The Competition Assessment of Plain Packaging Restrictions

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Part Ⅰ. Issues

1. Introduction

This article shall examine the regulatory impact analysis of Plain Packaging restrictions of tobacco products.

Plain Packaging laws restricts or prohibits printing any logo, colours, image and promotional information except the name of the brand and products which use standard colours and fonts. The "WHO Framework Convention on Tobacco Control (hereafter FCTC)" provides in Article 11 (Packaging and labelling of tobacco products) and Article 13 (Tobacco advertising, promotion and sponsorship) as follows:

FCTC Article 11
Packaging and labelling of tobacco products

1. Each Party shall, within a period of three years after entry into force of this Convention for that Party, adopt and implement, in accordance with its national law,

effective measures to ensure that:

(a) tobacco product packaging and labelling do not promote a tobacco product by any means that are false, misleading, deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions, including any term, descriptor, trademark, figurative or any other sign that directly or indirectly creates the false impression that a particular tobacco product is less harmful than other tobacco products (*underline added*). These may include terms such as "low tar", "light", "ultra-light", or "mild"; and

(b) each unit packet and package of tobacco products and any outside packaging and labelling of such products also carry health warnings describing the harmful effects of tobacco use, and may include other appropriate messages. These warnings and messages:

(i) shall be approved by the competent national authorities,

(ii) shall be rotating,

(iii) shall be large, clear, visible and legible,

(iv) should be 50% or more of the principal display areas but shall be no less than 30% of the principal display areas,

(v) may be in the form of or include pictures or pictograms.

2. Each unit packet and package of tobacco products and any outside packaging and labelling of such products shall, in addition to the warnings specified in paragraph 1(b) of this Article, contain information on relevant constituents and emissions of tobacco products as defined by national authorities.

3. Each Party shall require that the warnings and other textual information specified in paragraphs 1(b) and paragraph 2 of this Article will appear on each unit packet and package of tobacco products and any outside packaging and labelling of such products in its principal language or languages.

4. For the purposes of this Article, the term "outside packaging and labelling" in relation to tobacco products applies to any packaging and labelling used in the retail sale of the product.

Article 13

Tobacco advertising, promotion and sponsorship

1. Parties recognize that a comprehensive ban on advertising, promotion and sponsorship would reduce the consumption of tobacco products.

2. Each Party shall, in accordance with its constitution or constitutional principles, undertake a comprehensive ban of all tobacco advertising, promotion and sponsorship (underline added). This shall include, subject to the legal environment and technical means available to that Party, a comprehensive ban on cross-border advertising, promotion and sponsorship originating from its territory. In this respect, within the period of five years after entry into force of this Convention for that Party, each Party shall undertake appropriate legislative, executive, administrative and/or other measures and report accordingly in conformity with Article 21.

3. A Party that is not in a position to undertake a comprehensive ban due to its constitution or constitutional principles shall apply restrictions on all tobacco advertising, promotion and sponsorship (underline added). This shall include, subject to the legal environment and technical means available to that Party, restrictions or a comprehensive ban on advertising, promotion and sponsorship originating from its territory with cross-border effects. In this respect, each Party shall undertake appropriate legislative, executive, administrative and/or other measures and report accordingly in conformity with Article 21.

4. As a minimum, and in accordance with its constitution or constitutional principles, each Party shall:

(a) prohibit all forms of tobacco advertising, promotion and sponsorship that promote a tobacco product by any means that are false, misleading or deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions (underline added);

(b) require that health or other appropriate warnings or messages accompany all tobacco advertising and, as appropriate, promotion and sponsorship;

(c) restrict the use of direct or indirect incentives that encourage the purchase of tobacco products by the public;

(d) require, if it does not have a comprehensive ban, the disclosure to relevant governmental authorities of expenditures by the tobacco industry on advertising, promotion and sponsorship not yet prohibited. Those authorities may decide to make those figures available, subject to national law, to the public and to the Conference of

the Parties, pursuant to Article 21;

(e) undertake a comprehensive ban or, in the case of a Party that is not in a position to undertake a comprehensive ban due to its constitution or constitutional principles, restrict tobacco advertising, promotion and sponsorship on radio, television, print media and, as appropriate, other media, such as the internet, within a period of five years; and

(f) prohibit, or in the case of a Party that is not in a position to prohibit due to its constitution or constitutional principles restrict, tobacco sponsorship of international events, activities and/or participants therein.

5. Parties are encouraged to implement measures beyond the obligations set out in paragraph 4.

6. Parties shall cooperate in the development of technologies and other means necessary to facilitate the elimination of cross-border advertising.

7. Parties which have a ban on certain forms of tobacco advertising, promotion and sponsorship have the sovereign right to ban those forms of cross-border tobacco advertising, promotion and sponsorship entering their territory and to impose equal penalties as those applicable to domestic advertising, promotion and sponsorship originating from their territory in accordance with their national law. This paragraph does not endorse or approve of any particular penalty.

8. Parties shall consider the elaboration of a protocol setting out appropriate measures that require international collaboration for a comprehensive ban on cross-border advertising, promotion and sponsorship.

On November 11, 2011, the Parliament of Australia enacted the Tobacco Plain Packaging Act[1)]. Since the Plain Packaging Act is today considered the strictest regulation of tobacco packaging in the world, this article shall focus on

1） The legislation comprises two Acts. Before the two Acts were enacted, they were named the "Tobacco Plain Packaging Bill 2011" and the "Trademarks Amendment (Tobacco Plain Packaging) Bill 2011". Hereafter, this article shall refer to the two acts as the "Plain Packaging Act 2011" and the "Trademarks Amendment Act 2011". Moreover, the legislation shall be referred as the "Plain Packaging Act". Plain Packaging Act 2011 are available at: <http://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;query=Id%3A%22legislation%2Fbillhome%2Fr4613%22>〔2013年4月閲覧（last visited April 2013）〕

the circumstances in Australia, The purpose of this article is to examine Plain Packaging restrictions from the perspective of Regulatory Impact Analysis. Regulatory Impact Analysis (hereafter RIA) is a measure of each department of the government "to improve objectivity and transparency of decision-making by objectively analyzing potential impact, such as the costs and benefits arising from regulatory policy when enacted or revised[2)]". Competition assessment was also introduced in Japan as one of the analyses in October in 2007[3)].

However, since the measure is not completely established, RIA for competition assessment is not often used in Japan. Hence, the Ministry of Internal Affairs and Communications of Japan and the Fair Trade Commission developed and adopted a simple assessment method based on the OECD's Competition Assessment Toolkit. The assessment method is simple and qualitative for the convenience of each department.

When analyzing the impact of the Plain Package regulation, "competition assessment" to analyze the impact on the competitive situation in the trade is necessary. The "competition assessment" should not be just a checklist. It should be a cost-benefit analysis. This is because it is desirable that RIA is used as a measure which maintains the necessity of the restriction and enhances competition. .

In Part II, this article will introduce the general framework of analysis of RIA. In Part III, this article will examine impact analysis of Plain Packaging restrictions from the perspective of competition policy.

Part Ⅱ. Framework of Regulatory Impact Analysis (RIA) and Plain Packaging

2-1. OECD Board of Directors Advice

Regulations restrict the rights and freedoms of citizens and impose obligations on citizens in order to accomplish administrative purposes, e.g.

2)　"three year program of promotion of regulatory reform and public private partnership"（March19, 2004）

3)　In Japan, Government Policy Evaluations Act (Act No. 86 of 2001) was enacted.

maintenance of the public order, protection of life, conservation of environment, and consumer protection. This is also the case with the Plain Packaging regulations discussed in this article. Therefore, it is important to enhance the quality of regulation and to gain recognition of stakeholders or citizens through assessment in advance and publication of the results. Thus, regulatory impact analysis in advance takes on a very important role.

Advance regulatory analysis foresees regulatory effects and analyzes risks. In implementation, the analysis must be able to contribute to the examination of propriety of establishment, reform, or abolition of regulation as well as the details and degree of regulation[4].

Considering the global movement of RIA, the OECD Competition Committee created a Competition Assessment Toolkit to assess regulatory impact in RIA in January 2007. Then, in February 2008, the OECD Competition Committee Conference decided to precede working for formulating Recommendation on Competition Assessment to introduce competition assessment under RIA. After a series of discussions, the Toolkit was approved by documents and adopted by Council in October 22, 2011[5].

Then, the OECD Recommendation provided a unified framework of RIA. The abstract of the Recommendation is as follows:

(1) "Identification of Existing or Proposed Public Policies that Unduly Restrict Competition [I.A of the Recommendation]"

In this section, the OECD requires governments of parties to "introduce an appropriate process to identify existing or proposed public policies that unduly restrict competition and develop specific and transparent criteria for performing competition assessment, including the preparation of screening devices [I.A of the Recommendation]." Specifically, it shows examples of policies to which governments should give particular attention in performing competition assessment.

4） See, Interministerial Liaison Meeting on Policy Evaluation, "Implementation Guidelines for ex-ante Evaluation of Regulations", (August 24, 2007)

5） Published on the webpage of the OECD Competition Committee on November 17, 2008. See <http://www.oecd.org/document/10/0,3746,en_2649_40381664_44080714_1_1_1_1,00.html>〔2013 年 4 月閲覧（last visited April 2013）〕

(2) "Revision of Public Policies that Unduly Restrict Competition [I.B of the Recommendation]."

In this section, the OECD "requires governments of the parties to introduce an appropriate process for revision of existing or proposed public policies that unduly restrict competition and develop specific and transparent criteria for evaluating suitable alternatives [I.B.1 of the Recommendation]" and "adopt the more pro-competitive alternative [I.B.2 of the Recommendation]".

(3) "Institutional Setting [I.C of the Recommendation]."

In this section, the OECD requires governments of the parties to make competition assessment incorporated into policy making process in an efficient manner.

In the Recommendation, OECD requires that "In performing competition assessment, governments should give particular attention to policies that limit:
i)The number or range of market participants;
ii)The actions that market participants can take;
iii)The incentives of market participants to behave in a competitive manner;
iv)The choices and information available to consumers [I.A.2 of the Recommendation]."

Moreover, the OECD requires that assessment should confirm that there are no other reasonable, less anticompetitive ways to intervene when policies introduce a price or entry regulation scheme. Namely, it is provided that governments shall adopt more pro-competitive alternative consistent with the public interest objectives pursued and take into account the benefits and costs of implementation.

2-2. Current circumstances of adoption in Australia[6)]

The history of RIA in Australia begins with the "Competition Principles Agreement" which was recognised as part of a "National Competition Policy" between the federal government and states. The Competition Principles Agreement is innovative since it requires all relevant regulations which have impact on competition should be examined with the cost-benefit analysis. Therefore, competition restriction is not permitted except it is proved that the benefit to society brought by the restriction is more effective than its cost and that the purpose of the regulation is accomplished by the restriction. After that, RIA in Australia was greatly revised in 2006 and 2007. Now, the guideline, "Best Practice Regulation Handbook" is established and RIA in Australia is based on that.

In Australia, RIA is implemented in regulations relevant to public health, particularly the regulation of medical services. In 2009, RIA was conducted to analyze the regulation of chiropractic care enacted by the Office of Best Practice Regulation which is under the control of the Department of Finance and Deregulation. RIA was conducted since the provisions of the Regulation were different in each state (e.g. there was no regulation in Victoria although there was a regulation of commencement of business in the other states which provided registration system for judo therapists). The three options presented by the Office of Best Practice Regulation were as follows: ① to provide regulation of judo therapy on the neck throughout Australia, ② to provide regulation of judo therapy for all parts of body throughout Australia and ③ not to provide unified regulation of judo therapy. The Office decided that option ② was desirable. The reason was that in the option ②, it is possible to provide nation-wide regulation considering the public benefit because judo therapy for the cervical spine, which serves an important function of body, is a therapy related to human life. In addition, it was also intended to mitigate the impact of regulation of commencement of business enacted in the other states and to

6） See Rumi Tanaka "RIA at Victoria in Australia", Hyouka Quarterly, No.9, 2009, p.66

introduce competition into the in judo therapy service more broadly. Thus, the decision was intended to balance those factors.

As to Plain Packaging, a report of tobacco regulation enacted by the Department of Health and Ageing[7] discussed an increase of the tobacco tax and recommended it to stop or moderate smoking. In addition, Plain Packaging was discussed in past RIA reports.[8].

Part Ⅲ. Competition Assessment for Plain Packaging

3.1 Plain Packaging's impacts on competition of sale of tobacco.

(1) Effect to restrict advertisement (representation) or use of tobacco.

The aforementioned frame work of RIA in the recommendation and attempts to implement RIA in Australia are conformable with the evaluation in Act on Prohibition of Private Monopolization and Maintenance of Fair Trade (hereafter Anti-Monopoly Act). Namely, since the purpose of the Anti-Monopoly Act is to maintain fair competitive order, it shall be judged whether acts, which fall within the scope of requirements of the act in each provision of the Act, fulfill the requirements "unjustifiable" or "without justifiable reason" (unfair trade practice), by means of taking into account intention, purpose, condition, condition of competition relationships or circumstances of markets from the perspective of maintaining fair competitive order. The problem in Plain Packaging is that advertisements or representations on the packaging serve as a competitive measure through the brand. Obviously, advertisement and representation are two of the most significant competitive means to evoke consumer demand. Therefore, restricting information related to consumer

7）As to the relevant documents, see the webpage of the Australian Department of Health.
http://www.health.gov.au/internet/ministers/publishing.nsf/Content/mr-yr11-nr-nr243.htm〔2013 年 4 月閲覧〕(last visited April 2013)

8）See "Global Tobacco The Plain Risk to Global Tobacco"
http://www.smoke-free.ca/plain-packaging/documents/2011/Philip%20Morris%20-%20Annex%2012%20-%20Bloomquist,%20Berenberg%20Bank%20-%20The%20Plain%20Risk%20to%20Global%20Tobacco%20-%2021%20March%202011.pdf
〔2013 年 4 月閲覧〕(last visited April 2013)

preference by restricting the medium, frequency, place, contents, etc. of advertisement and representation of goods conducted by business persons is equal to depriving these persons of a significant means of competition. On the other hand, if a regulation of advertisement and representation enacted by a country is acknowledged as a means to enable consumers to make reasonable decisions, e.g. eliminating false or exaggerated advertisements or providing about minimum information which should be advertised to consumers, the regulation is not an issue under competition policy.

There is no doubt that brand advertisement and representation on the packaging of tobacco is a significant means of competition. Where the restriction stifles competition , the problem is how to justify the effect. On this point, while they are not directly related to tobacco regulation, the two cases below are regarded as the most significant precedents which generally clarified that safety or social reasonableness should be considered when analyzing "intention, purpose and condition of the act". Furthermore, from the perspective of maintaining fair competitive order, most scholars support the view that "justifiability of the purpose" and "justifiability of the means" shall be examined to decide social reasonableness of the act. For reference, the two main cases in the Anti- Monopoly Act which dealt with social objectives and competition restraints will be mentioned as follows.

【Social Objectives and Competition Restriction】

1 The Air Soft Gun Kyoukai case (Tokyo District Court, judgment of April 9, 1997[9]).

（Summary of facts）

X is manufacturer of Air Soft Guns (hereafter AS Gun) and BBs. Y is a trade association, members of which are small-to- medium sized manufacturers of AS Gun. X is not a member of Y.

Y provided self-regulations on the power of AS Gun and weight of the BBs. Y obligated its partners to sell products which met the standard and

9） Hanrei-jihou No.1629 p.70

pasted specific seals. However, X did not participate in Y and sold new AS Guns. Y disturbed X's sale of new products.

X filed this suit against Y claiming breach of the Anti-Monopoly Act and commitment of civil tort.

（Summary of the judgment）

Y breached Anti Monopoly Act.

The disturbance in this case is the act which fulfills the criteria of unfair trade practice . The reason given is that the disturbance is the trade associations' act which pressured customers (wholesale dealers) to make retail stores refuse business with X who did not met the self-regulation standard.

The purpose of the standard is justifiable since it intended to ensure consumers' safety. Moreover, as the court noted, the contents of the standard are reasonable. However, its implementation method is not inappropriate. In the end, Y breached Article 8.1.5 of the Anti-Monopoly Act.

2 TOSHIBA elevator service case

Judgment of Osaka District Court on July 30, 1990. Judgment of Osaka High Court on July 30, 1993[10)].

（Summary of facts）

X1 ordered parts of an elevator installed in its own building from Y (a maintenance operator belonging to a large manufacturer) to repair the elevator. However, Y did not accept the order claiming that Y only accepted the order of parts associated with order of exchange, repair and adjustment. In addition, when X2 (an elevator maintenance operator) asked Y to repair an elevator in another company's building, although Y repaired temporarily, since parts were not delivered on time, an accident occurred . As a result, the building owner cancelled its maintenance contract with X2.

10） Collection of decisions No. 40, p.651

X1 and X2 claimed damages stating Y's refusal to supply and late delivery of parts were unfair trade practices and constituted the tort of breach of public policy. Y rebutted that the refusal to supply and late delivery of parts were not in breach of the Anti-Monopoly Act with claiming that the purpose of the conducts is to ensure elevatorsafety and high accuracy of work.

（Summary of Judgment）

Y's conducts were unfair trade practices. The ultimate purpose of Anti-Monopoly Act is to secure general consumers' interest and to enhance democratic and sound development of the national economy. The Act prohibits unfair trade practice to accomplish the purpose. Hence, not only other businesses which are in competitive relationships but also general consumers who trade or intend to trade with the businesses can get the benefits of free trade in free competition and that interest shall be protected.

So, when it comes to examining "justifiability of purpose" and "appropriateness of means" of Plain Packaging regulation, how should the regulation be evaluated? This point will be discussed in the next section.

3.2. The view of Plain Packaging regulation.

(1) "Purpose" of Plain Packaging regulation

Generally, there are regulations covering information, advertisement, representation or business operation which relate to public health for the purpose of ensuring a specific level of medical services and protecting patients' interests. Because public health is directly related to life and well-being, medical treatment is an essential service for citizens and there is an asymmetry of information between doctors, who are suppliers of medical services, and patients, who are consumers of medical services. Taking into account that smoking poses a serious risk which directly relates to life and health, there is no doubt that the purpose of Plain Packaging regulation is to discourage smoking and to reduce smoking by preventing smokers, particularly juvenile smokers,

from taking up the habit. Plain Packaging Act in Australia intends and aims to: ①reduce the appeal of tobacco products to consumers,②increase the effectiveness of health warnings on the retail packaging of tobacco products,③ reduce the ability of the retail packaging of tobacco products to mislead consumers about the harmful effects of smoking or using tobacco products, ④ discouraging people from taking up smoking, or using tobacco products, ⑤ encouraging people to give up smoking, and to stop using tobacco products, ⑥ discouraging people who have given up smoking, or who have stopped using tobacco products, from relapsing, ⑦ reducing people's exposure to smoke from tobacco products.

(2) "Contents (means)" of Plain Packaging regulation

The Plain Packaging Act of Australia provides requirements of packaging of tobacco products for retail sale and outer surface as follows[11]:①restriction of decoration on packaging of all tobacco products for retail sale, other than as permitted by the regulations,②requires all packaging of tobacco products for retail sale to be drab dark brown and to have matt finish in principle,③ prohibition on trademarks and marks[12],④requirements for brand, business, company or variant names. The Act provides that any supply or manufacture of tobacco products which is not in accordance with the requirements shall be applied civil penalty and criminal penalty.

(3) "appropriateness of means" :Protection for consumers from tobacco harm

Tobacco is popular product among adults. Since adults have the ability to decide for themselves, regulations for them are different from those for the protection of juveniles[13]. There are so many popular items which may cause

11） Part 2, Division 1, 18 – 25, and Division 2, 26.

12） Masabumi Suzuki, Domestic Measures for Public Health Policy and International IP/ Trade Law - the Case of the Australian Plain Packaging Act-, Nagoya University Journal of Law and Politics (名古屋大学法政論集) No.247, pp. 374-350(1-25)(Dec. 2012).

13） The Tobacco Institute of Japan issues IC cards "taspo" for adults. Juveniles cannot purchase tobacco at vending machines with adult identification which manages the card. "Name", "membership number" and "mugshot" on the center of the card take a

health concerns for excessive consumption (e.g., alcohol). Nonetheless, why should only tobacco comply with Plain Packaging Act? As the aforementioned Toshiba elevator service case found "general consumers can get the benefits of free trade in free competition and the interest shall be protected", consumers have a right to purchase tobacco through competitive sales and packaging (brand).

Of course, social regulation is essential for the life of the people and it is necessary to prevent the supply of inappropriate products which cause damage to peoples' health. However, except for the issue of distribution of forged tobacco products in developing countries (and the damage to health associated with that), it is difficult to consider the supply of tobacco products to be inappropriate if the products are regular ones. This is because the tobacco industry is subject to other regulations which require them to manage the contents or ingredients.

The issue is the sufficient supply of information about tobacco dependence (nicotine dependence) to consumers. Taking this into account, it is possible to eliminate supply of inappropriate information by acts which regulate representation such as the Act against Unjustifiable Premiums and Misleading Representations, the harm may be excluded by thorough disclosure to consumers and by disclosure of information by third-party assessment bodies or public institutions.

Certainly, when it takes time and money for consumers to analyze complicated information relating to medical knowledge like the health hazards of smoking, government incentives to keep consumers away from tobacco in the first place may work strongly. However, the possibility of consumers' attitude toward information processing alone cannot be sufficient reasons to justify the regulation.

Actually, as long as medical support for nicotine dependence (treatment for tobacco

role to make adult identification stricter by enhancing attribution of original person through clarifying user identification and preventing from transferring or lending the cards to the juveniles.

dependence, guidance on non-smoking or reduce smoking) is conducted actively[14] and consumers are provided with abundant information, even from the viewpoint of Plain Packaging regulation there is less possibility to cause unjustifiable harm to consumers.

(4) "appropriateness of means" :The problem of negative externality by passive smoking

One thing worth to note when considering consumer harm is the point that smoking accompanies "externality". Externality (external effect) means an action of an actor which brings a benefit or cost to other actors without compensation. An environmental problem is one contemporary example of the externality. For example, smoke from factories may harm the health of residents around the factory and polluted nearby buildings. If negotiations did not cost money and all property rights were defined clearly, government regulation would not be necessary and people could eliminate externalities through negotiations. Thus, externalities come from both the fact that transaction cost is expensive and the scope of property rights are not defined clearly when people try to achieve effective results through market transactions.

Although tobacco represents an externality, it is hasty to adopt Plain Packaging regulation just to control the externality. In order to solve the externality of tobacco, a variety of alternative measures are available such as smoking sections (means to reduce harm from passive smoking)[15], imposing sanctions on smoking on street[16] and so on. Moreover, it is necessary to ascertain whether Plain Packaging regulation is effective in solving the externality.

14） These days, many kinds of non-smoking or reducing smoking programs are introduced. As to the works of Ministry of Health, Labour and Welfare, see "information page relates to tobacco and health".
< http://www.mhlw.go.jp/topics/tobacco/main.html>
〔2013 年 4 月閲覧〕（last visited April 2013）

15） In Japan, Article 25 of Health Promotion Act requires supervisors of facilities which are used by many people to take necessary measures to prevent passive smoking.

16） Recently, some local governments (Tokyo Special Wards, Nagoya city and so on) provided ordinances for the prohibition of smoking on the street.

(5) Representation Restriction

In order for competition to work effectively, it is important to choose providers based upon the contents of their service or its representations. However, as with Plain Packaging regulations, if consumers can obtain goods only based on uniform representation, competition between tobacco traders will be in danger[17]. If only uniform representation is accepted, as improvements and devices on quality of service are not directly reflected to management, there may be no room for business innovation and the opportunity to provide effective service. It is necessary to establish regulations for ingredients and advocacy system for the disadvantages of tobacco to the public, and to permit private business to provide representation freely. Even if certain rules are necessary from the perspective of health (regulations requiring the printing of the possibility of health hazards brought by tobacco, etc), such rules should not unreasonably harm competition of the quality of goods or consumers' interests. Enterprises should be free to decide advertisements or representation of their products in general. When regulations for advertisement or representation are necessary, only the regulations which prohibit truly inappropriate representations should be permitted. In the above-stated recommendation, it is provided that "[i]n performing competition assessment, governments should give particular attention to policies that limit … [t]he choices and information available to consumers". It seems necessary to note that requiring everyone to observe Plain Packaging regulations may limit choices and information about popular products such as "tobacco" and deviate from "appropriateness of means".

Moreover, public financial support for education programs on the danger of smoking and preferential tax treatment for such programs should be discussed.

17） It goes without saying that sale competition of tobacco which is restricted by Plain Packaging does not include illegal trade or terms of trade, certain degree of tobacco sale competition through advertisement and representation shall be permitted as one of the right of businesses, "free business". The "Anti-Monopoly Act shall be considered as a modern embodiment of "free business…"（Tomoyoshi Okada "Monopoly and freedom of business" Kizawa-sya, 1975, p.107）

(6) Effect of restricting participation

Restricting advertisement and representation of products, which are significant competitive measures for the products beyond the regulation of the sale of tobacco to juveniles and objective regulation of quality or ingredients for providers, may reduce incentives of new comers to improve efficiency or ingenuity. In the field of social regulation, public bodies should provide regulations for sale or ingredients. Moreover, under the principles of competition, market entry should be accepted for new enterprises that fulfill specific requirements or objective standards. Under Plain Packaging regulations, the effect of restricting participation in the market is less efficacious for new comers who do not have brand.

Part Ⅳ. The problem of non-existence of quantitative analysis by Plain Packaging

As mentioned above, although it is recognized that Plain Packaging regulations have a "justifiability of purpose", there are many problems with regard to "appropriateness of means". Finally, the necessity and importance of quantitative analysis for Plain Packaging will be pointed out. When examining Plain Packaging regulations, it is necessary to adopt quantitative analysis of the benefits of the regulation. For example it seems possible to quantitatively estimate changes of smoking rates or the number of diseases that are effected by Plain Packaging regulation. For these kinds of estimates, measures for risk assessment may be available[18].

The first is whether the number of ex-smokers and the number of smokers who reduced their smoking increased and whether tobacco consumption decreased (and whether risk of lung cancer or other illnesses also decreased)[19]

18〉 See, Ministry of Internal Affairs and Communications Final Report of "Study group of regulatory policy assessment", September 26, 2007.

19〉 In England, Plain Packaging was not adopted since it is claimed, in the conference to discuss introduction of Plain Packaging in 2008, that there was no scientific basis to show Plain Packaging decreases the smoking rate.
House of Commons, December 16th 2008
<http://www.publications.parliament.uk/pa/cm200809/cmhansrd/cm081216/

as well as the causal relationship between these two facts[20]. If possible, the causal relationships should be indicated quantitatively. For example, quantitative analysis which noted that, "Smoking rates of people is reduced to 0% by Plain Packaging".

Moreover, it seems necessary to simulate the amount of benefit associated with each alternative regulation. For example, such a simulation would note how the risk of lung cancer is changed upon ①Plain Packaging, ②alternative regulation A and so on.

Of course, quantitative analysis and simulations may be difficult in practice. However, many kinds of indications are available since indications of benefit

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debtext/81216-0001.htm>〔2013 年 4 月閲覧〕（last visited April 2013）
Moreover, in 1995, by the request of Health Canada, specialists investigated effects of Plain Packaging for juveniles. However, the investigation did not produce specific conclusion.
http://www.plain-packaging.com/downloads/Canada_Expert_Panel_Report_-_When_Packages_Can't_Speak_Mar_95_-_excerpt.pdf〔2013 年 4 月閲覧〕(last visited April 2013)

20） Concerning the causal relationship between Plain Packaging and changes of smoking preference, some opinions argue about how brands on the Packagings affect smoking choices and how Plain Packaging enhances the effects of health warnings, reduces misunderstandings on health harm of cigarettes and lessen the smokers' attraction to brands.
See:- Germain D et al 2009, "Adolescents' perceptions of cigarette brand image: does plain packaging make a difference?", Journal of Adolescent Health, (2009) 1-8
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which relates to safety or environment have demonstrated a fabulous example of indications from a variable with which is directly dealt by regulations to a variable which can be obtained as the result of the dealing[21].

In any case, when regulations like Plain Packaging are adopted which limit advertisement and brand representation, it is necessary to analyze their effects though quantitative methods. Moreover, it is also necessary to ascertain whether there are alternative measures which are less restrictive to competition with equivalent regulatory results[22].

The potential health risks associated with smoking warrants more efforts to limit the practice. These efforts should be accelerated and necessary regulations should continue to be adopted. However, regulatory impact analysis which

21) For example, in case of regulation of strictly regulated drunken-driving, indications of the effect of the regulation can be: 1) an increase in the number of arrests, 2) a decrease of number of drunken-driving accidents, and 3) a decrease in causalities in drunken-driving accidents. All these indications are available. Judging from the purpose of regulation, it is desirable in the order 3), 2), 1). However, quantitative estimate becomes more difficult in the order 3), 2), 1). Also, in case of provisions to provide standard of levels of air pollutants emissions, indications of the effect of the regulation can be: 1) a reduction of emission, 2) a decrease of density of the air pollutants in the air, 3) a decrease of exposure and 4) a decrease in the number of of patients. From the viewpoint of the policy of the regulation, the order 4), 3), 2), 1) is desirable. However, quantitative estimate become more difficult in the order 4), 3), 2), 1). See Final Report supra note 18.

22) This is important because of Article 8 of TRIPS Agreement. It provides as follows:

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

By providing that, the Agreement permits members to take necessary measures to protect public health. However, in that case, "necessity" and "consistence with Agreement" are required. The "necessity" requires to examine ① whether there is a causal relationship between the measure and the purpose and ② whether there are some measures which are less restrictive. Since Plain Packaging has never been introduced, ① existence of causal relationship is unknown (whether Plain Packaging reduces smoking rate) and no study proofs the existence scientifically. ② There are less restrictive measures to protect public health, like education activity (prevention of juvenile smoking), health warnings, taxation policy, and so on.

Hence, it is possible to claim Plain Packaging is not a necessary measure to protect public health and is in breach of the Article.

considers all the relevant costs and benefits should be thoroughly contemplated.

【附記】

本稿は、同志社大学法学部・大学院法学研究科 2011 年度第 3 回法学会講演会「知的財産の国際的保護―プレーン・パッケージング法の検討を中心に―」（2011 年 12 月 15 日）の報告原稿を元にしている。貴重な機会を提供下さった高杉直・同志社大学教授をはじめ関係各位に心より感謝申し上げたい。なお、本稿は、科学研究費補助金･基盤研究（A）「知的財産と競争法分野における国際的な統合と分散化を調整するフレームワークの構築」（研究代表者：鈴木將文・名古屋大学教授、課題番号：24243019）等の研究助成による研究成果の一部である。

【追記】

本稿脱稿後、Tania Voon, Andrew D. Mitchell, Jonathan Liberman, Glyn Ayres, Public Health And Plain Packaging of Cigarettes : Legal Issues（2012, Edward Elgar）に接した。これを踏まえた検討は他日を期したい。