. In making its prima facie case, a complainant may also seek to identify a possible alternative measure that is less trade restrictive, makes an equivalent contribution to the relevant objective, and is reasonably available. It is then for the respondent to rebut the complainant's prima facie case, by presenting evidence and arguments showing that the challenged measure is not more trade restrictive than necessary to achieve the contribution it makes toward the objective pursued and by demonstrating, for example, that the alternative measure identified by the complainant is not, in fact, 'reasonably available', is not less trade restrictive, or does not make an equivalent contribution to the achievement of the relevant legitimate objective." Appellate Body Report, *US - Tuna II (Mexico)* at par 323; Appellate Body Report, *US - COOL* at par. 379.

93 *See* Susie Frankel and Daniel Gervais, *Plain Packaging and the Interpretation of the TRIPS Agreement*, supra at p. 48.

94 TBT Article 2.2 includes the prevention of deceptive practices and the protection of human health or safety or animal or plant life or health as examples of legitimate policy objectives that WTO Members may freely pursue provided they do not adopt or apply measures that are more trade-restrictive than necessary to achieve those objectives. *See also* TBT Preamble, par. 6.

95 "Article 8.2 deals with measures aimed at preventing anti-competitive practices." *See* Nuno Carvalho, *The TRIPS Regime of Antitrust and Undisclosed Information*, supra at Sec. 8.7, fn. 187, p. 106. "[A] needed measure under Article 8.2 is the measure without which prevention of abuses cannot be achieved." *Id*., at p. 107.

96 Appellate Body Report, *US-Tuna II(Mexico)*, supra at par. 323, *citing* Appellate Body Report, *US - Wool Shirts and Blouses*, p. 14, DSR 1997:I, 323, at 335 and Appellate Body Report, *EC – Sardines*, pars. 277-280. *See also* Appellate Body Report, *US - COOL* at par. 379.

97 *Id*.

trade restrictive, or does not make an equivalent contribution to the achievement of the relevant legitimate objective."[98]

Since both TRIPS Article 8 and TBT Article 2.2 are "prohibitions"[99] rather than "exceptions", the burden of proof framework applicable for purposes of determining whether an encumbrance is "necessary" under Article 8, and thus, "justifiable" under TRIPS Article 20, will arguably be similar to that currently applicable to TBT Article 2.2.[100] Consequently, "the complaining party has the [prima facie] burden to establish that there is an encumbrance by special requirement" and "that the encumbrance is unjustified" within the meaning of TRIPS Article 20.[101] Once that burden has been satisfied, "the respondent [government] carries the [prima facie] burden to show that the encumbrance is justified."[102]

WTO panels consider the importance of the public interests at stake, the severity of the restrictions imposed, and the nature of the trademark owner's legitimate interests threatened when determining the threshold of evidence required to satisfy these burdens or proof. On the one hand, this would mean that "the higher the nature of the [public] interest," the greater the complainant's burden is likely to be, and "the more likely a measure is to be considered necessary"[103] within the meaning of Article 8. Thus, TRIPS Article 8 "would support the view that [protecting breastfeeding and preventing deceptive marketing practices] has high importance",[104] consistent with "the broad latitude" WTO members enjoy "in making (valid) public policy choices and decisions on how to implement them."[105] On the other hand, "the more trade restrictive a measure is" [or the more trademark-encumbering a special requirement is], "*the more evidence a party trying to justify the measure [special requirement] might be expected to have*, and the harder it might be to prove that alternative, less restrictive measures [special requirements] suggested by the complainant are inadequate" (emphasis added).[106] In addition, it is also likely that the evidentiary threshold a government will be required to meet in order to satisfy its *prima facie* burden will be influenced by the fact that "TRIPS (unlike GATT or GATS) contains obligations concerning *specific rights of individual right holders*, and specific boundaries on limitations [and] exceptions to such rights" (emphasis in original).[107]

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98 *Id*.

99 According to Professor Gervais, "Article 20 contains both an obligation (not to impose prohibited measures) but also the option of providing a justification." *See* Susie Frankel and Daniel Gervais, *Plain Packaging and the Interpretation of the TRIPS Agreement*, supra at p. 49.

100 The burden of proof framework applicable to a GATT Article XX multi-factor evaluation of the "necessity" of a measure that is not a technical regulation or standard, however, would not be suitable for purposes of TRIPS Articles 8 and 20. "Since GATT Article XX functions as a 'defense', the burden of proof is on the government to make "a prima facie case [by supplying sufficient evidence and arguments] showing that the measure is justified, [which may] vary according to what has to be proved". *See* World Trade Organization, "WTO Analytical Index - Guide to WTO Law and Practice" (June 2012), *GATT 1994 - General Agreement on Tariffs and Trade 1994, Interpretation and Application of Article XX*, at pars. 852-853, available at: http://www.wto.org/english/res_e/booksp_e/analytic_index_e/gatt1994_07_e.htm#fnt1161. Once that burden has been satisfied, the complainant must 'rebut that prima facie case' supported by sufficient evidence and arguments." *Id*.

101 *See* Susie Frankel and Daniel Gervais, *Plain Packaging and the Interpretation of the TRIPS Agreement*, supra at p. 49.

102 *Id*.

103 *Id*., at p. 46.

104 *Id.*

105 *Id*., p. 47.

106 *Id*., at pp. 46-47.

107 *Id*., at p. 47.

WTO jurisprudence, furthermore, indicates that the threshold of evidence a party must adduce to satisfy its *prima facie* burden with respect to a deceptive practices measure is "sufficient evidence",[108] while the threshold of evidence a party must adduce to satisfy its *prima facie* burden with respect to a public health measure is "sufficient scientific evidence".[109]

d. The PH BMS Framework Imposes Special Requirements That Encumber Trademark Use Under TRIPS Article 20

As previously discussed, the PH BMS Framework's primary objective is to protect public health via protection of breastfeeding and breastmilk. The PH BMS Framework's secondary objective of consumer protection endeavors to prevent breastmilk substitute and breastmilk supplement product advertising and labeling from misleading or otherwise confusing consumers so that they believe such products are equivalent or superior to breastfeeding and breastmilk, and/or are unable to discern and distinguish the proper use of each such product vis-à-vis the other when "medically indicated and only when necessary." [110]

To achieve these goals, Circular 2008-0006, Item VI.A.1(v) of the PH BMS Framework precludes the use on the principal panel of breastmilk substitute and breastmilk supplement product labels of a "brand name and/or trademark [of] any word or set of words that may be considered as nutritional, healthful, and superlative and other terms of similar import."[111] Such prohibition will thus adversely affect the use of BMS product word trademarks in two not necessarily mutually exclusive instances. First, the use of a trademark may be encumbered if the Philippine Department of Health ("PHDOH") determines that they constitute a prohibited "health claim" or "nutrition claim" under AO 2008-006, Item V.6-7, for which the terms "nutritional" and "healthful" serve as adjectives under Item IV,[112] and which are presumed to be potentially misleading and to undermine breastfeeding and breastmilk.[113] Second, trademark use may be encumbered if the PHDOH deems it a superlative which is presumed to be false or misleading and to undermine breastfeeding and breastmilk. Third, trademark use may be encumbered by virtue of Circular 2008-0006, ItemsV.3, which provides that "[a]ny information, whether in text or graphical form, which are not mentioned in these guidelines

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108 *See* Appellate Body Report, *US – Tuna II (Mexico)* at par. 323; Appellate Body Report, *US - COOL* at par. 379.

109 For example, in *EC-Asbestos*, the Panel concluded that its role in "taking into account the burden of proof, is to determine whether there is *sufficient scientific evidence* to conclude that there exists a risk for human life or health and that the measures taken by [the government of] France *are necessary in relation to the objectives pursued*" (emphasis added). *See* Panel Report, *European Communities – Measures Affecting Asbestos And Asbestos-Containing Products*, WT/DS135/AB/R (March 12, 2001), at par. 8.182. And, in *Clove Cigarettes*, the Panel concluded, that the WHO studies it had reviewed reflected "the best available scientific evidence", "show[ing] that the scientific community perceive cigarettes including additives that increase palatability…as having a characterizing flavour, as part of a same basket or category of cigarettes that attract consumers." *See* Panel Report, *United States - Measures Affecting the Production and Sale of Clove Cigarettes ("US-Clove Cigarettes")* WT/DS406/R (Sept. 2, 2011) at pars. 7.229-7.230, 7.414. The Panel ruled that there [was] extensive scientific evidence supporting the conclusion that banning clove and other flavoured cigarettes could contribute to reducing youth smoking." *Id.*, at par. 7.415.

110 *See* Lawrence A. Kogan, *The Philippines Breastmilk Substitute/Supplement Marketing Framework Violates WTO Law* (Part 1 of 2), LexisNexis 2013 Emerging Issues ("Part 1"), at Sec. III.3.b.ii.

111 Circular 2008-0006, Item VI.1.(v).

112 *Id.*, at Item IV, p. 4.

113 AO 2012-0027, Sec. 20.a.

may be a ground for the denial of the label applied for."[114] This vests the PHDOH with virtually unlimited and unaccountable authority to deny a breastmilk supplement product label depending on its subjective determination that a trademark, logo or brand name incorporated into the content, look or feel of a label will discourage or undermine breastfeeding.

The PHDOH September 2011 Memorandum reaffirmed and arguably broadened this non-use requirement. While it focused only on trademarks (as opposed to brand names that are not trademarks), the Memorandum effectively went beyond the term "superlative" in directing the Bureau of Food and Drugs/Food and Drug Administration ("BFAD/FDA"), when reviewing breastmilk substitute and breastmilk *supplement* product labels, "'not to allow any kind of trademarks that contain health and nutrition claims *or that may undermine breastfeeding and breastmilk* to be placed on the labels (Note that labels are marketing materials)'."[115] The 2011 Memorandum's imprecise language also implied that the BFAD/FDA possessed the authority to prohibit the use of validly registered trademarks and prevent the registration of applied-for and not-yet-applied-for trademarks falling within such parameters. The Philippine Department of Justice ("PHDOJ") Secretary Opinions No. 29 and 69, which are not considered "governmental measures" for purposes of this WTO review, did little to discount this expansive language with its general reference to non-registrable "deceptive or deceptively descriptive marks".[116] These PHDOJ opinions also raised questions concerning whether the PHDOH was poised to act beyond its authority and jurisdiction (*ultra vires*) by occupying the field of intellectual property law and procedure falling within the exclusive domain of the Philippine Intellectual Property Office, as provided for by the Philippine Intellectual Property Code (RA 8293), and thus, in contravention of TRIPS Article 15.

The PHDOH/Inter-Agency Committee ("IAC") September 2012 Memorandum clarified the meaning of the September 2011 Memorandum. It also extended the application of the 2011 Memorandum's labeling directive imposing such non-use requirement to all breastmilk substitute and breastmilk supplement "advertising, promotion or other marketing materials, whether written, audio or visual."[117] The 2012 Memorandum specifically mandated that the BFAD/FDA strictly enforce, with respect to all such materials, the prohibition against the *use of registered trademarks* (including trademarked brand names) on breastmilk substitute *and breastmilk supplement* product labels to make health and nutrition claims or to undermine breastfeeding or breastmilk.[118]

The September 2012 Memorandum refers to the amorphous standards set forth in Circular 2008-0006, Items V.3[119] and VI.A.1(v),[120] as well as, RIRR, Rule V Sections 13 and 15-17, which, presumably, will be employed for purposes of evaluating how and whether a trademark, alone, and/or in conjunction with other claims, could conceivably contain a health or nutrition claim, or

114 Circular 2008-0006, Item V.3.

115 *See* Republic of the Philippines Department of Justice, *Secretary Opinion No. 29, series 2012* (May 11, 2012), *supra* at pp. 2 and 5. *See also* Republic of the Philippines Department of Justice, *Secretary Opinion No. 69, series 2012* (Sept. 4, 2012), *supra* at p. 2.

116 *Id.*

117 *See* DOH Memorandum (Sept. 10, 2012), *supra*.

118 *Id.*

119 "Any information, whether in text or graphical form, which are not mentioned in these guidelines may be a ground for the denial of the label applied for." Circular 2008-0006, Item V.3.

120 "It shall be contrary to public policy to use as brand name and/or trademark any word or set of words that may be considered as nutritional, healthful, and superlative and other terms of similar support." Circular 2008-0006, Item VI.A.1(v).

otherwise undermine breastfeeding and breastmilk. However, it is uncertain whether the PHDOH can be relied upon to objectively evaluate whether such product word marks contain these types of claims based on the record(s) before it and the definitions set forth in the Codex Alimentarius Commission *Guidelines for Use of Nutrition and Health Claims* ("CAC/GL 23-1997"), as amended,[121] which it represents as having adopted.[122]

Circular 2008-0006, Item VI.A.1(v) and the September 2011 and 2012 PHDOH Memoranda constitute "special requirements" within the meaning of TRIPS Article 20 because they prescribe specific non-use requirements with respect to certain word marks of specific products (all breastmilk substitutes and breastmilk supplements (including infant formula, follow-up formula, other milk products, and liquid and solid complementary foods intended for infants and young children from 0-24 months of age) that are deemed to constitute specific types of claims: health claims, nutrition claims, and superlative and other claims that undermine breastfeeding or breastmilk. The effect of these special non-use requirements is to potentially, but significantly, reduce the visual or other impact of the chosen mark on consumers and therefore its distinctiveness, and to thereby substantially impede the ability of trademark owners and their licensees to distinguish such products from competing products in the Philippine marketplace, including counterfeit and substandard products.

In addition, AO 2012-0027, Section 14 provides that milk company, representative and agent donations of promotional items including products, equipment and materials "not otherwise falling within the scope of" the Milk Code or the RIRRs[123] shall contain "no name/no logo of the donating company nor brand names of covered products on the donated items."[124] This provision also constitutes a "special requirement" within the meaning of TRIPS Article 20. It prescribes specific non-use requirements for specific product-related intellectual property assets displayed or otherwise identified on or in connection with materials discussing specific categories of subject matter that serve to significantly restrict trademark owners' ability to distinguish their products and/or companies from competing companies and products in the Philippine marketplace.

e. The PH BMS Framework Unnecessarily/Unjustifiably Encumbers Foreign Trademark Owners' Legitimate Interests Under TRIPS Articles 8 and 20

As previously discussed in Part 1 of this analysis,[125] and in the immediately preceding section, the PH BMS Framework imposes broader-than-WHO Code restrictions and prohibitions on the use of proprietary trademarks, logos and brand names in infant formula, follow-up formula and

121 *See* Codex Alimentarius Commission, *Guidelines for Use of Nutrition and Health Claims*, ("CAC/GL 23-1997") (Adopted in 1997, Revised in 2004, Amended in 2001, 2008, 2009, 2010, 2011 and 2012), available at: www.codexalimentarius.org/input/download/standards/351/CXG_023e.pdf.

122 Circular 2008-0006, Item IV, p. 4.

123 RIRR, Rule VI Section 21 prohibits manufacturer, distributor or agent gifts of Milk Code-covered products "to any member of the general public, to hospitals and other health facilities…*without or without company name or logo or product or brand name*" (emphasis added).

124 AO 2012-0027, Sec. 14. AO 2012-0027, Section 14 goes beyond WHO Code Articles 4.3 and 6.8, which permits manufacturers to include their company names and logos on such items, but recommends that they not refer to proprietary products falling within the scope of the Code. *See* WHO Code Arts. 4.3, 6.8.

125 *See* Lawrence A. Kogan, *The Philippines Breastmilk Substitute/Supplement Marketing Framework Violates WTO Law* (Part 1 of 2), LexisNexis 2013 Emerging Issues ("Part 1"), at Sections III.2.c.v, III.3.b.iii.D.

complementary food product advertising, labeling and packaging. These encumbrances constitute special requirements within the meaning of TRIPS Article 20 that are arguably more trademark-encumbering, and thus, trade-restrictive than necessary to achieve the PH BMS Framework's policy objectives. To recall, the "necessity" or "justifiability" of a trademark-use encumbrance, within the meaning of TRIPS Articles 8 and 20, shall be assessed by comparing the encumbrance-ness of the special requirement, the degree to which said special requirement contributes to its underlying objective, and any reasonably available less trademark-use encumbering alternative, taking into account the risks non-fulfillment would create.

i. The Degree to Which PH BMS Framework's Trademark-Use Encumbrances Can Achieve its Objectives is Uncertain

Arguably, the trademark-use encumbering special requirements imposed by Circular 2008-0006, Item VI.A.1(v) and the 2011 and 2012 PHDOH Memoranda can be quite burdensome, even though the extent to which they are capable of contributing to the protection of breastfeeding and the prevention of deceptive advertising/marketing practices remains questionable.

A. Treating Trademark-Incorporating Puffery As False Or Misleading Statements Undermines Achievement of Objectives

First, it is difficult to see how the kind of one or two-word word marks, non-word marks (logos), or brand names not constituting a phrase or motto, identified by the PHDOH[126] as appearing on breastmilk substitute and breastmilk supplement product labels or in related advertising materials, could alone amount to a health or nutrition claim or to an otherwise false or misleading claim. This is especially true where such a mark, logo or brand name only generally and subjectively connotes nutritiousness or incorporates a superlative which, viewed by itself, under the U.S. Lanham Act[127] or the U.S. Federal Trade Commission Act ("FTC Act")[128] would constitute mere non-actionable "puffery."[129]

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126 In its September 2012 Memorandum to the BFAD/FDA, the PHDOH identified the following twelve word marks and/or logos as constituting health or nutrition claims or false or misleading claims that "should not be approved as brandname[s], among others: 1) Gentle[;] 2) A+[;] 3) Gold[;] 4) Grow[;] 5) H.A[.;] 6) Sensitive[;] 7) Bibo Trio[;] 8) Advance[;] 9) IQ[;] 10) Gain[;] 11), Vitaminized[;] and 12) Advance Formula[.]"*See* PHDOH Memorandum (Sept. 10, 2012), *supra*.

127 The PHDOH should review U.S. false advertising case law to see how courts have construed superlative product claims under Section 43(a) of the Federal Lanham Act (15 U.S.C. §§ 1051–1127 (2006), which precludes the making of false statements or representations in commercial advertising or promotion that are likely to deceive consumers and cause injury to the competitor plaintiff. While the Lanham Act provides competitors standing to sue (15 U.S.C. § 1125(a)(1)), it does not provide a private right of action to consumers. *Seven-Up Co. v. Coca-Cola Co.*, 86 F.3d 1379, 1383 n.5 (5th Cir. 1996); *Stanfield v. Osborne Indus., Inc.*, 52 F.3d 867, 873 (10th Cir. 1995); *Serbin v. Ziebart Int'l Corp.*, 11 F.3d 1163, 1177 (3d Cir. 1993); *Colligan v. Activities Club of New York, Ltd.*, 442 F.2d 686 (2d Cir. 1971).

128 *See* 15 U.S.C. §§ 45, 52, 55 (1980).

129 See *Edmundson v. The Procter & Gamble Co.*, 2013 WL 4035434 (9th Cir. Aug. 9, 2013), available at: http://cdn.ca9.uscourts.gov/datastore/memoranda/2013/08/09/11-56664.pdf. In *Edmunson*, a class action brought under California's Unfair Competition Law and Consumer Legal Remedies Act, the U.S. Court of Appeals for the Ninth Federal Circuit held that "[s]pecific, quantifiable 'statements of fact' that refer to a product's absolute characteristics may constitute false advertising, *while general, subjective, unverifiable claims are 'mere puffery' that cannot*" (emphasis added). *Id.*, at p.2 The Court found that "P&G's claim that the blades in Fusion Power cartridges 'have a patented blade coating for incredible comfort' is not a message that those cartridges are superior to Fusion Manual cartridges, and, in any event, *is non-actionable puffery because it is general, subjective, and cannot be tested*…[E]ven assuming P&G's advertising does convey the message that Fusion Power cartridges are generally superior to Fusion Manual cartridges, the advertising does not, contrary to Edmundson's

allegations, assert superiority in terms of the specific attributes of closeness, comfort, irritation and pressure. Rather, the packaging for Fusion Power cartridges says only that the blades in the cartridges 'have a patented bladed coating for incredible comfort; phrases such as 'less irritation,' 'more comfort' and 'reduce[d] pressure' are found on the packaging for all Fusion cartridges, and are a comparison between Fusion cartridges and P&G's 'MACH3' cartridges, not between Fusion Power and Fusion Manual cartridges. Similarly, nowhere does the packaging claim that Fusion Power blades are more comfortable 'vs. Fusion Manual' blades" (emphasis added). *Id*., at pp. 2-4. *See also* Advertising Self-Regulatory Council (ASRC), *NAD Determines Tropicana Ad is Puffery Following Campbell Challenge*, Press Release (July 30, 2013), available at: http://www.asrcreviews.org/2013/07/nad-determines-tropicana-ad-is-puffery-following-campbell-challenge/ ("The National Advertising Division has determined that the claim 'world's best fruit and vegetable juice,' included in broadcast advertising for Tropicana Products, Inc., is puffery. The claim was challenged by Campbell Soup Company, maker of V8 V-Fusion fruit/vegetable juice…The core issue for NAD was whether the challenged advertising communicated a claim that Tropicana Farmstand was superior to competing fruit-and-vegetable juices or whether the challenged claims constituted puffery. NAD noted in its decision that *a claim that a product is the world's 'best' may constitute puffery depending on the context in which it appears. 'If the use of the superlative is vague and fanciful and suggests no objective measure of superiority, then the claim is likely to be puffery. If, on the other hand, adjectives such as 'best' or 'greatest' are accompanied by specific attributes which are likely to suggest that product is comparatively 'better' in some recognizable or measurable way, the defense of 'puffery' is unlikely to prevail*. The issue for NAD was whether the juxtaposition of the claim with the reference to the 'cooler' and the simultaneous crashing down [on] the floor of other fruit and vegetable juices conveyed the message that other fruit and vegetable products are inferior…The challenger based its position, in part, on a consumer survey it had commissioned. However, NAD noted in its decision, when asked specifically asked about what the commercial communicated about 'other' products, only 19 respondents (5.2%) mentioned the challenger's product, V-8 (and only one of the 19 respondents believed that the commercial conveyed a superiority message over V-8)" (emphasis added). *Id*. *See* Tropicana Products, Inc., NAD Case Report No. 5610 (July 3, 2013), available at: http://case-report.bbb.org/search/search.aspx?doctype=2&casetype=1. See also *American Italian Pasta Co. v. New World Pasta Co.*, 371 F.3d 387, 390-391 (8th Cir. 2004), available at: http://media.ca8.uscourts.gov/opndir/04/06/032065P.pdf. In *Edmunson*, the Court of Appeals for the Eighth Federal Circuit held that American Italian Pasta Company's use of the phrase "America's Favorite Pasta", when construed together with the phrases "Quality Since 1867," "Made from 100% Semolina," and "Made with Semolina" also appearing on product packaging, constituted non-actionable puffery. The Court distinguished non-actionable puffery from "literally false factual commercial claims" and "literally true or ambiguous factual claims 'which implicitly convey a false impression or are likely to deceive consumers'", that are each actionable under Lanham Act section 43(a). According to the Court, "[p]uffery and statements of fact are mutually exclusive. If a statement is a specific, measurable claim or can be reasonably interpreted as being a factual claim, i.e., one capable of verification, the statement is one of fact. Conversely, if the statement is not specific and measurable, and cannot be reasonably interpreted as providing a benchmark by which the veracity of the statement can be ascertained, the statement constitutes puffery. *Defining puffery broadly provides advertisers and manufacturers considerable leeway to craft their statements, allowing the free market to hold advertisers and manufacturers accountable for their statements, ensuring vigorous competition, and protecting legitimate commercial speech*" (emphasis added). In *Pizza Hut, Inc. v. Papa John's Int'l, Inc.*, 227 F.3d 489, 497 (5th Cir. 2000), the U.S. Court of Appeals for the Fifth Federal Circuit held that "non-actionable 'puffery' comes in at least two possible forms: (1) an exaggerated, blustering, and boasting statement upon which no reasonable buyer would be justified in relying; or (2) a general claim of superiority over comparable products that is so vague that it can be understood as nothing more than a mere expression of opinion.'". In *Cook, Perkiss and Liehe, Inc. v. Northern Cal. Collection Serv., Inc.*, 911 F.2d 242, 246 (9th Cir. 1990), the U.S. Court of Appeals for the Ninth Federal Circuit held that "statements are non-actionable puffery where they constituted 'general assertions of superiority' rather than 'factual misrepresentations'". Similarly, in *Tylka v. Gerber Prods. Co.*, No. 96-1647, 1999 WL 495126, at *8 (N.D. Ill. July 1, 1999), the federal district court held that, "claims that Gerber's baby food was the 'most nutritious' available were 'meaningless sales patter' because they were general, vague, and all-encompassing". And, in *Gillette Co. v. Norelco Consumer Prods. Co.*, 946 F. Supp. 115, 131 (D. Mass. 1996), the federal district court found that "exaggerations about pain from using competitor's razor were puffery". In addition, in *Am. Express Travel Related Servs. Co. v. MasterCard Int'l Inc.*, 776 F. Supp. 787, 790 (S.D.N.Y. 1991), the federal district court found "that exaggerations about [the] difficulty of finding an ATM machine that accepted competitor's bank card were puffery." *See* Rebecca Tushnet, *Running the Gamut from A to B: Federal Trademark and False Advertising Law*, 159 U. Penn. L. Rev. 1305, 1338 (2011) at fn# 130, available at: http://scholarship.law.georgetown.edu/cgi/viewcontent.cgi?article=1629&context=facpub. *See also* Balough Law Offices, LLC, *USPTO Finds Dunkin' Donuts Slogan Mere Puffery* (11/27/12), available at: http://www.jdsupra.com/legalnews/uspto-finds-dunkin-donuts-slogan-mere-p-49924/ ("Dunkin' Donuts may claim it has the 'Best Coffee in America' but the U.S. Patent and Trademark Office (USPTO) found the phrase was mere "puffery" and had not acquired a secondary meaning sufficient to be registered [as a trademark] on the principal register."). *Id*.

U.S. Lanham Act Section 43(a) jurisprudence reflects disputes between marketplace *competitors* and considers *consumer* rather than *regulator* perceptions of what is "false or misleading" solely to ensure fair competition. It is relevant for purposes of this analysis because "[t]he Philippine Trademark Law…amended by Republic Act No. 8293 otherwise known as the Intellectual Property Code of the Philippines, *which is of American origin*, contains provisions [including Section 169.1[130]] *similar to those of the United States Lanham Act*" (emphasis added).[131] Consistent with such jurisprudence, in order to find a particular BMS product trademark, logo or brand name otherwise constituting non-actionable puffery actionable, the PHDOH would need to affirmatively find that ordinary consumers would likely construe said word mark, logo or brand name, in its contextual setting, together with a separate statement(s) appearing on BMS product labeling, packaging and/or in related advertising materials, as conveying a factually false or misleading/misrepresentative health or nutrition claim(s).[132]

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130 *See* Augusto Bundang, *It's a Knockout! Publicity Rights in the Philippines*, World Intellectual Property Review (10/1/12), available at: http://www.worldipreview.com/article/it-s-a-knockout-publicity-rights-in-the-philippines ("[T]he case of *Andres Sanchez v Honorable Judge Ramon Paul Hernando, Emmanuel Pacquiao and the Office of the City Prosecutor of Quezon City*, decided on July 7, 2009…started when Emmanuel Pacquiao, the Philippine boxing icon and eight-time world champion, initiated a criminal suit for violation of Section 169.1 in relation to Section 170 of the Intellectual Property Code of the Philippines (IP Code)…The case was filed against Sanchez who sought to quash it. The trial court denied the move of Sanchez and ruled that the 'image rights' pertaining to a public figure are protected in *Section 169.1 of the IP Code which mirrors the US Lanham Act* (emphasis added)." *Id*.

131 See *Parallel Importation or Exclusive Distributorship*, APEC Competition Policy and Law Database (12/17/03), available at: http://www.apeccp.org.tw/doc/Philippines/Case/phcas05.htm.

132 *See* Al Lewis, *Kellogg Co. Meets a Cereal Litigator, Mr. Blood - Commentary: Lawyer Polices Thin Line Between Puffery and Lies*, Marketwatch, (May 31, 2013), available at: http://www.marketwatch.com/story/kellogg-co-meets-a-cereal-litigator-mr-blood-2013-05-31 ("'Eating a bowl of Kellogg's Frosted Mini-Wheats cereal for breakfast is clinically shown to improve attentiveness by nearly 20%,' The Kellogg Co. once advertised. The iconic cereal maker from Battle Creek, Mich. has agreed to set up a $4 million fund to reimburse consumers who purchased Frosted Mini-Wheats between Jan. 28, 2008, and Oct. 1, 2009, believing, perhaps, that this dubious claim is true…But cereal companies have always thrived upon over-the-top marketing claims…These sorts of claims amount to puffery and puffery is perfectly permissible under advertising laws. *Where Kellogg went wrong was in making a very specific claim - 20% better attentiveness - that can't be backed up, and that reasonable people might believe*, Mr. Blood said" (emphasis added)). Similarly, in *Williams v. Gerber Products Co.*, 552 F.3d 934 (9th Cir. 2008), the Appellate Court for the Ninth Federal Circuit held that, although "Gerber's *claim that Snacks is 'nutritious,' were it standing on its own, could arguably constitute puffery, since nutritiousness can be difficult to measure concretely*", (emphasis added), said claim was deceptive when combined with "a number of features of the packaging Gerber used for its Fruit Juice Snacks product which could likely deceive a reasonable consumer…This statement certainly contributes, however, to the deceptive context of the packaging as a whole." *Id*., at 939, 941 fn#3. *See also* Federal Trade Commission, Concurring Statement of Commissioner J. Thomas Rosch, *In the Matter of POM Wonderful*, Docket No. 9344 (Jan. 10, 2013), available at: http://www.ftc.gov/os/adjpro/d9344/130116pomroschstatement.pdf ("I would agree that *if POM's ads simply made health claims, standing alone, they could not properly be challenged as false or deceptive*. But they do not stand alone. In some instances the alleged health claim is expressly linked to a claim that the POM products treat, prevent or reduce the risk of heart disease or prostate cancer. *The link between POM and the treatment, prevention or reduction of risk of those very serious diseases is at least implicit in many other instances*. Those express and implicit links *create a net impression that the highest possible level of substantiation exists for the POM product being advertised*, and that claim is false") (emphasis added). *Id*., at JTR-2; *See also* United Kingdom Advertising Standards Agency (ASA), *ASA Adjudication on POM Wonderful LLC* (April 8, 2009), available at: http://www.asa.org.uk/Rulings/Adjudications/2009/4/POM-Wonderful-LLC/TF_ADJ_46101.aspx (The UK ASA found that, "Although…immortality was *one interpretation of the claim 'Cheat death' we were concerned that it could also be interpreted, especially when read in conjunction with the claim 'The antioxidant power of pomegranate juice', as meaning that pomegranate juice contributed in some way to a longer life*. We noted complainants had stated both interpretations. We concluded that the claim was ambiguous and if read as a health claim, rather than an obvious untruth, it was capable of objective substantiation. We considered the evidence submitted by POM Wonderful to support the antioxidant benefits of pomegranate juice but concluded that it fell short of showing any direct relation between consuming the product and a longer life. *Although, we noted there was no intention to mislead or to make an objective claim about longer life we concluded that the claim 'Cheat death' was misleading*") (emphasis added). *Id*; Abhishek K. Gurnani and Ashish R. Talati, *"The World's Most*

USFTC jurisprudence, meanwhile, reflects U.S. regulator efforts, pursuant to Sections 5, 12 and 15 of the FTC Act, to protect *consumers* against unfair or deceptive industry practices, including false or misleading food product advertisements and promotional activities that can materially affect their decision making in the marketplace.[133] It is relevant for purposes of this analysis because it explains how a robust regulatory evaluation may be undertaken to distinguish actionable false or misleading statements from non-actionable "puffery" to maintain a balance between consumer protection, commercial free speech and free markets (trade). According to the *FTC Policy Statement on Deception* ("FTC Deception Statement"), the USFTC will primarily consider: 1) whether there is "a representation, omission or practice that is likely to mislead the consumer"; 2) "the practice from the perspective of a consumer acting reasonably in the circumstance"; and 3) the materiality of "the representation, omission, or practice."[134]

The USFTC has stated that it "will not pursue cases involving obviously exaggerated or puffing representations, i.e., those that the *ordinary* consumers do not take seriously", while acknowledging that "[s]ome exaggerated claims…may be taken seriously by consumers and are actionable" (emphasis added).[135] In distinguishing between cases of non-actionable puffery and actionable false or misleading statements, the USFTC employs the "reasonable consumer" standard. "The test is whether the consumer's interpretation or reaction is reasonable...in light of the claim."[136] Although "a company is not liable for every interpretation or action by a consumer",[137] it will be held liable for a "reasonable" interpretation of its "material" statements or practices, "even [if]…not shared by a majority of consumers in the relevant class, or by particularly sophisticated consumers. A material practice that misleads a significant minority of reasonable consumers is deceptive."[138] "When a seller's representation conveys more than one meaning to reasonable consumers, one of which is false, the seller is liable for the misleading interpretation. An

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Trusted Article on Puffery": Non-Actionable Puffery or Misleading?, Food and Drug Law Institute, Update Magazine Issue 6 (2008), available at: http://www.americanbar.org/content/dam/aba/administrative/litigation/materials/2012_food_supplements_2nd_annual_clewrkshp/2012_aba_panel3_the_worlds_most_trusted.authcheckdam.pdf (discussing how the National Advertising Division (NAD) of the Council of Better Business Bureau had determined that, "Pom Wonderful's (Pom) use of several claims for their new line of juices [,including] "Cheat Death," "Life Preserver," "Outlive Your Spouse," [and] "Life Guard"…in efforts to project a healthy image for their new beverage product…[when used] independently may constitute non-actionable puffery [, but]…when combined with a statement describing the horrors of cancer, such claims would mislead consumers as to the relation between the marketed product and the treatment and/or prevention of cancer.") *Id*., at p. 43.

133 "Section 5 of the FTC Act declares unfair or deceptive acts or practices unlawful. Section 12 specifically prohibits false ads likely to induce the purchase of food, drugs, devices or cosmetics. Section 15 defines a false ad for purposes of Section 12 as one which is 'misleading in a material respect.'" See *Federal Trade Commission Policy Statement on Deception*, 103 F.T.C. 174 (1984), appended to Cliffdale Assoc. Inc., 103 F.T.C. 110 (1984), available at: http://www.ftc.gov/bcp/policystmt/ad-decept.htm.

134 *Id*., at p. 2.

135 *Id*., at p. , citing *Pfizer, Inc*, 81 F.T.C. 23, 64 (1972) ("[T]here is a category of advertising themes, in the nature of puffing or other hyperbole, which do not amount to the type of affirmative product claims for which either the Commission or the consumer would expect documentation."). *Id.* "The term 'Puffing' refers generally to an expression of opinion not made as a representation of fact. A seller has some latitude in puffing his goods, but he is not authorized to misrepresent them or to assign to them benefits they do not possess [cite omitted]. Statements made for the purpose of deceiving prospective purchasers cannot properly be characterized as mere puffing. Wilmington Chemical, 69 F.T.C. 828, 865 (1966)." *Id.*

136 *Id*., citing *Heinz W. Kirchner*, 63 F.T.C. 1282 (1963). See also *National Dynamics*, 82 F.T.C. 488, 524, 548 (1973), *aff'd*, 492 P.2d 1333 (2d Cir.), *cert. denied*, 419 U.S. 993 (1974), *reissued* 85 F.T.C. 39-1 (1976).

137 FTC Deception Statement.

138 *Id.*

interpretation will be presumed reasonable if it is the one the respondent intended to convey."[139] Where advertising representations or promotional practices target a specific audience, the USFTC will determine "the effect of the [representation or] practice on a reasonable member of that group."[140]

As the trier of fact, the USFTC will consider all evidence to determine "how reasonable consumers are likely to respond." This includes an evaluation of "the entire advertisement, transaction, or course of dealing"[141] – i.e., "the totality of the ad or the practice" to discern the clarity of the representation, the conspicuousness of any qualifying information, the importance of any omitted information, other sources of omitted information, and the familiarity of the public with the product or service.[142] A representation or practice will be deemed "material" if it "is likely to affect a [reasonable] consumer's choice of or conduct regarding a product."[143]

Unlike the balanced approach generally taken by U.S. courts and regulators, the Philippine BMS Framework's reference to the "total effect" of breastmilk substitute and breastmilk supplement product advertising or labeling, including the use of incorporated trademarks, logos and brand names, seemingly goes beyond preventing objectively false or misleading (deceptive) statements that could materially affect a reasonable consumer's decision to discontinue breastfeeding. It constitutes a heavy-handed regulatory approach that also precludes otherwise non-actionable puffing statements that reasonable consumers (ordinary commercially educated/literate pregnant women, mothers, and caregivers), under the circumstances, would not believe.

To recall, RIRR, Rule V Section 13 and AO 2012-0027, Section 19.1.6 state that "the 'total effect' should not directly or indirectly suggest that buying their product would produce better individuals, or result[] in greater lover, intelligence, ability, harmony or in any manner bring better health to the baby or other such exaggerated and unsubstantiated claim."[144] In addition, AO 2008-006, Item VI.A.1.v precludes the use of word marks that may be considered "superlative" on BMS product labels. These regulatory instruments do not accept the "central assumption underlying the defense of puffery…that consumers 'get it'…[i.e., that]…ordinary consumers will not believe that a widget marketed as the 'Best Widget in the World' really is the best widget on the planet", and thus, that consumers "can be expected to distinguish between those advertising claims of fact and those of (obviously exaggerated fiction."[145]

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139 *Id*. "A secondary message understood by reasonable consumers is actionable if deceptive even though the primary message is accurate. *Sears, Roebuck & Co.*, 95 F.T.C. 406, 511 (1980), aff'd 676 F.2d 385, (9th Cir. 1982); Chrysler, 87 F.T.C. 749 (1976), aff'd, 561 F.2d 357 (D.C. Cir.), reissued 90 F.T.C. 606 (1977); *Rhodes Pharmacal Co.*, 208 F.2d 382, 387 (7th Cir. 1953), aff'd, 348 U.S. 940 (1955)." *Id*. See also "*National Comm'n on Egg Nutrition*, 88 F.T.C. 89, 185 (1976), enforced in part, 570 F.2d 157 (7th Cir. 1977); Jay Norris Corp., 91 F.T.C. 751, 836 (1978), aff'd, 598 F.2d 1244 (2d Cir. 1979)." *Id*.

140 FTC Deception Statement.

141 *Id*.

142 *Id*.

143 *Id*.

144 RIRR, Rule V Sec. 13; AO 2012-0027, Sections 19.1.6.

145 *See* Victor F. DeFrancis, *Remembrance of Things Pasta: the Eighth Circuit Addresses Puffery*, American Bar Association Consumer Protection Update, Vol. 12 No. 1 (Fall 2004), at p. 10, available at: http://www.ftc.gov/bcp/scofflaw/documents/annual_reilly.pdf.

Rather, the PH BMS Framework arguably presumes that "[s]uperlatives in advertising are rife with significance – implying first in sheer number, percentage, or place in a series", that "[m]ost superlative terms are not as ambiguous as terms such as 'easy' 'amazing,' 'prime,' 'wonderful,' 'excellent' – all of which [U.S.] courts have explicitly recognized as obvious puffery,"[146] *and* that "'defining puffery broadly' to provide clarity to advertisers and manufacturers actually creates uncertainty for consumers".[147] It also generally presumes that Filipino consumers are unable to distinguish puffery from false or misleading statements. In other words, the PH BMS Framework administratively presumes that average Filipino consumers (pregnant women, mothers and caregivers) are not adequately informed, not commercially savvy, and not capable of making reasonable and rational decisions with respect to such products. However, by employing an overbroad paternalistic approach to compensate for such deemed incapacities that is likely to result in many false positives, the PH BMS Framework is unlikely to fully achieve its objective of preventing truly deceptive advertising and labeling that undermines breastfeeding.

B. Banning Inferred Implied Trademark-Incorporating Nutrition And Health Claims Undermines Achievement of Objectives

Second, even if a word mark, non-word mark logo or brand name could be construed together with other statements appearing on/in BMS product labeling, packaging and advertising materials as making an implied health or nutrition claim, the PH BMS Framework prevents such an analysis because it precludes health and nutrition claims altogether, based on the presumption they are always "potentially misleading".[148] This approach denies foreign BMS product companies their constitutionally protected right to substantive and procedural due process of law which would entitle them to a hearing and the opportunity to scientifically substantiate such claims.[149] It also

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146 *Id*., at p. 12.

147 *Id*.

148 AO 2012-0027, Sec. 20.a.

149 Section 1 of Article III (of the Bill of Rights) of the 1987 Philippine Constitution states that, "No person shall be deprived of life, liberty, or property without due process of law, nor shall any person be denied the equal protection of the laws." *See* 1987 CONSTITUTION OF THE REPUBLIC OF THE PHILIPPINES, available at: http://www.lawphil.net/consti/cons1987.html. *See* Supreme Court of the Philippines, *Concurring Opinion of Associate Justice Brion*, in *Felix B. Perez and Amante G. Doria v. Philippine Telegraph and Telephone Company and Jose Luis Santiago*, G.R. No. 152048 (April 2009), available at: http://sc.judiciary.gov.ph/jurisprudence/2009/april2009/152048-brion.htm ("At its most basic, procedural due process is about fairness in the mode of procedure to be followed. It is not a novel concept, but one that traces its roots in the common law principle of natural justice…In the U.S., the due process clause of the U.S. Constitution provides the guarantee for procedural due process, and has used a general balancing formula to identify the procedural guarantees appropriate to a particular context…*Article III, Section 1 of the Philippine Constitution contains the constitutional guarantee against denial of due process, and is a direct transplant from an American root – the Bill of Rights of the American Constitution*") (emphasis added). *Id*; Supreme Court of the Philippines, *Separate Concurring Opinion of Associate Justice Carpio* in *Antonio M. Serrano v. Gallant Maritime Services, Inc. and Marlow Navigation Co., Inc.*, G.R. No. 167614 (March 2009), available at: http://sc.judiciary.gov.ph/jurisprudence/2009/march2009/167614-carpio.htm ("Section 1, Article III, of the Constitution states that no person shall be deprived of property without due process of law…The right to property is not absolute - the prohibition against deprivation of property is qualified by the phrase 'without due process of law.' Thus, *the State may deprive persons of property through the exercise of police power. However, the deprivation must be done with due process*. Substantive due process requires that the means employed in depriving persons of property must not be unduly oppressive…*Moreover, the exercise of police power, to be valid, must be reasonable and not repugnant to the Constitution"*) (emphasis added). *Id*. *See also* Marcelino C. Maxino, *Due Process Clause Does Not Apply - A Running Commentary on the Impeachment Trial*, The Negros Chronicle (Feb. 19, 2012), available at: http://www.negroschronicle.com/web-archives/opinion/Due%20Process%20Clause%20Does%20Not%20Apply.html ("The Due Process Clause of the 1987 Constitution is a reproduction of the Due Process Clause of the 1935 Constitution, *which, in turn, was lifted from the Fifth Amendment to the*

arguably blurs the distinct legal standards used by and jurisdictional lines existing between the IAC, the PHDOH and the BFAD/FDA as set forth in the Milk Code,[150] and the BFAD/FDA-dominated IAC Secretariat established by the IAC pursuant to AO 2012-0027,[151] as previously discussed.[152] In other words, it empowers the PH DOH to overreach and dominate both the BMS product advertising and labeling regulatory review processes on ostensible public health grounds. It also effectively denies PH anti-competition (DOJ/DTI) and commercial trade (DTI) regulators the opportunity to gain the expertise necessary to prevent truly deceptive and/or anticompetitive advertising and labeling practices cast in the form of false or misleading trademark-incorporating nutrition or health claims, or superlatives, which arguably poses a long-term risk to Filipino consumers.

Such regulatory overreach is not limited to the Philippines, however. As the result of the USFTC's very recent decision in *In Matter of Pom Wonderful, LLC*,[153] U.S. legal and industry commentators have accused that agency of a not too dissimilar regulatory "power grab". Apparently, the USFTC reached its determination that marketers of respondent's "100% Pomegranate Juice and POMx supplements deceptively advertised their products and did not have adequate support for claims that the products could treat, prevent, or reduce the risk of heart disease, prostate cancer, and erectile dysfunction",[154] by relying on its own subjective judgment ("net impressions")[155] rather than upon objective extrinsic evidence of consumer perceptions - how consumers actually interpreted the product advertising materials and label in question.[156]

United States Constitution. It is a cardinal rule of statutory construction that when one jurisdiction borrows a provision of law from another jurisdiction, it borrows not only the text of the law but also the meaning attached to that text by the jurisdiction of origin. Furthermore, the borrowing jurisdiction is presumed to know the meaning of the provision as interpreted by the courts of the jurisdiction of origin") (emphasis added).

150 Milk Code Sec. 12.

151 *See* AO 2012-0027, Sec. 5. "The Food and Drugs Administration (FDA) is duly designated as the Secretariat of the IAC." *Id*. *See also* RIRR, Rule V, Sec. 12. Although "[t]he…(IAC) shall review all advertising, promotion or other marketing materials…[t]he [PH]DOH based on the latest scientific information and products may modify the messages, provided that wide dissemination of the message to all concerned is ensured." *Id*. *See also* Lawrence A. Kogan, *The Philippines Breastmilk Substitute/Supplement Marketing Framework Violates WTO Law* (Part 1 of 2), LexisNexis 2013 Emerging Issues ("Part 1"), at Sec. III.3.b.iii.C.II.

152 *Id.,* at Sec. III.3.b.iii.C.II.

153 See United States Federal Trade Commission, *In the Matter of Pom Wonderful LLC*, Docket No. 9344, Opinion of the Commission (Jan. 10, 2013), available at: http://www.ftc.gov/os/adjpro/d9344/130116pomopinion.pdf.

154 *See* United States Federal Trade Commission, *FTC Commissioners Uphold Trial Judge Decision that POM Wonderful, LLC; Stewart and Lynda Resnick; Others Deceptively Advertised Pomegranate Products by Making Unsupported Health Claims*, Press Release (1/16/13), available at: http://www.ftc.gov/opa/2013/01/pom.shtm.

155 "It is well established that the Commission has the common sense and expertise to determine 'what claims, including implied ones, are conveyed in a challenged advertisement, so long as those claims are reasonably clear'. *Kraft, Inc.*, 970 F.2d at 319; accord *FTC v. Colgate Palmolive Co.*, 380 U.S. 374, 391-92 (1965)…*Extrinsic evidence is unnecessary to establish the impression that consumers would take away from an ad if the claims are reasonably clear from the face of the advertisement*. *Kraft Inc.*, 970 F.2d at 319 (holding that 'the Commission may rely on its own reasoned analysis to determine what claims, including implied ones, are conveyed in a challenged ad, so long as those claims are reasonably clear from the face of the advertisement'") (emphasis added). *Id*., at pp. 7-8.

156 *See* Alliance for Natural Health, *FTC Proceeds with Raw Power Grab on Health Claims—In Effect Thumbing Its Nose at Congress* (Jan. 22, 2013), available at: http://www.anh-usa.org/ftc-proceeds-with-raw-power-grab-on-health-claims/ ("The FTC is being draconian about what it considers an implied disease claim. One commissioner noted in remarks accompanying the decision: 'It is difficult to imagine any structure/function claims that POM could associate with its products in the marketplace without such claims being interpreted, under the FTC precedent set in this case, as disease-related claims.' *In making these judgments, the agency has relied on what is legally called its own 'net impression,' i.e., totally subjective judgment, and has ignored the ALJ's request for a higher standard of "extrinsic evidence," the sort of evidence that would come for example by testing how consumers actually interpret a label*" (emphasis added). *Id*.

As one USFTC Commissioner observed, the USFTC employed its own agency standard for substantiating structure/function claims in lieu of the more rigorous USFDA standard for substantiating express or implied health and qualified health claims, and thereby blurred the distinct congressionally established legal standards and jurisdictional lines[157] existing between the USFTC and the USFDA.[158] In this Commissioner's view, such an approach permitted the USFTC to conclude that "the mere mention of 'health' or healthy functioning can imply a disease-related efficacy (i.e., a health claim in FDA terms) and that the mere mention of scientific evidence can imply a related establishment claim" (which presumably would not be possible under the USFDA standard).[159] Legal and industry commentators also alleged that the USFTC used this approach to effectively place "a gag order" on food manufacturers preventing them from "talk[ing] about health benefits, period" which infringed their right commercial free speech.[160] The similarities between the

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157 *See* United States Federal Trade Commission, *Enforcement Policy Statement on Food Advertising* (May 1994), at Introduction, available at: http://www.ftc.gov/bcp/policystmt/ad-food.shtm#Health ("The FTC, FDA, and USDA share jurisdiction over claims made by manufacturers of food products pursuant to a regulatory scheme established by Congress through complementary statutes. Section 5 of the Federal Trade Commission Act…prohibits 'unfair or deceptive acts or practices,' and, in the case of food products, Sections 12 and 15 of the FTC Act prohibit 'any false advertisement' that is 'misleading in a material respect.' FDA's authority is embodied in part in Section 403(a) of the Federal Food, Drug, and Cosmetic Act (FDCA) which prohibits 'labeling [that] is false or misleading in any particular.' Since 1954, the FTC and the FDA have operated under a Memorandum of Understanding,5 under which the Commission has assumed primary responsibility for regulating food advertising, while FDA has taken primary responsibility for regulating food labeling"). *Id*.

158 *See* Federal Trade Commission, Concurring Statement of Commissioner Maureen K. Ohlhausen, *In the Matter of POM Wonderful*, Docket No. 9344 (Jan. 10, 2013), at MKO-3, available at: http://www.ftc.gov/os/adjpro/d9344/130116pomohlhausenstatement.pdf. ("In particular, Congress and the Food and Drug Administration have created carefully drawn boundaries between different types of claims regarding the effect of food and dietary supplement products on nutrition and health. FDA regulations distinguish between various categories of claims that may be associated with food products and dietary supplements –including "qualified health claims," "health claims," and "structure/function" claims – and the level of substantiation required for each category of claim. According to FDA guidance, health claims and qualified health claims expressly or by implication characterize the relationship of a substance to a disease (e.g., heart disease) or health-related condition (e.g., high blood pressure). By contrast, structure/function claims describe the effect that a substance has on the structure or function of the body for maintenance of good health and nutrition but do not make reference to a disease. *The FDA imposes different and more stringent requirements on health claims than it does on structure/function claims*" (emphasis added)). *Id*.

159 *See* Federal Trade Commission, Concurring Statement of Commissioner Maureen K. Ohlhausen, *In the Matter of POM Wonderful*, Docket No. 9344 (Jan. 10, 2013), at MKO-3, available at: http://www.ftc.gov/os/adjpro/d9344/130116pomohlhausenstatement.pdf. "[T]he Commission too easily f[ound] implied disease efficacy or establishment claims in advertisements for foods, absent extrinsic evidence…[which]…may tend to undermine an important balance that is struck in the regulation of food, supplement, and drug advertising under the FTC Act and other federal laws...*I am concerned that the majority's interpretation of certain exhibits blurs these boundaries and creates an inconsistency between FTC advertising requirements and FDA food labeling and advertising requirements by concluding that the mere mention of 'health' or healthy functioning can imply a disease-related efficacy (i.e., a health claim in FDA terms) and that the mere mention of scientific evidence can imply a related establishment claim*" (emphasis added). *Id*., at MKO-2 and MKO-3.

160 *See* Alliance for Natural Health, *FTC Proceeds with Raw Power Grab on Health Claims—In Effect Thumbing Its Nose at Congress* (Jan. 22, 2013), *supra* ("The full Commission further ruled that a double-blind random-controlled trial (RCT) is required for any 'efficacy' claim and two double blind RCTs for any claim that might seem to be related to a disease. The $35 million on peer-reviewed scientific research previously spent by POM was brushed aside because the studies were not RCTs, which are commonly used for drug testing…*The agency is…requiring the hugely expensive pharmaceutical standard of the double-blind RCTs. As we have often noted, companies do not usually attempt RCTs because of their expense, unless they hold a patent on the substance being tested. And it is not possible to patent natural substances such as food. The FTC understands this. In effect, they are saying that food manufacturers will not be allowed to talk about health benefits, period. It is a complete gag order. The ruling also blurs the line between the FTC and the FDA. The double-blind RCT for disease claims is an FDA labeling standard for drugs. The FTC is supposed to regulate advertising, not decide what is a drug*. Its mandate is to ensure that advertisements are not deceptive or misleading—something that certainly does not require the pharmaceutical RTC standard! Now the FTC is unnecessarily and arbitrarily deciding to use an FDA drug standard for disease claims in advertising") (emphasis added). *Id*.

UFTC's recent exercise of authority in the *Pom* case and the broad discretion the PHDOH and its BFAD/FDA possess to undertake BMS product advertising and label reviews should not be ignored or underestimated. They strongly suggest the PHDOH will endeavor to infer implied health claims from as many infant formula, follow-up formula and/or complementary food product labels and advertising materials incorporating trademarks, logos and brand names as is possible.[161] Unfortunately, Filipino consumers, like U.S. consumers, will be none the wiser for it.

Indeed, this kind of treatment arguably amounts to "health information censorship" that undermines Philippine public policy goals by denying Filipino consumers their statutory right to information.[162] The proscription against inclusion of such information on/in breastmilk substitute and breastmilk supplement product labels and advertising materials is tantamount to denying Filipino consumers access to science and an important and worthwhile marketplace education in such products.[163] Such access and education could help them to make more informed decisions, with assistance from their physicians, regarding whether or not to continue/discontinue breastfeeding following an infant's first 6-12 months of life and beyond.

This type of treatment also amounts to regulatory paternalism, which will inevitably pave the way for a "dumbed-down" consumer marketplace, despite the relatively high literacy rate "among [Filipino] men and women exposed to different forms of mass media.[164] This high literacy rate is

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161 *See* United States Federal Trade Commission, *Enforcement Policy Statement on Food Advertising* (May 1994), at Sec. IV, available at: http://www.ftc.gov/bcp/policystmt/ad-food.shtm#Health. *See also* Kacey Culliney, *EFSA Health Claims to Spark 'Nutrition Dark Age', Says Attorney*, Bakery and snacks.com (April 18, 2013), available at: http://www.bakeryandsnacks.com/Markets/EFSA-health-claims-to-spark-nutrition-dark-age-says-attorney ("The EU's Nutrition and Health Claims Regulation (NHCR) explicitly lists what claims manufacturers can use on pack. But US food law attorney Jonathan Emord says the heavy-handed, 'Napoleonic' approach the EU takes on regulating health claims – based on EFSA scientific opinions – works against the consumer…Emord said fear around use of health claims was not just apparent in Europe, but the US as well, although less so…The attorney said that while the regulatory regime in the US under the Food and Drug Administration (FDA) is not as heavy-handed as EFSA, manufacturers still operated in fear of the robust regulations.") *Id*.

162 *See*, Republic of the Philippines Department of Trade and Industry, Consumer Welfare and Business Regulation - Consumer Rights, *The Eight Basic Consumer Rights*, supra.

163 "Emord said there is no shortage of scientific health benefits of ingredients but that an enormous disconnect exists with this reserve of academia and the consumer marketplace. 'One of the things that benefits consumers, is access to science information. Denying us access to science on a basis that is less than perfect is damaging. If instead of the heavy hand, you had a freedom for communication with less than perfect information, consumers would begin to experiment more,' he said. 'And while this is less than perfect, we are still dealing with legally available ingredients remember,' he added. Emord said that even with tentative scientific information, consumers should be allowed to make their own purchasing decisions. He said that if there was more science on pack, purchases would occur and there would be health benefits for consumers." *See* Kacey Culliney, *EFSA Health Claims to Spark 'Nutrition Dark Age', Says Attorney*, Bakery and snacks.com (April 18, 2013), *supra*.

164 *See* Republic of the Philippines National Statistics Office, *Literacy of Men and Women in the Philippines (Results from the 2008 Functional Literacy, Education and Mass Media Survey)*, available at: http://www.census.gov.ph/content/literacy-men-and-women-philippines-results-2008-functional-literacy-education-and-mass-media ("Basic literacy is almost universal in the Philippines. Of the estimated 68 million Filipinos 10 years old and over in 2008, 95.6 percent are basically literate. The basic literacy rate is 96.1 percent among females and 95.1 percent among males…The 2008 FLEMMS results also show that the functional literacy rate among females is higher than among males. Overall, functional literacy rate is 88.7 percent for females and 84.2 percent for males. Among the 15 to 24 age group, 94.0 percent of females as compared to 88.7 percent of males are functionally literate. Meanwhile, 87.6 percent of females and 84.1 percent of males in the 25 to 64 age group are functionally literate…Functional literacy rate is also generally high among men and women exposed to different forms of mass media. *Among men, functional literacy rate ranges from 93.0 percent for those who watched television to 95.5 percent for those who surfed the internet. Among women, it ranges from 94.7 percent for those who watched television to 97.0 percent for those who surfed the internet*") (emphasis added). *Id*. *See also* Republic of the Philippines National Statistics Office Gender Development Committee, *Gender Fact Sheet – Literacy of Men and Women in the Philippines (Results from the 2008 Functional Literacy, Education and Mass Media Survey)* (March 2011), available at:

evidenced by the very high social consciousness and sophistication of young Filipino consumers under age 40, an apparently important demographic group obviously including pregnant women and mothers,[165] where "brand trust" rather than mere trademark recognition is playing a greater role in consumer purchasing decisions.[166] In other words, such health information censorship is likely to harm Filipino infants and young children in both the short *and* long term.[167]

In this regard, the Philippine Government would be well served by reviewing how the USFDA honors U.S. consumers' right to information and advertisers' commercial free speech rights with respect to food label-related health claims. For example, the U.S. Food, Drug and Cosmetic Act ("USFDCA") permits the making of limited or qualified health claims (including for infant formula products[168]) for consumer information purposes,[169] if they can be scientifically substantiated. The

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http://www.census.gov.ph/sites/default/files/attachments/aodao/article/Gender%20Factsheet%20-%20Literacy%20of%20Men%20and%20Women%20in%20the%20Philippines%20-%20March%202011%20No.11-01.pdf; UNESCO, *Supporting Maternal and Child Health Improvement and Building Literate Environment (SMILE) Mindanao Project, Country Profile: Philippines*, available at: http://www.unesco.org/uil/litbase/?menu=4&programme=130; UNESCO, *Community-based Adult Learning and Development Programme (CALDP), Country Profile: Philippines*, available at: http://www.unesco.org/uil/litbase/?menu=4&programme=31.

165 *See* Digital Market Asia, *APAC Consumers More Likely to Spend on Socially Conscious Brands* (Aug. 27, 2013), available at: http://www.digitalmarket.asia/2013/08/apac-consumers-more-likely-to-spend-on-socially-conscious-brands/ (discussing how Nielsen's latest Global Survey on Corporate Social Responsibility reflects that APAC markets such as the Philippines "lead the chart of markets that are high on socially conscious consumers", with 68%/2012 and 71%/2013 of consumers will to spend more on products from socially responsible companies). *See also* Nielsen, *Nielsen Identifies Attributes of the Global Socially-Conscious Consumer - Half of Consumers under Age 40 Willing to Pay Extra for Products and Services from Socially-Responsible Companies*, Press Release (March 27, 2012), available at: http://www.nielsen.com/us/en/press-room/2012/nielsen-identifies-attributes-of-the-global--socially-conscious-.html (discussing how Nielsen's survey shows, "overall, that younger consumers are more willing to spend extra for products and services from socially-responsible companies", and that "*the highest concentration of socially-conscious consumers is in the Philippines, where 68 percent of respondents are willing to pay extra for products*") (emphasis added); The Nielsen Company, *A Nielsen Report, The Global, Socially-Conscious Consumer* (March 2012), available at: http://www.fi.nielsen.com/site/documents/NielsenGlobalSocialResponsibilityReportMarch2012.pdf ("In the study, the highest concentration of socially-conscious consumers were found in the Philippines, where 68 percent of respondents said they were willing to pay extra for products and services from companies that had implemented programs to give back to society…This survey confirmed the importance of social media in cause marketing. Socially-conscious consumers are more likely than consumers overall to trust ads found on social networks and they were also more likely than total respondents (59% vs. 46%) to say they use social media when making a purchase decision.") *Id*., at pp. 3 and 5.

166 *See* Lawrence A. Kogan, *Hong Kong's Draft Infant Formula & Complementary Foods Marketing Code Violates WTO Law (Part 3 of 3)*, LexisNexis Emerging Issues 7049 (Aug. 2013), *supra* at Sec. II.4.c.i.A-B; Cheryl Hall, *To Build a Brand, Build Trust, Say Authors of 'Can't Buy Me Like'*, Dallas News (July 6, 2013), available at: http://www.dallasnews.com/business/columnists/cheryl-hall/20130706-to-build-a-brand-build-trust-say-authors-of-cant-buy-me-like.ece; Brent Gleeson, *6 Ways Brands Build Trust Through Social Media*, Forbes (10/31/12), available at: http://www.forbes.com/sites/brentgleeson/2012/10/31/6-ways-brands-build-trust-through-social-media/.

167 "'Cereals marketed to children are a very good example of how censorship of health information produces the perverse effect of disabling and rendering dysfunctional that market', Emord said. 'In the realm of cereal, it's sad because you're hurting children.' Emord said the market has shifted towards high sugar and high salt options because of the lack of health claims on pack. He added that if manufacturers were able to say more about health benefits associated with grains and other ingredients, there would be an 'extraordinary' change in the marketplace. 'Unfortunately, in Europe, the market is so dumbed down by the heavy hand of EFSA, you end up with a tendency on the part of cereal makers to aim at taste as the sole distinguishing characteristic, rather than health." *Id*. See also Alliance for Natural Health, *FTC Proceeds with Raw Power Grab on Health Claims—In Effect Thumbing Its Nose at Congress* (Jan. 22, 2013), *supra* ("Food, drug, and constitutional law attorney Jonathan Emord called the decision 'arbitrary and capricious' and said, 'The breadth of [the FTC's new two-RCT] requirement is truly astonishing…After today's decision, the health marketplace will be dumbed down considerably to the detriment of health conscious consumers"). *See* Kacey Culliney, *EFSA Health Claims to Spark 'Nutrition Dark Age', Says Attorney*, Bakery and snacks.com (April 18, 2013), *supra*.

168 *See* United States Food and Drug Administration, *Qualified Health Claims About Atopic Dermatitis Risk - 100% Whey-Protein Partially Hydrolyzed Infant Formula and Reduced Risk of Atopic Dermatitis*, Docket No. FDA-2009-Q-0301 (5/24/11), available

substantiation process usually entails the USFDA's thorough review of the scientific evidence supporting a qualified health claim pursuant to the evidence-based review system the agency developed for the scientific review of health claims and qualified health claims.[170] The USFDA's evidence-based review system is also shaped, in part, by the very same commercial free speech concerns that motivated the Philippine Supreme Court to hold that the complete direct or indirect ban of BMS product advertising was unconstitutional. In *Pearson v. Shalala*,[171] the Court of Appeals for the District of Columbia Federal Circuit held that "the First Amendment does not permit FDA to reject health claims that the agency determines to be potentially misleading *unless* the agency also reasonably determines that a disclaimer would not eliminate the potential deception" (emphasis added).[172]

C. Inadequately Addressing Confusingly Similar Trademark-Incorporating Labels and Advertising Materials Undermines Achievement of Objectives

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at: http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm073992.htm#whey. *See also* United States Food and Drug Administration, *Enforcement Letter – Re: Qualified Health Claim Petition for the Relationship Between 100% Whey-Protein Partially Hydrolyzed Infant Formula and Reduced Risk of Atopic Dermatitis (Docket No. FDA-2009-Q-0301)* (May 24, 2011), available at: http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm256731.htm ("Based on FDA's consideration of the scientific evidence submitted with the petition and other pertinent scientific evidence, FDA concludes that that the current scientific evidence is appropriate for consideration of a qualified health claim regarding the relationship between the consumption of 100 percent whey-protein partially hydrolyzed infant formula and a reduced risk of atopic dermatitis, provided that the qualified health claims are appropriately worded so as not to mislead consumers"). *Id.*; Carolyn S. Chung, Sedigheh Yamini, and Paula R. Trumbo, *FDA's Health Claim Review: Whey-protein Partially Hydrolyzed Infant Formula and Atopic Dermatitis*, Pediatrics Vol. 130 (Aug. 1, 2012), pp. e408-e414, available at: http://pediatrics.aappublications.org/content/130/2/e408.full ("Because the relationship between W-PHFs and the reduced risk of AD is uncertain, the agency issued a letter of enforcement discretion for the use of 4 qualified health claims…The FDA concluded that the use of bold type as set forth above is necessary, in light of the significant public health risk that would be created by the feeding of these formulas to infants who are allergic to milk or to infants with existing milk allergy symptoms. Furthermore, the fact that the articulation of a relationship between the consumption of W-PHF and a reduced risk of developing the allergic disease of AD could mislead consumers to think that these formulas are an appropriate choice for such infants."). *Id.*, at e413.

169 "The Nutrition Labeling and Education Act of 1990 (NLEA) (Pub. L. 101-553) amended the FDCA to provide the FDA with specific authority to require nutrition labeling of most foods regulated by the Agency. It was designed to give consumers more scientifically valid information about foods they eat. Among other provisions, the NLEA directed FDA to issue regulations providing for the use of statements that describe the relationship between a substance and a disease ('health claims') in the labeling of foods, including dietary supplements, after such statements have been reviewed and authorized by FDA." *See* United States Food and Drug Administration, *Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims - Final* (Jan. 2009), at available at: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm073332.htm ; United States Food and Drug Administration, *Nutritional Labeling and Education Act (NLEA) Requirements (8/94 - 2/95) - Guide to Nutrition Labeling and Education Act (NLEA) Requirements* (Aug. 1994), available at: http://www.fda.gov/iceci/inspections/inspectionguides/ucm074948.htm.

170 *See* United States Food and Drug Administration, *Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims - Final* (Jan. 2009), available at: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm073332.htm ("This guidance document describes the evidence-based review system that FDA intends to use to evaluate the publicly available scientific evidence…health claims or qualified health claims on the relationship between a substance and a disease or health-related condition. This guidance document explains the agency's current thinking on the scientific review approach FDA should use and is intended to provide guidance to health claim petitioners.") *Id.*

171 See *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir.1999).

172 *Id.*

The PH BMS Framework's imposition of special requirements restricting the use of trademarks, logos and brand names on/in infant formula, follow-up formula and complementary food containers/labels and advertising materials fails to address the Framework's objective of preventing deceptive marketing practices capable of confusing consumers regarding the proper use of each such product relative to the other, when "medically indicated and only when necessary."[173]

Curiously, the PH DOH has not publicly invoked its authority under RIRR, Rule XIV Section 56, on public health and unfair competition grounds, to curtail confusingly similar trademarks, logos and brand names allegedly used by the same manufacturer on otherwise distinct infant formula and follow-up formula products. Section 56 empowers the PHDOH to "periodically review whether or not to allow or prohibit the use of brand names or company logos of products within the scope of [the Milk] code which are similar to the brand names or logos utilized for products not covered by [said] Code, including the physical appearance of the container, taking into consideration the possibility of product confusion, the balance between a free market economy as against the decline and fall of breastfeeding rates among mothers and women of reproductive age, and public welfare and benefit being its ultimate yardstick."[174] The PHDOH is arguably hesitant to invoke Section 56 with respect to infant formula, follow-up formula and/or other milk products (e.g., grow-up milk) because it would indirectly signal to the marketplace and to consumers that follow-up formula and other milk products marketed exclusively as breastmilk *supplements* intended for young children *6-12 months of age and older* may *not* be covered by the PH BMS Framework after all, consistent with WHO Code Annex 3. As a result, said Framework arguably does little to address the potential for consumer confusion over these allegedly "confusingly similar" products which WHO/UNICEF and breastfeeding activists claim undermines breastfeeding.[175]

Circular 2008-0006, Item VI.A.1(i) expresses the PHDOH's singular effort to address potential consumer confusion arising from the use of similar trademarks, logos and brand names

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173 RIRR, Rule I Sec. 2.

174 RIRR, Rule XIV Sec. 56.

175 *See*, *e.g.*, World Health Organization, *Information Concerning the Use and Marketing of Follow-up Formula* (July 17, 2013), supra, at p. 2 (alleging that formula milk manufacturers and distributors are employing an indirect marketing strategy that relies on product packaging, branding and labeling (including word marks and non-word marks) to confuse, and thus, induce mothers to use follow-up formula as infant formula during the first 6 months of an infant's life" and thereafter); IBFAN, *WHO States that Follow-up Formula is Not Necessary and that Marketing May Mislead Parents*, Press Release (July 25, 2013), available at: http://ibfan.org/ibfan/pressrelease25jul13; UNICEF United Kingdom, The Baby Feeding Initiative, *A Guide For Health Workers to Working Within the International Code of Marketing of Breastmilk Substitutes* (2013) at pp. 16-17, available at: http://www.unicef.org.uk/Documents/Baby_Friendly/Guidance/guide_int_code_health_professionals.pdf ("In the recent Infant Feeding Survey (2010), 46% of mothers said that they had seen an advert for first-stage formula milk, despite such adverts being banned, indicating a significant confusion in what was being advertised"). *See also* Nina J Berry, Sandra Jones and Don Iverson, *It's All Formula to Me: Women's Understandings of Toddler Milk Ads*, 17(3) Breastfeeding Review (2010); Nina J Berry, Sandra Jones and Don Iverson, *Toddler Milk Advertising in Australia: The Infant Formula Ads We Have When We Don't Have Infant Formula Ads*, University of Wollongong Research Online (2010), available at: http://ro.uow.edu.au/cgi/viewcontent.cgi?article=1630&context=hbspapers , *in* P. Ballantine & J. Finsterwalder (Eds.), ANZMAC Annual Conference 2010: Australian and New Zealand Marketing Academy Conference 2010 – "Doing More with Less" (pp. 1-8), available at: http://anzmac2010.org/proceedings/papers.html#B; http://anzmac2010.org/proceedings/pdf/anzmac10Final00376.pdf; Lawrence A. Kogan, *Hong Kong's Draft Infant Formula & Complementary Foods Marketing Code Violates WTO Law (Part 3 of 3)*, LexisNexis Emerging Issues 7049 (Aug. 2013), *supra* at Sec. II.4.c.iii (discussing how this hardly scientific 2008 prize-induced survey of Australian parents asked to recall formula advertisements they believed they had seen during the prior year (2007), had failed to consider the depth, duration and nature of the respondents' familiarity with the products, brands and companies identified, apart from such advertising – i.e., the degree to which their recall was attributable to 'brand trust').

incorporated on infant formula and follow-up formula product marketing materials. It mandates the use (in English and Filipino) on the principal display panel of all breastmilk substitute and breastmilk supplement product *containers/labels*, of the following distinct product category/designation names, in addition to the brand name/trademark of the specific product concerned: "Infant Formula", "Formula for Special Medical Purposes Intended for Infants" and "Milk Supplement."[176]

Unfortunately, however, this effort is not aided, and is arguably undermined by, Circular 2008-0006, Items VI.A.3(i)-(ii) which do nothing to help distinguish and differentiate such products in consumers' minds. They require the use of the following boldfaced Arial font messages in English and Filipino on the principal display panel of the containers/labels of *both* breastmilk substitute *and* breastmilk supplement products covered by the PH BMS Framework - "BREASTMILK IS BEST FOR BABIES UP TO 2 YEARS OF AGE AND BEYOND"[177] and "IMPORTANT NOTICE: THERE IS NO SUBSTITUTE FOR BREASTMILK".[178] And, each of these messages are to be printed in a font size which is one-third (1/3) of the size of the biggest letter on the label."[179]

In addition, this effort is not aided, and is arguably undermined by, AO 2008-006, Items VI.B.9(i)-(ii), which mandate the following identical messages in English and Filipino on each breastmilk substitute *and* breastmilk supplement product container/label to be printed in bold font Arial type 1/6 the size of the biggest letter at the uppermost level of the information display panel: "The Use of *Infant Formula/Milk Supplements* must only be upon the advice of a health professional" (emphasis added),[180] and "The unnecessary and improper use of *this* product may be dangerous to your child's health".[181] AO 2012-0027, Sections 21.B.a-b require the inclusion of identical primary messages for advertisements of Milk Supplements,[182] but not for advertisements of infant formula.

Each of these prescribed messages discussed above also constitute special requirements because they mandate the inclusion of additional statements on formula milk product containers/labels of a minimum font size, beyond those required for food safety and preparation and manufacturer identification purposes. These additional statements serve to occupy valuable space on formula milk product containers/labels and partially 'crowd out' an already restricted trademark, which encumbers the ability of trademark owners and their licensees to "use" their word marks to distinguish their products from competing products in the Philippine marketplace.

Thus, while these special requirements primarily inform consumers that infant formula and follow-up formula products are unlike breastmilk, they contribute little to preventing trademark-related consumer confusion between infant formula and follow-up formula such products.

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176 Circular 2008-0006, Item VI.A.1(i).
177 *Id*., at Item VI.A.3(i).
178 *Id*., at Item VI.A.3(ii).
179 *Id.* Circular 2008-0006, Item VI.B.4(v) and AO 2012-0027, Sections 21.A.a-b require certain messages be included on the principal display panels of BMS product containers/labels regarding the food safety risk of bacterial infection associated with infant formula and follow-on formula normal use and misuse. Since these messages appear consistent with Codex Standards they are not objectionable.
180 *Id*., at Item VI.B.9(i).
181 *Id*., at Item VI.B.9(ii).
182 AO 2012-0027, Sections 21.B.a-b.

ii. The WHO Code-Implementing United Kingdom BMS Framework Offers a Reasonably Available Less Trademark-Encumbering Alternative to the PH BMS Framework

The WHO Code-implementing framework of the United Kingdom offers a reasonably available less trademark-encumbering alternative to the PH BMS Framework. As previously discussed in Part 1 of this analysis,[183] the UK BMS Framework consists of the *Infant Formula and Follow-on Formula (England) Regulations 2007* ("Statutory Instrument ('SI') 2007/3521"), as amended, which covers the labeling, advertising and presentation of both infant formula and follow-up formula products.[184] SI 2007/3521, which implements for the UK/England EU Directive 2006/141/EC, expressly restricts infant formula advertising to only scientific or manufacturer/wholesaler trade publications not intended for general public readership. Infant formula advertising must contain only scientific and factual information, and cannot imply or create a belief that bottle-feeding is equivalent or superior to breast feeding so as to undermine it.

A. Infant Formula Trademark-Use Encumbrances

SI 2007/3521, as amended, imposes only one express legislative restriction on the use of trademarks, logos and proprietary brand names relating to infant formula, which is consistent with WHO Code Article 4.3. SI 2007/3521, Regulation 24(4)(c) prohibits all UK Secretary of State-approved[185] infant formula manufacturer and/or distributor-donated equipment and educational information, including information regarding infant feeding, from being "marked or labelled with the name of a proprietary brand of infant formula."[186]

In addition to this uncontroversial trademark-use encumbrance, the persuasive but legally non-binding revised UK Department of Health ("UKDOH") Guidance Notes accompanying/interpreting SI 2007/3521[187] indicate that the UK BMS Framework imposes other such encumbrances. In light of the content-based restrictions that SI 2007/3521, Regulation 21 imposes on general advertisements of infant formula products placed by manufacturers in scientific or wholesale trade publications, the UKDOH, like the UK Food Standards Agency before it, mandates that "any [such] general advertisements…*must not* feature a brand name, trade mark, business name or logo uniquely associated with an infant formula" (emphasis added).[188] Apparently, the UKDOH has interpreted the use of word marks, non-word mark logos and brand names in infant formula advertising as

183 *See* Lawrence A. Kogan, *The Philippines Breastmilk Substitute/Supplement Marketing Framework Violates WTO Law* (Part 1 of 2), LexisNexis 2013 Emerging Issues ("Part 1"), at Sec. III.3.b.v.A.

184 *See* Government of the United Kingdom, *Statutory Instrument 2007 No. 3521 - The Infant Formula and Follow-on Formula (England) Regulations 2007* (Jan. 11, 2008), as amended by Government of the United Kingdom, *Statutory Instrument 2008 No. 2445 - The Infant Formula and Follow-on Formula (England) (Amendment) Regulations 2008* (Sept. 16, 2008), *supra* and *See* Government of the United Kingdom, *Statutory Instrument 2011 No. 3012 - Transfer of Functions (Food) Regulations 2011* (Dec. 14, 2011), *supra*.

185 See *UKDOH Guidance Notes on the Infant Formula and Follow-on Formula Regulations 2007 (as amended)* (March 2013), *supra* at par. 77.

186 SI 2007/3521, Regulation 24(4)(c).

187 See *UKDOH Guidance Notes on the Infant Formula and Follow-on Formula Regulations 2007 (as amended)* (March 2013), *supra* at p.5.

188 *Id*., at par. 67. The same prohibition was contained in the 2009 version of the UK Food Standards Agency's Guidance Notes. *See* Government of the United Kingdom Department of Health *("UKDOH") Guidance Notes on the Infant Formula and Follow-on Formula Regulations 2007*, Revision 2, (March 2009) at par. 67, available at: http://www.food.gov.uk/multimedia/pdfs/guidancenotes2008amendmar09.pdf.

being potentially inconsistent with SI 2007/3521 Regulations 21(b) and 17(2)(a), as well as the WHO Code,[189] which seek to prevent infant formula advertisements from undermining or discouraging breastfeeding.[190]

Since, as previously discussed, the UKDOH deems infant formula suitable for use by infants up to 6 months of age and follow-on formula suitable for use by infants over 6 months of age, then the practical impact of this trademark-use encumbrance is limited to infant formula advertised as bona fide breastmilk substitutes for use by infants under 6 months old. Such treatment is entirely consistent with the WHO Code and arguably less trademark-use encumbering than PH BMS Framework trademark-use restrictions applicable to infant formula, follow-up formula *and* complementary foods advertised for use by infants and young children *up to 24 months of age or older*.

The UKDOH also mandates that text or pictures used in infant formula labeling and advertisements "*must not* make reference to terms such as 'the best' or 'the ideal method' of infant feeding" (emphasis added)[191] – i.e., to superlatives qualifying as puffing statements. The UKDOH has apparently interpreted the use of such text or pictures *in conjunction with the subject matter of infant feeding* as idealizing infant formula in violation of SI 2007/3521, Regulation 17(3)(b),[192] consistent with and in implementation of Articles 13(5), 13(8)(b) and 14(1) of EU Directive 2006/141/EC.[193] Nevertheless, the UKDOH has not suggested that it will interpret these requirements as prohibiting the use of superlative trademarks or logo-related text or pictures in infant formula labeling and advertising that make reference to subject matter *other than* infant feeding which does not otherwise undermine or discourage breastfeeding.

Arguably, the UKDOH has imposed these trademark-use encumbrances in anticipation of Articles 10(1)-(2) of new EU Regulation No. 609/2013. Beginning in 2016, said regulation will require that infant formula advertising, labeling and presentation not be designed "to discourage breastfeeding", and that it "not include pictures of infants, or other pictures or text which may idealise the use of such formulae".[194] Pursuant to Articles 11(1)(c) and (e) of EU Regulation No. 609/2013, the EU Commission is empowered to promulgate separate rules that impose "specific requirements on [the] labelling, presentation and advertising of food referred to in Article 1(1) [including infant formula, follow-on formula and processed cereal-based and baby food products[195]], including the authorisation of nutrition and health claims in relation thereto",[196] and "requirements concerning promotional and commercial practices relating to infant formula."[197] These new acts could potentially result in further trademark-use encumbrances.

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189 See *UKDOH Guidance Notes on the Infant Formula and Follow-on Formula Regulations 2007 (as amended)* (March 2013), *supra* at par. 3.
190 *Id.,* at par. 58.
191 *Id*., at pars. 29, 31 and 59.
192 *Id*. Presumably, such prohibition applies to trademarks used alone *or* as part of slogans or mottos, in conjunction with information about infant feeding.
193 EU Directive 2006/141/EC, Articles 13(5) and 13(8)(b).
194 EU Regulation No 609/2013, Articles 10(1)-(2).
195 *Id*., at Articles 1(1)(a)-(b).
196 *Id*., at Art. 11(1)(c).
197 *Id*., at Art. 11(1)(e).

As previously discussed, SI 2007/3521, Regulations 17(4) and 21(b) also narrowly restrict the types of health and nutrition claims that can be included in infant formula advertising and labeling to only those that are (positively) listed and capable of satisfying the conditions specified in Annex IV of EU Directive 2006/141/EC. The UKDOH Guidance Notes indicate that, with respect to infant formula, the Agency will likely follow the European Commission's treatment of advertising and labeling claims that describe changes in bodily functions (functionality claims) and *imply* an effect on health (implied health claims) as health claims subject to the Annex IV restrictions. As a result, they will not be permitted unless they fall within such Annex IV list. EU Directive 2006/141/EC, Article 2 makes clear that the definition of health claim for purposes of making such determination will be that contained in Articles 2(1) 2(4) and 2(5) of Regulation (EC) No 1924/2006.[198] It does not appear, at the present time, however, that the EU Commission and/or the UKDOH intends to view trademarks, logos and brand names (alone or incorporated in mottos or slogans) in *infant formula* advertising materials as functional or implied health claims subject to authorization, but this is likely to change once the UKDOH implements EU Regulation No. 609/2013.

B. Follow-on Formula Trademark-Use Encumbrances

As previously discussed,[199] SI 2007/3521 establishes different rules for the advertising of follow-on formula which do not impose trademark-use restrictions on the general advertising of such products. Nevertheless, if follow-up formula advertising or labeling materials contain health claims or nutrition claims, they are controlled by European Regulation (EC) No 1924/2006 which governs the making of such claims with respect to foods.[200] This means that unless an express or implied follow-up formula nutrition or health claim is contained in the preapproved list of nutrient claims set forth in the Annex to Regulation 1924/2006, as amended, or in the preapproved list of health claims set forth in EU Regulation No 1047/2012, it will be subject to the review and authorization procedure of Regulation 1924/2006, Article 15. Although said procedure will involve the participation of both the European Food Safety Authority ("EFSA") and the UK national competent authority – i.e., the UKDOH,[201] it is EFSA that will render the final decision concerning authorization.[202]

Article 2(1) of Regulation 1924/2006 defines a "health claim" as including any non-mandatory [textual] message or representation…including pictorial, graphic or symbolic representation in any form, which suggests or implies that a food has particular characteristics."[203] Consistent therewith,

198 EU Directive 2006/141/EC, Art. 2.

199 *See* Lawrence A. Kogan, *The Philippines Breastmilk Substitute/Supplement Marketing Framework Violates WTO Law* (Part 1 of 2), LexisNexis 2013 Emerging Issues ("Part 1"), at Sec. III.3.b.v.B.

200 *See UKDOH Guidance Notes on the Infant Formula and Follow-on Formula Regulations 2007 (as amended)* (March 2013), *supra* at par. 40; European Commission, *Guidance on the Implementation of Regulation No 1924/2006 on Nutrition and Health Claims Made on Foods – Conclusions of the Standing Committee on the Food Chain and Animal Health* (Dec. 14, 2007), *supra* at p. 4.

201 "[A]n application for authorization…shall be sent to the national competent authority of a Member State…[which] shall inform without delay the Authority; and make the application and any supplementary information supplied by the applicant available to the Authority." EC Regulation 1924/2006, at Articles 15(1), 15(2)(a)(ii)-(iii); 16(2).

202 *Id*., at Articles 16(1), 16(3)-(6). It is possible for EFSA to modify its decision in response to public comments received during the brief 30 day period of public consultation following EFSA's publication of its decision. *Id*., at Art. 16(4).

203 *Id*., at Art. 2(1).

Preamble paragraph 4[204] and Article 1(3) of Regulation 1924/2006[205] indicate that it is possible for a trademark (word mark or non-word mark) or brand name appearing in follow-on formula advertising, labeling and presentations (including packaging) to be deemed an implied nutrition or health claim, and to thus fall subject to EFSA review and authorization pursuant to Article 15 of said regulation. Were a follow-on formula product-related word mark, non-word mark and/or brand name so construed, it could avoid EFSA review and authorization only if it is accompanied by (or linked to) a related nutrition or health claim contained in the same follow-on formula product-related advertising, labeling or packaging that complies with the requirements of Regulation 1924/2006.[206] The UKDOH Guidance Notes interpreting Regulation 1924/2006 for UK food companies indicates that "[t]he claim must be relevant to the trademark or brand name. Article 1(3) requires the claim to be in either the Annex of approved nutrition claims or the EU Register of authorised health claims and the product must meet the requirements to make the accompanying claim."[207]

Neither SI 2007/3521 nor the accompanying UKDOH Guidance Notes have yet to address the application of Regulation 1924/2006, Article 1(3) to follow-on formula product-related advertising, labeling and presentation materials. Yet, Article 28(2) of Regulation 1924/2006 provides a transitional derogation that postpones the application of Article 1(3) for products bearing trademarks or brand names (but not fanciful names) existing before 1 January 2005 until January 20, 2022.[208] Although it would appear that a follow-on formula product bearing a trademark or brand name registered since January 1, 2005 could fall subject to Article 1(3) and possibly be deemed an implied health claim subject to EFSA authorization before 2022, another transitional derogation contained in Article 28(6)(b) prevents that provision from applying to such marks. It states that any express or implied health claim not subject to Member State evaluation and authorization "may continue to be used provided an application [was] made [to the UK Competent Authority (UKDOH) and EFSA] pursuant to [Article 15 of] this Regulation before 19 January 2008."[209] The UKDOH Guidance Notes indicate that such permitted use may continue only until the

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204 *Id*., at Preamble par. 4 ("This Regulation should also apply to trade marks and other brand names which may be construed as nutrition or health claims.") *Id*.

205 *Id*., at Art. 1.3. It provides that, "A trade mark, brand name or fancy name appearing in the labelling, presentation or advertising of a food which may be construed as a nutrition or health claim…" *Id*.

206 *Id*., at Art. 1.3. *See also* Department of Health (UK), *Letter to Interested Parties - Update from the European Commission's Working Group Meeting on Nutrition and Health Claims* (Jan. 11, 2013), supra at p. 2. ("There was a discussion about whether a picture or graphic symbol used in food labelling (e.g. a picture of an eye on a food supplement containing lutein) would be an Article 10(3) [of EC Regulation 1924/2006] health claim and so would need to be accompanied by an authorised, specific health claim from the list of Article 13 or 14 health claims. There was general agreement that this was the correct interpretation.") *Id*.

207 *See* Government of the United Kingdom Department of Health, *Nutrition and Health Claims Guidance to Compliance with Regulation (EC)1924/2006 on Nutrition and Health Claims Made on Foods, Version 2* (Nov. 2011), at Sec. 9.5, Q.33, available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/204320/Nutrition_and_health_claims_guidance_November_2011.pdf. The UKDOH Guidance Notes interpreting Regulation 1924/2006 clearly indicate that "[i]f a trademark or brand name appearing on a food or in the presentation or advertising of a food implies a nutrition or health claim, it will come within the scope of the Regulation." *Id*., at par. 38.

208 Article 28(2) renders Article 1(3) inapplicable to follow-on formula advertising, labeling or packaging bearing trade marks or brand names existing before 1 January 2005 which do not comply with this Regulation, until Jan. 19, 2022. *Id*., at Art. 28(2). *See* European Commission, *Regulation (EC) No 1924/2006 of the European Parliament and of the Council, (Dec. 20, 2006) On Nutrition and Health Claims Made on Foods*, as amended, available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2006R1924:20100302:EN:PDF.

209 *Id*. See also *UKDOH Guidance Notes on the Infant Formula and Follow-on Formula Regulations 2007 (as amended)* (March 2013), *supra* at par. 43.

Commission's Standing Committee reaches a decision on the application.[210] "Until such time[,] the Consumer Protection from Unfair Trading Regulations and the Food Safety Act 1990, will apply to health claims made on follow-on formula and make it an offence to falsely describe a food or mislead as to its nature, substance or quality."[211] It can be expected that, during such transitional period, the Advertising Standards Authority will play a considerable oversight role.

Although neither SI 2007/3521 nor the accompanying UKDOH Guidance Notes address the application of Regulation 1924/2006, Article 1(3) to follow-on formula product-related advertising, labeling and presentation materials, Articles 10(1)-(2) and 11(1)(c) of Regulation 609/2013 appear to suggest that similar trademark-use restrictions could be imposed on follow-on product advertising and labeling in the future. Article 10(1) provides that "the labelling, presentation and advertising of infant formula *and follow-on formula* shall be designed so as not to discourage breast-feeding" (emphasis added).[212] Article 10(2) provides that "the labelling *of follow-on formula* shall not include pictures of infants, or other pictures or text which may idealise the use of such formulae" (emphasis added).[213] And, Article 11(1)(c) empowers the EU Commission to promulgate separate rules that impose "specific requirements on [the] labelling, presentation and advertising of food referred to in Article 1(1) [consisting *inter alia* of follow-on formula and processed cereal-based and baby food products[214]], including the authorisation of nutrition and health claims in relation thereto".[215]

Under the UK BMS Framework, therefore, it seems possible for follow-on formula advertising, labeling or packaging-related trademarks, logos and brand names otherwise constituting non-actionable puffery, either alone or as incorporated into a slogan or motto, to be deemed an actionable implied health claim subject to restriction of use, if such marks are linked to an express or implied nutrition or health claim addressing that particular product within the same media.[216] While such restrictions are less trademark-use encumbering than those imposed by the PH BMS Framework, they may yet constitute "unjustifiable encumbrances" vis-à-vis other countries' requirements, within the meaning of TRIPS Articles 8 and 20, as at least one legal commentator has already alleged.[217]

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210 *Id*.

211 *Id*. "The [UK] Food Labelling Regulations 1996 also make it an offence to make medicinal claims which state or imply that a product can prevent, treat or cure a human disease." *Id*., at par. 44.

212 EU Regulation No 609/2013, Art. 10(1).

213 *Id*., at Art. 10(2). This provision notably did not preclude the use of text or pictures in follow-on formula advertising.

214 *Id*., at Articles 1(1)(a)-(b).

215 *Id*., at Art. 11(1)(c).

216 *See e.g.*, Kacey Culliney, *EFSA Health Claims to Spark 'Nutrition Dark Age', Says Attorney*, Bakery and snacks.com (April 18, 2013), *supra*; Robert Verkerk, *Implementing an EU Health Claim Converting Scientific Language to Consumer Language*, Agro FOOD industry hi-tech Vol. 24(2) March/April 2013, 32-35, available at: http://www.teknoscienze.com/Articles/Agro-FOOD-INDUSTRY-hi-tech-Implementing-an-EU-health-claim-converting-scientific-language-to.aspx#.UioTzZLCaSp.

217 *See* Shane Starling, *Could the WTO Overturn EU Health Claim Laws?*, NUTRAingredients.com (April 22, 3013), available at: http://www.nutraingredients.com/Regulation/Could-the-WTO-overturn-EU-health-claim-laws. (discussing how, according to Emmanuel Saurat, an associate in the Brussels office of Sidley Austin, the European Union's nutrition and health claims regulation (NHCR) underlying the UK BMS Framework "may restrict commercial free speech, trade between EU and non-EU countries as well as the use of trade marks", and how "NHCR prohibitions…may provoke actions by the governments that have signed up to the WTO."). *Id*.

iii. Assessing the Risks that Non-Fulfillment of PH BMS Framework Legitimate Objectives Would Create Due to Adoption of the Reasonably Available Less Trademark-Use Encumbering UK BMS Framework

The Philippine Government's adoption of the UK BMS Framework would pose little risk that the PH BMS Framework's policy objectives would not be fulfilled for at least two reasons. First, the UK BMS Framework, unlike the PH BMS Framework, employs extensive measures to ensure that follow-on formula labeling, advertising and packaging incorporating trademarks, logos and brand names will not result in consumer confusion regarding such products that can lead to the undermining of breastfeeding and breastmilk. Second, the UK BMS Framework, unlike the PH BMS Framework, recognizes and permits some express and implied health or nutrition claims, including claims entailing the use of trademarks, logos and brand names, which can be proven by evolving science. This enables consumers to identify, discern and discount the types of false, misleading or deceptive advertising and labeling practices that can serve to undermine or discourage breastfeeding and breastmilk.

A. UK BMS Framework Employs Extensive Measures to Avoid Consumer Confusion

The UKDOH Guidance Notes accompanying SI 2007/3521 reflect that the UKDOH has gone to much greater lengths than the PHDOH to develop special measures to ensure that follow-on formula product advertising and labeling materials incorporating trademarks, logos and brand names do not directly or indirectly discourage or undermine the breastfeeding of infants *up to 6 months of age*. For example, the UKDOH has mandated that "[n]on-mandatory text or pictures in…follow-on formula advertisements *must not* make reference to 'breastmilk', 'breastfeeding', 'moving on from breastfeeding' or 'closer to/inspired by breastmilk'" (emphasis added).[218] In addition, "non-mandatory text or pictures in…follow-on formula advertisements *must not* make reference to terms such as 'the best' or 'the ideal method' of infant feeding" (emphasis added),[219] which arguably targets infant feeding-related statements only. These prohibitions are intended to make a clear distinction between infant formula and follow-on formula products so as to avoid any risk of confusion between them which can directly or indirectly discourage or undermine breastfeeding, consistent with the requirements of SI 2007/3521, Regulations 22, 19, 18(2)(a).

Other UKDOH Guidance Note prescriptions also endeavor to achieve this result. "When advertising to the public or health care professionals, formula manufacturers must…ensure that…consumers recognise that advertisements for follow-on formula relate exclusively to products for older babies and not infant formula" (emphasis added).[220] "[C]ompanies will therefore *need to* ensure that formula advertising does not[: 1)] promote a range of formula products by making the brand the focus of the advert, rather than specific products[; 2)] include pictures or text which directly or indirectly relate or compare [follow-on formula] products to breastmilk…[t]o minimise the risk of consumers making a connection between follow-on formula and the act of feeding infants from

218 *See UKDOH Guidance Notes on the Infant Formula and Follow-on Formula Regulations 2007 (as amended)* (March 2013), *supra* at par. 58.
219 *Id.*, at pars. 28 and 59.
220 *Id.*, at par. 47.

birth"[221][; and 3)] focus primarily on the promotion of ingredients, or the effect of ingredients, which are common to both follow-on formula and infant formula."[222] Consistent with SI 2007/3521, Regulations 18(2) and 19, "[m]anufacturers must ensure that infant formula and follow-on formula are labelled in such a way that it enables consumers to make a clear distinction between infant formula and follow-on formula so as to avoid any risk of confusion."[223] And, consistent with SI 2007/3521, Regulations 18(2), 19, 20(2), and 22, this requirement is also made applicable "to the presentation [shape, appearance or packaging] and advertising of infant formula and follow-on formula."[224]

To further ensure against consumer confusion between infant formula and follow-on formula products, the UKDOH Guidance Notes provide further instructions. "[M]anufacturers should ensure…when drafting…follow-on formula labelling" that: 1) "the specific term[]…'follow-on formula' should be clearly [conspicuously] featured on the packaging, in a font size no smaller than the brand name[225][; 2)] information on [follow-on formula] labels, such as pictures and blocks of text should differentiate [it from infant formula;[226] 3)]…the colour scheme of follow-on formula packaging…should be clearly different [from]…[t]he colour scheme used for infant formula packaging[227][; and 4)] [n]onmandatory references to breastmilk or breastfeeding should not be made on follow-on formula packaging."[228] Also, to avoid possible consumer confusion over infant and follow-on formula products, "[t]he term 'follow-on formula' should not feature solely in: [1)] the text of the 'Important Notice' [concerning the superiority of breast feeding and advice on when infant formula should be used,][229]where provided," in labeling and in advertising;[230] and 2) "pictures of follow-on formula packaging which are featured in the advertisement".[231]

Moreover, the UKDOH Guidance Notes accompanying SI 2007/3521 prescribe the inclusion of certain information "to help consumers understand that it relates exclusively to follow-on formula [and not to infant formula]. For example, follow-on formula advertising materials should state that "[f]ollow-on formula is suitable only for particular nutritional use by infants over the age of six months", and should clearly feature pictures of "infants…over six months" of age.[232] "In addition, manufacturers should ensure that" print advertisements for follow-on formula products are not "placed within or adjacent to any article or photo spread featuring the feeding of babies under six months of age or babies that could be perceived as being under 6 months."[233]

B. UK BMS Framework Considers Evolving Science When Considering Health and Nutrition Claims

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221 *Id*., at pars. 48 and 70.
222 *Id*., at par. 48.
223 *Id*., at par. 50.
224 *Id*.
225 *Id*., at pars. 51 and 70.
226 *Id*., at par. 51.
227 *Id*., at pars. 51 and 70.
228 *Id*., at par. 51.
229 *Id*., at pars. 27 and 57.
230 *Id*., at par. 70.
231 *Id*.
232 *Id*.
233 *Id*.

The UK BMS Framework (in implementation of the EU Framework) has also gradually come to recognize that some implied health and/or nutrition claims, including those entailing the use of a follow-on formula or complementary food product trademark, logo or brand name,[234] can be proven with evolving science and should be permitted. This is indicative of the very slow and iterative *ad hoc* facts-driven process currently under way to more generally prevent deceptive food advertising and labeling practices from denying consumers the critical information they need to make informed decisions in the marketplace. At this juncture, it apparently reflects a growing trend among mostly developed country governments[235] concerned about the proliferation of persuasive

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234 *See* European Commission - *MEMO/07/267 - Questions and Answers on Health and Nutrition Claims* (6/28/07), available at: http://europa.eu/rapid/press-release_MEMO-07-267_en.htm ("Within 15 years, existing brand names suggesting health benefits (such as promises of weight loss) and which do not meet the requirements of the Regulation [EC Regulation No. 1924/2006] must be phased out and removed from the market. No new trademarks or brand names which imply health or nutritional benefits will be allowed to be put on the EU market unless the claims implied can be substantiated, in line with the provisions of the Regulation…This timeframe was considered to be a reasonable period for companies to make the necessary adjustments and changes to their branding.") *Id*.

235 *See, e.g.*, Government of Canada, Canadian Food Inspection Agency, *Guide to Food Labelling and Advertising, Chap. 8.1 – Health Claims* (modified 7/22/13), available at: http://www.inspection.gc.ca/english/fssa/labeti/guide/ch8e.shtml#a8_1 ("Health claims may be stated explicitly with words, or implied through symbols, graphics, logos or other means such as a name, trade mark or seal of approval.") *Id*; Food Standards Australia New Zealand, *Consultation Paper - Regulation of Infant Formula Products in the Australia New Zealand Food Standards Code* (Sept. 26, 2012), at Sec. 6.4, available at: http://www.foodstandards.gov.au/code/infant/documents/Infant%20formula%20review%20Consultation%20Paper%20FINAL.pdf ("The Review of Food Labelling Law and Policy (Blewett et al., 2011) recommended that applications for trade names and trademarks be scrutinised by the relevant agencies to identify and reject words and devices that have the effect of inferring health implications that are otherwise prohibited under the Code (Recommendation 21). In its consideration of this recommendation, the COAG Legislative and Governance Forum on Food Regulation (the Forum) commented (2011) that under the uniform food laws in each jurisdiction, the use of trade names or trademarks, including devices and brand identifiers, cannot be used as a means to make claims about food that would otherwise not be allowed under the Food Standards Code. This position is irrespective of the position on Recommendation 20 relating to health claims…In its response, the Forum have requested that the Food Regulation Standing Committee (FRSC) investigates and reports on the scope of trade mark law and provisions of the Code, with a view to suggesting improvements in the manner in which food and trade mark regulators work together to ensure problematic trademarks as they relate to food are identified prior to their being registered. FRSC has signalled that this work will be completed in 2013."); Consumers Federation of Australia, *Health Focused Food Trademarks Trick Shoppers* (Nov. 22, 2012), available at: http://consumersfederation.org.au/health-focused-food-trademarks-trick-shoppers/ ("Manufacturers are trademarking healthy words such as 'natural', 'healthy' and 'fresh' to give the impression that a product is healthier than it seems. Other product names suggest eco-friendliness as consumers are often willing to pay premium for perceived environmental benefits," says CHOICE spokesperson Ingrid Just. 'The problem is that while food labelling and consumer protection laws prohibit the use of the word 'health' on food products and other claims that might mislead consumers, companies can sidestep these laws by using the words in trademarks,' says Ms Just…Trademark law prohibits the registration of a trademark likely to deceive or cause confusion, but nutritional analysis is not part of the approval of new trade marks by IP Australia. In contrast, Food Standards Australia New Zealand (FSANZ) is in the process of developing a standard for health claims that would only allow these claims to be made on food products that meet agreed nutritional criteria. Further, the claims will have to be supported by robust scientific evidence.") *Id*. *See also* US Food and Drug Administration, *Code of Federal Regulations Title 21, 21CFR101.14* (Revised as of April 1, 2013), available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=101.14 ("PART 101 -- FOOD LABELING Subpart A--General Provisions, Sec. 101.14 Health claims: general requirements. (a)Definitions…(1)Health claim means any claim made on the label or in labeling of a food, including a dietary supplement, that expressly *or by implication*, including 'third party' references, written statements *(e.g., a brand name including a term such as 'heart'), symbols (e.g., a heart symbol)*, or vignettes, characterizes the relationship of any substance to a disease or health-related condition. *Implied health claims include those statements, symbols, vignettes, or other forms of communication that suggest*, within the context in which they are presented, that a relationship exists between the presence or level of a substance in the food and a disease or health-related condition" (emphasis added). Arguably, this regulatory update reflects the FTC Administrative Law Judge's issuance of the of the following Orders in *In the Matter of Pom Wonderful, LLC*: I) for Respondents "not [to] make any representation, in any manner, expressly or by implication, including through the use of a product name, endorsement, depiction, illustration, trademark, or trade name, that such product is effective in the diagnosis, cure, mitigation, treatment, or prevention of any disease, including, but not limited to…II) for Respondents "not [to] make any representation, in any manner, expressly *or by*

but potentially false and misleading advertising and labeling claims professing unsubstantiated health and nutrition benefits associated with the use of "novel foods" such as vitamin supplements,[236] pharmaceutical supplements,[237] and food supplements.[238] Thus far, BMS product

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implication, including through the use of a product name, endorsement, depiction, *illustration, trademark, or trade name, about the health benefits*, performance, or efficacy of any Covered Product…" *See* United States Federal Trade Commission Office of Administrative Law Judges, *In the Matter of Pom Wonderful LLC*, Docket No. 9344, Initial Decision (May 17, 2012) at p. 332, available at: http://www.ftc.gov/os/adjpro/d9344/120521pomdecision.pdf.

236 See, e.g., *Green – Swan Pharmaceuticals Cr, AS -v- Statni Zemedelska A Potravinarska Inspekce, Ustredni Inspektorat*, European Court of Justice (Ninth Chamber), EUECJ C-299/12 (July 18, 2013), available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:62012CJ0299:EN:HTML (holding that, under "Article 2(2)(6) of Regulation (EC) No 1924/2006…as amended…a health claim need not necessarily expressly state that the consumption of a category of food, a food or one of its constituents 'significantly' reduces a risk factor in the development of a human disease", and that under "Article 28(2) of Regulation No 1924/2006, as amended…a commercial communication appearing on the packaging of a food may constitute a trade mark or brand name, within the meaning of that provision, provided that it is protected, as a mark or as a name, by the applicable legislation") *Id*.; Shane Starling, *Loophole Free: EU's Highest Court Backs Health Claim Regulation in Disease Ruling*, NUTRAingredients.com (July 19, 2013), available at: http://www.nutraingredients.com/Regulation/Loophole-free-EU-s-highest-court-backs-health-claim-regulation-in-disease-ruling ("The ruling found Czech pharma-supplements firm, Green-Swan Pharmaceuticals, was indeed making un-backed osteoporosis disease risk factor reduction claims for a trademarked calcium-vitamin D3 product. In coming to that conclusion it affirmed that a disease risk factor reduction claim under the EU 2006 nutrition and health claims regulation (NHCR) could be implied and did not have to contain words like 'significant reduction' to fall under the remit of that law…The Court also confirmed the use of certain trademarks until 2022, if they existed before 2005 as is written in the NHCR. That was an affirmation that…may provoke revision among certain EU member states [which have disregarded the transition period], even though the ECJ ruling says it is member states who must first determine what is a valid trademark.") *Id*.

237 *See* Steve Hawkes, *Britons Being Ripped-off By 'Exaggerated' Food Supplement Claims*, The Telegraph (Aug. 22, 2013), available at: http://www.telegraph.co.uk/finance/personalfinance/consumertips/household-bills/10257475/Britons-being-ripped-off-by-exaggerated-food-supplement-claims.html ("[A] number of companies including Boots and Seven Seas were making 'ambiguous' claims about their effectiveness of their products on packaging to lure shoppers into buying their products. Other products such as Bioglan Probiotic capsules and Bimuno Prebiotic powder were using health claims, such as 'helps maintain digestive balance', that have been rejected as unproven by the European Union."); Denis Campbell, *Which? Attacks 'Exaggerated' Food Supplement Health Claims*, The Guardian (Aug. 22, 2013), available at: http://www.theguardian.com/science/2013/aug/22/which-health-supplements-misleading ("Some manufacturers – including well known names such as Boots, Seven Seas and Vitabiotics – are still helping to sell their products through 'clever language' that confuses buyers, despite the EU having outlawed such practices, according to research by the consumer organisation Which?. It looked at a number of popular supplements and assessed whether the claims made on their packaging were in line with what the EU's European Food Safety Authority (Efsa) allows. In its opinion, three types of supplement – Bioglan Probiotic capsules, Bimuno Prebiotic powder and Seven Seas Cardiomax – 'made unproven health claims on their packaging and websites'."). *Id*.; Eat Well Global, *IFT 2013: Much Ado About Probiotics – Increasing Popularity in the Face of Labeling Controversy* (July 30, 2013), available at: http://eatwellglobal.com/ift-2013-much-ado-about-probiotics-increasing-popularity-in-the-face-of-labeling-controversy-2/.

238 *See* Shane Starling, *Ireland: Even Terms Like 'Live Cultures' Are Implied (&Banned) EU Probiotic Health Claims*, NUTRAingredients.com (June 5, 2013), available at: http://www.nutraingredients.com/Regulation/Ireland-Even-terms-like-live-cultures-are-implied-banned-EU-probiotic-health-claims ("Since no probiotic has yet won a health claim under the EU nutrition and health claim regulation (NHCR), monikers like 'probiotic' are banned in marketing and promotional materials to consumers, although there has been some debate about terms like 'live cultures'.") *Id*.; Sarah Schmidt, *'Prebiotics' Food Label Under Scrutiny*, The Star Phoenix (May 9, 2012), available at: http://www2.canada.com/saskatoonstarphoenix/news/story.html?id=3b9a4438-20ce-4149-8dd7-83a2180a487c ("Some foods with 'prebiotics' will likely have to drop the health claim because they may not meet the government's proposed labelling rule, Health Canada is warning the food industry. In response to the explosion of food products with 'prebiotics' on their labels and in advertisements, Health Canada has concluded the use of the term is an implied health claim."). *Id*.; Shane Starling, *UK Dept of Health: 'Contains Glucosamine' an Implied Health Claim*, NUTRAingredients.com (Feb. 20, 2012), available at: http://www.nutraingredients.com/Regulation/UK-Dept-of-Health-Contains-glucosamine-an-implied-health-claim ("The UK Department of Health has indicated nutrition-sytle claims like 'contains glucosamine' or 'contains probiotics' will be deemed implied health claims if they are the subject of negative EFSA opinions.") *Id*.

labeling and advertising claims have not, in and of themselves, given governments cause for concern.

In this regard, the European Food Safety Authority ("EFSA") has managed to approve several health and/or nutrition claims made by formula milk manufacturers. For example, during 2009, EFSA ruled that a formula manufacturer was able to scientifically substantiate that omega-3 forms, docosaheaenoic acid (DHA) added to its proprietary formula could benefit eye health (visual development) in infants up to the age of twelve months.[239] Said manufacturer was also permitted to label its product "with the logo of a child's eye and the words 'proven to support visual development'," [240] which raised objections from breastfeeding activist groups 'concerned' that such claims could cause consumer confusion between such products and infant formula.[241] During 2010, EFSA ruled that a formula manufacturer was able to scientifically substantiate that thiamin (vitamin B1) added to its proprietary follow-on formula, growing-up milk/toddlers milk and cereal-based weaning foods intended for children from birth to three years, "plays and important role in the carbohydrate and energy metabolism of food".[242] During 2011, EFSA ruled that one formula

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239 *See* Shane Starling, *EFSA On Omega-3 Claims: Yes to Eye Health, No to Brain*, NUTRAingredients.com (March 24, 2009), available at: http://www.nutraingredients.com/Regulation/EFSA-on-omega-3-claims-yes-to-eye-health-no-to-brain ("The French arm of Mead Johnson Nutritionals has had two omega-3 eye health claims approved by the European Food Safety Authority (EFSA), but had three infant brain health claims turned down by the scientific assessor.") *Id*. This application had been submitted pursuant to Article 14 of Regulation (EC) No 1924/2006 via the Competent Authority of France. *See* European Food Safety Authority, EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), *Opinion of the Scientific Committee/Scientific Panel - EFSA-Q-2008-688*, EFSA Journal (March 13, 2009), available at: http://www.efsa.europa.eu/en/efsajournal/pub/1003.htm; http://www.efsa.europa.eu/en/efsajournal/doc/1003.pdf ("The following wording reflects the scientific evidence: 'DHA contributes to the visual development of infants'. In order to bear the claim a formula should contain at least 0.3% of the total fatty acids as docosahexaenoic acid. Such amounts can be easily consumed as part of a balanced diet. The target population is infants (formula-fed infants born at term from birth up to 12 months and breastfed infants after weaning up to 12 months."). *Id*.

240 *See* Bruno Waterfield, *EU Rules Formula Milk Can Claim It Is As Healthy as Breast Feeding*, The Telegraph (April 6, 2011), available at: http://www.telegraph.co.uk/news/worldnews/europe/eu/8432808/EU-rules-formula-milk-can-claim-it-is-as-healthy-as-breast-feeding.html ("There was anger on Wednesday after a vote in the European Parliament failed by eight votes to muster enough support to prevent a claim that formula milk can improve a baby's eyesight...But the same claim for the synthetic version of DHA used in formula milk is disputed by experts, including WHO and Royal College of Paediatrics and Child Health, who fear it could mislead mothers... Advice given to MEPs by the WHO found that to 'date no solid evidence exists to be able to say that adding DHA to infant formula will have important clinical benefits'. 'General promotion of these products may induce mothers to use infant formula in the first six months of life and/or stop continued breast feeding after this period,' warned the UN public health body. Unicef also predicted that allowing the claims would 'undermine' efforts to promote breast feeding. "There can be little doubt that the use of such health claims can mislead parents into thinking that the formulas are as good as, if not better than breast milk," said Dr Nicholas Alipui, director of programmes at UNICEF.

241 *See* Ben Bouckley, *Baby Milk Campaign Group Claims EFSA Oversight in DHA Approval*, NUTRAingredients.com (Feb. 18, 2011), available at: http://www.nutraingredients.com/Regulation/Baby-milk-campaign-group-claims-EFSA-oversight-in-DHA-approval ("An approved EFSA claim[] that omega-3 form DHA contributes to the visual development of infants risks misleading consumers, due to a committee oversight in approving the relevant health claim, says UK-based breast-feeding advocacy group Baby Milk Action").

242 *See* European Food Safety Authority, EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), *Opinion of the Scientific Committee/Scientific Panel - EFSA-Q-2008-183*, EFSA Journal (July 9, 2010), available at: http://www.efsa.europa.eu/en/efsajournal/pub/1690.htm; http://www.efsa.europa.eu/en/efsajournal/doc/1690.pdf ("Following an application from IDACE submitted pursuant to Article 14 of Regulation (EC) No 1924/2006 via the Competent Authority of France, the Panel on Dietetic Products, Nutrition and Allergies was asked to deliver an opinion on the scientific substantiation of a health claim related to thiamine and carbohydrate and energy-yielding metabolism…The following wording reflects the scientific evidence: 'Thiamine contributes to normal carbohydrate and energy-yielding metabolism'…The Panel considers that, in order to bear the claim, follow-on formulae should comply with the criteria of composition of follow-on formulae as laid down in Directive 2006/141/EC… processed cereal-based foods for infants and young children should comply with the criteria of composition of these foods as laid down in Directive 2006/125/EC; other foodstuffs intended for infants and

manufacturer was able to scientifically substantiate that alpha-linolenic acid added to proprietary follow-on formula was "an essential fatty acid [that] contributes to brain and nerve tissue development" in infants and children from birth to three years.[243] During 2013, EFSA ruled that a single formula manufacturer, in three separate claims, was able to scientifically substantiate that iron, magnesium and vitamin A added to proprietary follow-on formula and cereal-based foods for infants and young children (from birth to three years), respectively, "contributes to normal cognitive development",[244] "contributes to normal development of bone",[245] and "contributes to the normal function of the immune system".[246]

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young children should provide at least 15 % of the reference values for nutrition labelling for foods intended for infants and young children as laid down in Directive 2006/125/EC; all other foodstuffs should be at least a source of thiamine as per Annex to Regulation (EC) No 1924/2006."). *Id*.

243 *See* European Food Safety Authority, EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), *Opinion of the Scientific Committee/Scientific Panel - EFSA-Q-2009-00197*, EFSA Journal (March 25, 2011), available at: http://www.efsa.europa.eu/en/efsajournal/pub/2130.htm; http://www.efsa.europa.eu/en/efsajournal/doc/2130.pdf ("Following an application from HiPP GmbH & Co Vertrieb KG submitted pursuant to Article 14 of Regulation (EC) No 1924/2006 via the Competent Authority of Germany, the Panel on Dietetic Products, Nutrition and Allergies was asked to deliver an opinion on the scientific substantiation of a health claim related to alpha-linolenic acid and contribution to brain and nerve tissue development…The Panel considers that, in order to bear the claim follow-on formulae should comply with the criteria of composition of follow-on formulae as laid down in Directive 2006/141/EC; other foodstuffs intended for infants and young children should contain a minimum of 15 % of the adequate intake of 0.5 E %. Such amounts can be easily consumed as part of a balanced diet. The target population is infants and children up to three years.") *Id*.

244 *See* European Food Safety Authority, EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), *Opinion of the Scientific Committee/Scientific Panel - EFSA-Q-2008-199*, EFSA Journal (July 11, 2013), available at: http://www.efsa.europa.eu/en/efsajournal/pub/3335.htm; http://www.efsa.europa.eu/en/efsajournal/doc/3335.pdf ("Following an application from IDACE, submitted pursuant to Article 14 of Regulation (EC) No 1924/2006 via the Competent Authority of France, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to iron and contribution to normal cognitive development…The Panel considers that, in order to bear the claim, follow-on formulae should comply with the criteria of composition of follow-on formulae as laid down in Directive 2006/141/EC…processed cereal-based foods for infants and young children should comply with the criteria of composition of these foods as laid down in Directive 2006/125/EC; other foodstuffs intended for infants and young children should provide at least 15 % of the reference values for nutrition labelling for foods intended for infants and young children as laid down in Directive 2006/125/EC. Such amounts can be easily consumed as part of a balanced diet. The target population is infants and children up to three years.") *Id*.

245 *See* European Food Safety Authority, EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), *Opinion of the Scientific Committee/Scientific Panel - EFSA-Q-2008-150*, EFSA Journal (July 11, 2013), available at: http://www.efsa.europa.eu/en/efsajournal/pub/3331.htm; http://www.efsa.europa.eu/en/efsajournal/doc/3331.pdf ("Following an application from IDACE, submitted pursuant to Article 14 of Regulation (EC) No 1924/2006 via the Competent Authority of France, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to magnesium and contribution to normal development of bone…The Panel considers that the following wording reflects the scientific evidence: 'Magnesium contributes to normal development of bone'...The Panel considers that, in order to bear the claim: follow-on formulae should comply with the criteria of composition of follow-on formulae as laid down in Directive 2006/141/EC…processed cereal-based foods for infants and young children should comply with the criteria of composition of these foods as laid down in Directive 2006/125/EC; other foodstuffs intended for infants and young children should provide at least 15 % of the reference values for nutrition labelling for foods intended for infants and young children as laid down in Directive 2006/141/EC.") *Id*.

246 *See* European Food Safety Authority, EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), *Opinion of the Scientific Committee/Scientific Panel - EFSA-Q-2008-160*, EFSA Journal (July 10, 2013), available at: http://www.efsa.europa.eu/en/efsajournal/pub/3334.htm; http://www.efsa.europa.eu/en/efsajournal/doc/3334.pdf ("Following an application from IDACE, submitted pursuant to Article 14 of Regulation (EC) No 1924/2006 via the Competent Authority of France, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to vitamin A and contribution to normal development and function of the immune system…The Panel considers that the following wording reflects the scientific evidence: 'Vitamin A contributes to the normal function of the immune system'…The Panel considers that, in order to bear the claim: follow-on formulae should comply with the criteria of composition of follow-on formulae as laid down in Directive 2006/141/EC…processed cereal-based foods for infants and young children should comply with the criteria of composition of these foods as laid down in Directive

By comparison, the PH BMS Framework totally prohibits all health and nutrition claims and the use of superlatives in trademarks and brand names. It has also signaled that health and nutrition claims will be inferred from trademark, logo and brand name use for the purpose of denying such claims entirely. This strongly suggests that the Philippine Government continues to be unduly influenced and intimidated by the WHO, UNICEF and breastfeeding activists. These stakeholders have effectively called for the rejection of evolving science relied upon by governments in evaluating health and nutrition claims made with respect to follow-on formula and complementary food products because they are concerned that such science will ultimately undermine their breastfeeding agenda-based campaigns.[247] Unfortunately, these stakeholders selectively choose to ignore how the emotion-laden politics of breastfeeding absolutism can serve to undermine the primary objective of the PH BMS Framework and the WHO Code, not to mention the WHO Global Strategy on Infant and Young Child Feeding.

The PHDOH's reticence to consider such claims in service to these constituencies arguably compromises the health and nutrition (development) of infants and young children in the Philippines. As previously discussed, the Philippines suffer from serious indigenous institutional, industrial, agricultural and infrastructure limitations that have rendered it unable to achieve the PH BMS Framework's policy objectives. Such breastfeeding absolutism also strategically ignores how the WHO Code does not apply to (cover) follow-up formula and complementary food products marketed and/or intended exclusively for use as breastmilk *supplements* by infants 6-12 months of age and older. This is especially true where precautions have been taken to ensure that trademarks, logos and brandnames used in follow-up formula advertising and labeling do not lead to consumer confusion between such products and bona fide breastmilk substitutes intended for use by infants up to 6 months of age.

In sum, the UK BMS Framework (in implementation of the evolving EU Framework) creates little risk of nonfulfillment because it imposes trademark-use encumbrances that are largely consistent with the WHO Code. These trademark-use encumbrances are designed only to curtail the marketing of follow-on formula products for use by infants *up to 6 months of age* in order to ensure that breastfeeding and breastmilk are not discouraged or undermined. They are not designed to cover follow-on formula products or complementary food products that are specifically advertised, labeled and presented for use by older infants and young children *over 6-12 and 12-36 months of age*, the marketing practices concerning which the WHO Code was never intended to address.

2006/125/EC; other foodstuffs intended for infants and young children should provide at least 15 % of the reference values for nutrition labelling for foods intended for infants and young children as laid down in Directive 2006/125/EC.") *Id*.

247 *See* Bruno Waterfield, *EU Rules Formula Milk Can Claim It Is As Healthy as Breast Feeding*, The Telegraph (April 6, 2011), supra. "There was anger on Wednesday after a vote in the European Parliament failed by eight votes to muster enough support to prevent a claim that formula milk can improve a baby's eyesight...But the same claim for the synthetic version of DHA used in formula milk is disputed by experts, including WHO and Royal College of Paediatrics and Child Health, who fear it could mislead mothers...Advice given to MEPs by the WHO found that to 'date no solid evidence exists to be able to say that adding DHA to infant formula will have important clinical benefits'. *'General promotion of these products may induce mothers to use infant formula in the first six months of life and/or stop continued breast feeding after this period,' warned the UN public health body. Unicef also predicted that allowing the claims would 'undermine' efforts to promote breast feeding. 'There can be little doubt that the use of such health claims can mislead parents into thinking that the formulas are as good as, if not better than breast milk,' said Dr Nicholas Alipui, director of programmes at UNICEF*" (emphasis added). *Id*.

IV. Conclusion

The prior discussion presents sufficient *prima facie* evidence to show that the various integrated legal instruments comprising the PH BMS Framework that impose trademark-use restrictions and/or prohibitions on follow-up formula and complementary food product advertising, labeling and packaging materials constitute special requirements within the meaning of TRIPS Article 20. *Prima facie* evidence has also been adduced establishing that these special requirements are more trademark-use encumbering, and thus, more trade-restrictive than necessary to achieve the PH BMS Framework objectives of protecting public health via protection of breastfeeding and protecting consumers via prevention of deceptive advertising and labeling practices that can mislead consumers and discourage breastfeeding.

As a result, the Government of the Philippines now bears the burden of proving that these special requirements are "necessary" under TRIPS Article 8.1 and 8.2, and thus, "justified" encumbrances of legitimate trademark uses (i.e., "legitimate interests") under TRIPS Article 20. In satisfying its burden of proof, the Philippine Government must remember that since fanciful, arbitrary and/or suggestive marks are deserving of greater legal protection than descriptive or generic marks, it will need to meet a relatively higher evidentiary threshold with respect to them.[248]

The Philippine Government will have difficulty establishing necessity because various PH BMS Frameworks provisions are themselves incapable of achieving the framework's policy objectives. For example, because the PH BMS Framework does not permit BMS product express or implied health or nutrition claims, including those incorporating trademarks, logos and brand names (because of a presumption that they are misleading, idealize such products, and will undermine breastfeeding), Filipinos have been deprived of their consumer rights to information and their right to freedom of choice, and remain relatively uneducated about such products and less able to discern if and when to use them. In addition, few if any PH BMS Framework measures ensure that follow-on formula labeling, advertising and packaging incorporating trademarks, logos and brand names are sufficiently distinguishable from infant formula labeling, packaging and advertising to prevent follow-on formula from being passed-off as infant formula in the Philippine marketplace.

Evidence has also been adduced showing that the advertising/marketing and labeling provisions of the UK BMS Framework which incorporate trademark-use encumbrances present a reasonably available less trademark-use restrictive alternative which would pose little risk to the fulfillment of the PH BMS Framework's public policy objectives at the Philippine Government's chosen level of protection. As a result, the Philippine Government bears the evidentiary burden of showing that the UK BMS Framework does not constitute such an alternative in light of the risks that nonfulfillment would create. The satisfaction of this burden, however, will be quite difficult.

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248 *See, e.g.*, United States Patent and Trademark Office, *Protecting Your Trademark – Enhancing Your Rights Through Federal Registration: Basic Facts About Trademarks* (2012), available at: http://www.uspto.gov/trademarks/basics/BasicFacts.pdf. *See also* Berkman Center for Internet & Society, *Frequently Asked Questions (and Answers) about Trademark: What to Expect When You're Expecting to Be Sued for Trademark Infringement, Chilling Effect*, available at: http://chillingeffects.org/trademark/faq.cgi.

The UK BMS Framework has gone to considerable lengths to ensure that follow-on formula product advertising and labeling materials incorporating trademarks, logos and brand names do not idealize such products relative to breastfeeding, and that such products are sufficiently identifiable and distinguishable from infant formula products to prevent against consumer confusion that can lead to follow-on formula products being passed-off as infant formula. In addition, the UK BMS Framework recognizes and permits some express and implied health or nutrition claims in follow-on formula product labeling, packaging and advertising, including claims entailing the use of trademarks, logos and brand names, that can be proven by evolving science. This would serve to educate Filipino consumers and allow them to discern and discount the types of false, misleading or otherwise deceptive advertising or labeling practices that could undermine or discourage breastfeeding and breastmilk.

The Government of the Philippines must recognize that the policy space it is afforded to pursue public interest objectives such as public health and nutrition and consumer protection from unfair trade practices is circumscribed by the scope of trademark owners' rights and legitimate interests, and that *these constraints apply equally to developing country WTO Members*. TRIPS Article 8 states explicitly that member governments may adopt measures only if they are necessary for those purposes, and only if they are TRIPS-consistent. Even paragraph 3 of the Doha Decision of 2003 implementing paragraph 6 of the Doha Declaration generally acknowledges that, while governments have the right to impose measures that expropriate intellectual property rights in furtherance of the public good, the TRIPS Agreement requires them to ensure that any limitations they impose on such private rights and interests will be adequately compensated.

The Government of the Philippines must also remain vigilant to ensure that whatever public interest BMS product marketing legislation finally emerges from the new Philippine Congress[249] contains trademark-use restrictions that are consistent with the terms of the WTO TRIPS Agreement.

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249 *See* Lawrence A. Kogan, *The Philippines Breastmilk Substitute/Supplement Marketing Framework Violates WTO Law* (Part 1 of 2), LexisNexis 2013 Emerging Issues ("Part 1"), at Sec. IV.2.

National Foreign Trade Council and its membership concerning the interplay between international trade rules and food safety, health and environmental regulations.