FRATINIVERGANO
EUROPEAN LAWYERS
TRADE PERSPECTIVES©

Issue No. 19 of 22 October 2010

Regulations on 'plain packaging' of cigarettes: a case of WTO 'plain inconsistency'?

The Australian Government has announced that it is considering the adoption of a regulation regarding the '*plain packaging*' (or '*generic packaging*') of cigarettes as part of its '*National Preventive Health Strategy*'. In particular, the regulation would provide for the mandatory use of the '*plain packaging*' for all cigarettes. Consequently, cigarettes' packaging would be standardised in their appearance and the brands would be indicated exclusively by the simple text of their names, without any combination of colour or signs. This measure poses controversial issues between the public interests to protect health on the one side, and, on the other side, WTO obligations regarding the trade in products such as cigarettes, as well as trademark holders' rights and the applications by WTO Members of technical regulations that may amount to non-tariff barriers.

The consideration by governments of '*plain packaging*' requirements for cigarettes is not recent. Canada, New Zealand and United Kingdom have already discussed proposals on the same matter. However, in none of those cases the proposal was approved. Governments base their argument for the adoption of '*plain packaging*' regulations on health protection. In this respect, the Australian Government declared that the regulation under discussion has the objective of (1) inhibiting the initiation of tobacco use and of reducing its consumption, (2) making health warnings more effective, and (3) avoiding that consumers are mislead or deceived by the adorned packaging.

The consistency of a '*plain packaging*' regulation with WTO obligations is likely to be challenged. In particular, WTO panels might be required to evaluate whether the measure at stake is more restrictive than necessary to achieve the public health interest that it intends to protect. Legal grounds for such claim may be found, *inter alia*, on Articles 2.2 and 2.4 of the Agreement on Technical Barriers to Trade (hereinafter, TBT Agreement) and Articles 8(1) and 20 of the TRIPs Agreement.

According to the terms of Article 2.2 of the TBT Agreement, '*plain packaging*' could be considered a technical regulation more trade restrictive than necessary to reduce smoking rates and, thereby, protecting human health. First, the imposition of a technical regulation such as the '*plain packaging*' requires scientific basis or any other sufficient technical evidence to demonstrate the causal link of the measure with its objective. In this case, however, a report by the Australian Senate Community Affairs References Committee was issued in December 1995 stating that there is no '[…] *sufficient evidence to recommend that tobacco products be sold in generic packaging […]*'. Therefore, it appears that the existence of scientific basis to support the '*plain packaging*' could be challenged, given the possible lack of evidence regarding the

effectiveness of allegedly '*less attractive*' packaging cigarettes on the consumers' choice not to smoke. Second, it appears that the burden on imported cigarettes producers to comply with Australia's '*plain packaging*' standard would be excessively trade restrictive; therefore, it is possible that alternative measures, which are less trade restrictive, yet efficient to reduce tobacco consumption, could be suggested.

In this respect, the Article 2.4 of the TBT Agreement states that WTO Members shall use relevant international standards '*as a basis*' when formulating technical regulations in order to promote the harmonisation of such standards and avoid unnecessary obstacles to trade. Having this in mind, the World Health Organisation (hereinafter, WHO) concluded the '*Framework Convention on Tobacco Control*' (hereinafter, the Convention), which provides for minimum health standards concerning, *inter alia*, the packaging of cigarettes. Although Australia is party on the Convention, it is not clear whether its regulation on '*plain packaging*' is based on the Convention's standards or not. Thus, if questioned under this provision at the WTO, Australia would have to demonstrate that its '*plain packaging*' regulation, supposedly an excessive higher standard, is not in conflict with the Convention principles, *inter alia*, the protection of human health, as well as the respect of national and international law obligations, when setting the standards.

Furthermore, the adoption of the '*plain packaging*' appears to greatly affect the trademark holders with respect to their (indirect) rights under the WTO TRIPs Agreement. The balance between the interests of public health protection and intellectual property rights is provided under the Article 8(1) thereof, which states that WTO *Members '[...] may adopt measures necessary to protect public health [...], provided that such measures are consistent with the provisions of this Agreement.'* Similar to the rationale mentioned under the Article 2.2 of the TBT Agreement, it could be argued that the effectiveness of '*plain packaging*' is not based on sufficient evidence to establish a causal link with the reduction of smoking rates. And, even in the case that the effectiveness of such measure is proven, it is possible that alternative measures, which are less restrictive to the rights of trademark holders, and consistent with the TRIPs Agreement, could be put in place to achieve the same objective of reduction of smoking incidence and health protection. Lastly, Article 20 of the TRIPs Agreement provides that '*the use of a trademark in the course of trade shall not be encumbered by special requirements, such as [...] use in a manner detrimental to its capability to distinguish the goods [...]'*. In particular, the restriction to be imposed on the use of trademarks is said to limit the distinction between branded cigarettes. Thus, the alleged restriction (*i.e.*, prohibition of the use of brand adornments as originally registered by the trademark holders), would be unjustifiable, as the standardised appearance of the '*plain packaging*' is said to lack sufficient basis and to be excessive.

Considering the significant commercial impact of the '*plain packaging*' to producers of cigarettes and to trademark holders, in parallel to the fundamental public health interests of national governments, the question on the effectiveness and proportionality of the '*plain packaging*' regulations looks posed to trigger a complex discussion when weighing and balancing the interests at stake. This discussion must be seen in a broader context, where proportionality of governmental action must be maintained at all times and at all costs. Independently of the type of regulation, the effects on trade must always be measured by the principles of proportionality, reasonableness and consistency of action. Serious doubts on the proportionality of such measure have already been expressed. Reasonableness appears to be questionable in as much as the magnitude of such measure is tantamount to a de facto prohibition of use of trademark rights and legitimate marketing expectations. Consistency is clearly defeated by reality: similar policies are not (and should not be) imposed on other products that could arguably be considered as having equivalent health risks. In particular, such policies could one

day (if consistently and paradoxically applied) impose '*plain packaging*' on alcoholic beverages, food products rich in fat or cholesterol content, confectionary, sweets and drinks rich in sugar, high-speed and high-powered (i.e., polluting) vehicles, etc. The possible scenario is clear and, arguably, frightening. Governments must be able to regulate and pursue legitimate objectives, but this undertaking must be proportional, reasonable, consistent and balanced. 'Plain packaging', as in the intention of Australia, does not appear to meet these conditions.

Consequently, it appears critical for operators affected by such regulations to engage at all levels with governments and decision-makers in order to protect their legitimate commercial interests and assess whether it may be necessary to go as far as triggering WTO dispute settlement in order to challenge the consistency of disproportionate and unnecessarily trade restrictive 'plain packaging' regulations with WTO Members' international obligations.

EU Commission plans an '*omnibus decision*' and reviews the timetable for adoption of the list of permitted health claims made on foods

The EU Commission announced on 27 September 2010 its intention to review the envisaged process for the adoption of the EU list of permitted health claims on food products (also known as '*Article 13 claims*'). According to Article 13(3) of Regulation (EC) No. 1924/2006 of the European Parliament and the Council on nutrition and health claims made on foods, the EU Commission had to adopt an EU list of permitted health claims (other than those referring to the reduction of disease risk and to children's development and health) and all necessary conditions for the use of these claims by 31 January 2010 at the latest, after consulting the European Food Safety Authority (hereinafter, EFSA).

EU Member States had to provide the EU Commission with lists of claims by 31 January 2008 accompanied by the conditions applying to them and by references to the relevant scientific justification. However, as the timetable foreseen in EU law could not be respected, mainly because of the large number of health claims to be assessed by EFSA (originally more than 44,000, then consolidated into a list of 4,638 of which, according to EFSA's website, only 1,746 have so far been assessed), the EU Commission announced that the list of permitted claims will now be established in two steps. First, the list of permitted health claims for all substances other than so-called 'botanicals' will be adopted, presumably next summer in a single '*omnibus decision*'. EFSA opinions on all claims other than 'botanicals' are expected to be finalised by the end of June 2011 and, subsequently, the claims regarding the botanicals will be considered. EFSA has so far published two series of opinions on Article 13 claims and will publish most likely a third one in the coming weeks. EFSA and the EU Commission have received numerous comments from stakeholders or members of the public on these opinions.

However, the reason behind the new timeframe and procedure does not appear to be merely EFSA's delay in the claim-assessment and the ensuing impossibility for the EU Commission to issue the corresponding regulatory decisions. It is also a question of equal treatment of operators. Originally, the EU Commission had planned a process facilitating a progressive adoption of the list of permitted Article 13 health claims, with a view to protect consumers from unsubstantiated health claims displayed on products which remain on the market until the completion of the evaluation. Following concerns about potential market distortions between operators whose claims are rejected and those for which assessments are still pending, the list of permitted claims will now be published at once for all Article 13.1 health claims (other than for 'botanicals'), rather than through batch-by-batch decisions. The EU Commission stated that this approach will also be beneficial for the consumer, who, once the list is adopted and fully

operational, will be assured that all health claims on the market have been substantiated by science. The question is what will happen in the meantime?

According to CIAA, the EU Confederation of Food and Drink Industries, the new approach '*will create more legal certainty for manufacturers and reduce the implementation burdens incurred by multiple labelling changes*' and '*help in creating a level playing field vis-à-vis an appropriate time-frame for claim approvals, guaranteeing open and fair competition among food manufacturers in their use of health claims and thus helping stimulate innovation*.' Consumer organisations argue that it is not acceptable to leave consumers longer in the dark while EFSA continues to assess the claims, particularly because a large number of the analysed claims have so far been rejected. The new timetable simply gives companies more time to use claims that have not been backed by EFSA.

Article 10 of Regulation (EC) No. 1924/2006 on nutrition and health claims prohibits health claims unless they are authorised in accordance with this Regulation and included in the lists of authorised claims. Currently (as there is no list of permitted claims yet), all claims made by manufacturers on food products have to be considered under general food labelling law. Thus, under Directive 2000/13/EC on the labelling of foodstuffs, the labelling must not be such as could mislead the purchaser. Directive 2006/114/EC concerning misleading and comparative advertising, defines 'misleading advertising' as any advertising which in any way, including its presentation, deceives or is likely to deceive the persons to whom it is addressed or whom it reaches and which, by reason of its deceptive nature, is likely to affect their economic behaviour or which, for those reasons, injures or is likely to injure a competitor. Therefore, basically, claims must not mislead the consumer, but they do not have to be scientifically proven before they go on the market. It is up to the EU Member States' national enforcement authorities to work out whether a claim deceives or not.

In practice, the new procedure and time-table means that, even though EFSA has assessed and continues to assess claims, consumers won't know for a while which health claims are finally approved by the EU Commission. To give an example, on 15 October 2009 EFSA has issued a scientific opinion (in form of batch) on the substantiation of health claims related to various food(s)/food constituent(s) claiming maintenance of joints, maintenance of bone and maintenance of muscles pursuant to Article 13(1) of Regulation (EC) No. 1924/2006. EFSA's Panel concluded that '*on the basis of the data presented, a cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) evaluated in this opinion and the maintenance of normal joints, normal bones and normal muscles*.' A regulatory decision on these specific claims will, according to the EU Commission's new time-table, not be taken before the end of June 2011. Although it is unlikely that the EU Commission will contradict EFSA's scientific judgment, as EFSA's opinions are not legally binding, the Commission may interpret the cause and effect relationship in a different way and, theoretically, include certain claims in the list of permitted claims. Thus, for claims which have been scientifically assessed and for which the assessment has been made public, but there is no regulatory decision yet, manufacturers are left in sort of a limbo on whether they are permitted to claim something or not. Consumers, on the other hand, may be confronted (almost two years after the rejection by EFSA) with claims that are not scientifically proven, but not (yet) banned.

The regulation of health claims, a derogation from the principle set out in Directive 2000/13/EC to prohibit the use of information that attributes medicinal properties to food, has proven to be a complicated matter where important commercial interests of manufacturers stand against the basic right of consumers not to be deceived by means of unfounded marketing claims.

Conclusion of the Anti-Counterfeiting Trade Agreement negotiations including a compromise on geographical indications

The Anti-Counterfeiting Trade Agreement (hereinafter, ACTA) negotiations were concluded following the 11th round of talks in Tokyo, where the delegates seem to have resolved the last controversial issues, including whether ACTA shall also apply to geographical indications or not. ACTA is negotiated by Australia, Canada, the EU (for its 27 Member States), Japan, Mexico, Morocco, New Zealand, the Republic of Korea, Singapore, Switzerland and the US (therefore**,** representing approximately more than half of the world's trade) for establishing state-of-the-art provisions on the enforcement of intellectual property rights, including provisions on civil, criminal, and border enforcement measures, cooperation mechanisms among ACTA Parties and establishment of best practices for effective Intellectual Property Rights enforcement (see Trade Perspectives, Issue No. 9 of 7 May 2010). ACTA would establish a new international legal framework that countries can join on a voluntary basis and would create its own governing body outside existing international institutions such as the WTO, the World Intellectual Property Organization (WIPO) or the United Nations, where anti-counterfeiting and anti-piracy agreements seem to be improbable.

A key feature of ACTA would mandate that customs officials have "*ex officio*" (i.e., upon their own initiative) authority to seize counterfeit goods without a request from the rights holders or a court order. US food manufacturers were worried that the EU's demand to cover geographical indications in ACTA could mean that products such as American parmesan cheese, Parma ham, champagne or gorgonzola could be treated as illegal items and subject to customs seizures.

The released draft consolidated text of the ACTA, which reflects the outcome of the round of the negotiations held in Tokyo, states, as to the scope, that '*intellectual property*' comprises '*all categories of intellectual property that are the subject of Sections 1 through 7 of Part II of the Agreement on Trade-Related Aspects of Intellectual Property Rights*' (the WTO's TRIPs Agreement). Therefore, ACTA includes the protection of geographical indications which are defined in Article 22 of the TRIPs as '*indications which identify a good as originating in the territory of a Member, or a region or locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin*.' Section 3 of the draft ACTA text concerns '*Border Measures*' and states in Article 2.X that '*(I)n providing, as appropriate, and consistent with a Party's domestic system of IPR protection and without prejudice to the requirements of the TRIPS Agreement, for effective border enforcement of intellectual property rights, a Party should do so in a manner that does not discriminate unreasonably between intellectual property rights and that avoids the creation of barriers to legitimate trade*.'

It seems that this provision reflects the compromise reached. The principle that parties should provide border measures without discriminating between intellectual property rights and that parties should avoid creating barriers to legitimate trade seems to reassure the EU, which did not want there to be any scope for possible discrimination in favour of trademarks by virtue of trademarks receiving better protection under ACTA than *sui generis* geographical indication regimes.

There seems to be still slight disagreement on part of the text in the section on border measures. It appears that the EU would like to delete the word '*unreasonably*' from the phrase stating that countries should implement border measures '*in a manner that does not discriminate unreasonably between intellectual property rights*.' The word '*unreasonably*' leaves

this provision up to interpretation, and could lead ACTA Parties to interpret this phrase in an open-ended manner. In particular, the EU fears that this text could be used to discriminate against geographical indications and in favour of trademarks.

The question is what this agreement will mean in practice, in relation to EU-protected geographical indications? Does the implementation of border measures '*in a manner that does not discriminate unreasonably between intellectual property rights*' mean that products like US parmesan would not be seized by customs if entering the EU market or another member's customs territory (if the product is trademark protected)? A statement from all the negotiating parties said that the participants agreed to work expeditiously to resolve the small number of outstanding issues that require further examination in capitals, with a view to finalising the text of the agreement as promptly as possible.

Canada's policy on renewable energy is questioned in the context of government procurement under the EU-Canada trade talks

The commitments on government procurement are currently the subject of the ongoing negotiations for the EU-Canada Free Trade Agreement (hereinafter, EU-Canada FTA). While the EU aims at achieving maximum expansion of its sectors of manufacturing goods and services through the participation of its suppliers and producers to Canada's provincial and municipal purchasing procurement, Canada imposes limitations in the same procurement domains with regard to its renewable energy policies, in particular concerning the province of Ontario.

It is not the first time that the Canadian renewable energy policy, notably Ontario's Green Energy Act (hereinafter, the Act), is questioned by the EU and other WTO Members. In fact, the Act is already being challenged by Japan at the WTO in the dispute concerning *Canada - Certain Measures Affecting the Renewable Energy Generation Sector*, having the US and the EU as third parties (see Trade Perspectives, Issue No. 17 of 24 September 2010). The Act provides for the so called '*feed-in tariffs programme*', which consists in the payment of fixed prices, above the market price, to operators of installations that generate renewable energy in Ontario. The payment for renewable energy of above-market prices is contingent to a certain percentage of local content of goods and services used in the generation of energy. According to Japan's main arguments, supported by the EU and US, the Act discriminates between national and foreign goods and investments, as well as violating Canada's WTO obligations on subsidisation.

With regard to the current EU-Canada negotiations, the relevant provision of the Act allows for the procurement of electricity supply or capacity, derived from renewable energy sources, to be carried out with special conditions and criteria in order to encourage the participation of aboriginal people and other interested groups in the development and competition of provincial government purchasing. Consequently, Ontario's procurement process could be limited to local bidders. This scheme is to stimulate the local production of renewable energy, as part of the provincial representatives' intention to make Ontario an export-oriented hub for renewable energy manufacturing. However, the government procurement preferential conditions to local providers go against the interests of the EU to extend its market through the participation in such governmental purchasing proceedings. Hence, the trade-offs under negotiation in the EU-Canada FTA involve both countries' industrial, energy and commercial policies , which makes it even more difficult for the parties to reach an agreement. In this context, Canada's provincial

representatives are actively participating in the negotiations with the EU in order to defend their position and to avoid the negative impact of government procurement commitments.

It is important to observe that the preferential conditions for the participation of local bidders in provincial procurement in Canada are not likely to be challenged under the WTO Government Procurement Agreement (hereinafter, GPA), since Canada has specific commitments and exceptions in its schedule that could be interpreted as to allow such measures. Nonetheless, the negotiations on government procurement are also being pushed by the EU at the WTO plurilateral level in order to request the parties on the GPA, including Canada, to extend their commitments.

The objectives and means concerning renewable energy policies, whether related to the government procurement scheme or the feed-in tariffs programme, are a delicate subject which encompasses significant economic and environmental impacts. As already mentioned, these policies stand to pose in the near future many interrelated concerns regarding international obligations at the WTO level, as well as in the context of FTAs such as the EU-Canada FTA. Therefore, it is fundamental for the business sector to visualise the connection of these different measures and be aware of the potential economic impacts they can have in terms of market access for goods and services related to the renewable energy.

Recently Adopted EU Legislation

- *Commission Regulation (EU) No 886/2010 of 7 October 2010 entering a name in the register of protected designations of origin and protected geographical indications [Prleška tünka (PGI)]*

- *Regulation (EU) No 913/2010 of the European Parliament and of the Council of 22 September 2010 concerning a European rail network for competitive freight*

- *Commission Regulation (EU) No 915/2010 of 12 October 2010 concerning a coordinated multiannual control programme of the Union for 2011, 2012 and 2013 to ensure compliance with maximum levels of and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin*

- *Commission Regulation (EU) No 923/2010 of 14 October 2010 entering a name in the register of protected designations of origin and protected geographical indications [Asparago di Badoere (PGI)]*

- *Commission Regulation (EU) No 917/2010 of 12 October 2010 entering a name in the register of protected designations of origin and protected geographical indications (Fourme de Montbrison (PDO))*

- *Commission Regulation (EU) No 918/2010 of 12 October 2010 entering a name in the register of protected designations of origin and protected geographical indications [Kiełbasa lisiecka (PGI)]*

- *Commission Regulations (EU) No 895/2010 of 08 October 2010 entering a name in the register of protected designations of origin and protected geographical indications [Halberstädter Würstchen (PGI)]*

- *Commission Regulations (EU) No 896/2010 of 08 October 2010 entering a name in the register of protected designations of origin and protected geographical indications [Schrobenhausener Spargel/Spargel aus dem Schrobenhausener Land/Spargel aus dem Anbaugebiet Schrobenhausen (PGI))*

- *Commission Regulations (EU) No 897/2010 of 08 October 2010 entering a name in the register of protected designations of origin and protected geographical indications (Suska sechlońska (PGI))*

- *Commission Regulations (EU) No 898/2010 of 08 October 2010 entering a name in the register of protected designations of origin and protected geographical indications [Patata della Sila (PGI)]*

- *Commission Regulations (EU) No 899/2010 of 08 October 2010 entering a name in the register of protected designations of origin and protected geographical indications (Mogette de Vendée (PGI))*

- *Commission Regulations (EU) No 900/2010 of 08 October 2010 entering a name in the register of protected designations of origin and protected geographical indications [Estepa (PDO)]*

- *Commission Regulations (EU) No 901/2010 of 08 October 2010 entering a name in the register of protected designations of origin and protected geographical indications (Fava Santorinis) (PDO)]*

Ignacio Carreño, Eugenia Laurenza, Anna Martelloni, Natália S. Ruschel and Paolo R. Vergano contributed to this issue.