Intellectual Property

This section is devoted to giving readers an inside view of the crossing point between intellectual property (IP) law and risk regulation. In addition to updating readers on the latest developments in IP law and policies in technological fields (including chemicals, pharmaceuticals, biotechnology, agriculture and foodstuffs), the section aims at verifying whether such laws and policies really stimulate scientific and technical progress and are capable of minimising the risks posed by on-going industrial developments to individuals' health and safety, inter alia.

The Case of Plain Packaging of Cigarettes

Alberto Alemanno and Enrico Bonadio***

In a bid to reduce smoking rates, Australia is set to become the first country in the world to introduce legislation requiring "plain packaging" for cigarettes. "Plain packaging" (also known as "generic packaging") means that all forms of tobacco branding are required to be labelled exclusively with simple unadorned text. This means that trademarks, graphics and logos are removed from cigarette packs with the exception of the brand name which is displayed in a standard font. By standardising the appearance of all cigarette boxes, plain packaging aims to make all packs look unattractive and render health warnings more prominent.

This legislative move by Australia finds its origin in the National Health Taskforce discussion paper issued in 2008[1], which put forth recommendations on how to address a number of health issues over the next decade. The stated goal of the plain packaging, as recently enshrined by the Australian Federal Government, is (a) to curb the initiation of tobacco use, reduce tobacco consumption and incidences of relapse in those who quit smoking; (b) to enhance the effectiveness of package warnings; and (c) to remove the power of the packaging to mislead and deceive consumers.

Australia is not alone. The United Kingdom, Canada and New Zealand are also considering laws for making this marketing restriction mandatory.

However, plain packaging raises both health-related and legal tricky issues. Indeed, it is being persistently challenged not only by the tobacco industry as to its legality, but also its genuine effectiveness for public health in reducing tobacco consumption levels.

On the one hand, supporters of generic packaging argue that this innovative way of marketing cigarette packs would make them look not only less attractive but also contribute to make health warnings ("Smoking can kill you") more visible. Warnings on plain white packages may be more effective at grabbing attention and enhancing recall than warnings on regular packages.

On the other hand, tobacco companies argue that generic packaging would not be very effective in serving the stated purpose of reducing smoking and protecting human health. To support this claim, they often refer to the lack of evidence proving that generic packaging (i) makes cigarette boxes less attractive to consumers and health warnings and renders the information more visible and (ii) as a result induces smoking cessation[2]. Plain packaging could even increase smoking uptake – it is argued – because companies would be prompted to compete on the basis of cigarette prices only. This would make tobacco cheaper and more af-

* Associate Professor, HEC Paris, France.

** Lecturer, University of Abertay Dundee, United Kingdom.

1 The report is available on the Internet at <http://www.preventativehealth.org.au/internet/preventativehealth/publishing.nsf/Content/discussion-technical-1> (last accessed on 7 July 2010).

2 In a 1995 report entitled "The Tobacco Industry and the Costs of Tobacco-Related Illness" (released by the Australian Senate Community Affairs References Committee) the following conclusion was reached: *"The Committee received a range of often conflicting evidence on the efficacy of generic packaging. While some evidence suggested that generic packaging would reduce the attractiveness of cigarettes for children, other evidence raised some doubts concerning the effectiveness of this approach. The Committee believes that more research needs to be undertaken into the role generic packaging could play in an integrated strategy addressing the problem of adolescent smoking. The Committee considers that, on the basis of the evidence received, there is not sufficient evidence to recommend that tobacco products be sold in generic packaging."* (para. 3.54). The report is available on the Internet at <http://www.plain-packaging.com/Australia> (last accessed on 7 July 2010). Moreover, in the UK Parliamentary session of 25 June 2009 the Minister of State for Public Health, Ms Gillian Merron, was reported to have said: *"There is some evidence that branding on cigarette packs may increase brand awareness among young people but it is not conclusive.* […] *While there is also evidence to suggest that branding on packs may mislead customers about the relative safety of different tobacco products, that too is very limited. No studies have been undertaken to show that plain packaging of tobacco would cut smoking uptake among young people or enable those who want to quit to do so. Given the impact that plain packaging would have on intellectual property rights, we would undoubtedly need strong and convincing evidence of the benefits to health, as well as its workability, before this could be promoted and accepted at an international level – especially as no country in the world has introduced plain packaging"*. This excerpt is available on the Internet at <http://www.publications.parliament.uk/pa/cm200809/cmpublic/health/090625/pm/90625s09.htm> (last accessed on 7 July 2010).

fordable for consumers, particularly amongst young people. As alternative, it is believed that other less invasive instruments than generic packaging would be far more effective in the struggle against smoking, for example, educational campaigns, health information and warnings on cigarette boxes, etc.

Moreover, according to Big Tobacco, plain packaging represents an encroachment on the rights of trademark owners and their ability to use their trademarks properly and lawfully. Indeed, the most threatening argument used against plain packaging consists in its alleged incompatibility with WTO law. In particular, such a marketing restriction might turn out to contravene TRIPs provisions on trademarks, thus triggering a dispute before the WTO dispute settlement adjudication bodies. Critics argues that plain packaging would violate several TRIPs trademark-related provisions, i.e. Articles 17, 20 and 15(4) TRIPs and Article 6-*quinquies* (B) Paris Convention, which is incorporated by reference into TRIPs pursuant to its Article 2(1)[3].

One of the most relevant questions concerning the alleged TRIPs-incompatibility of generic packaging relates to Article 8(1) TRIPs.

This provision states that "*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*."

It should be noted that any WTO Member State seeking to adopt a measure (e.g. a public health measure) pursuant to Article 8(1) should prove *inter alia* that this is (i) necessary for the promotion of the public interest in sectors of vital importance (e.g. to protect human health) and (ii) consistent with the TRIPs Agreement[4].

The first requirement, i.e. a necessity test, is twofold. A causal link needs to be established between the measure and the protection of the specific public interest, and then the measure should be the least restrictive on intellectual property rights (IPRs). The scope of this provision is further limited by the second abovementioned requirement, i.e. that the measure be compatible with the TRIPs Agreement.

First, plain packaging could fail to satisfy the abovementioned causal link requirement. Because of the uncertainty surrounding its inherent ability and effectiveness to reduce the incidence of smoking, it might be difficult for states seeking to adopt generic packaging to prove the existence of a causal relationship between such a measure and the protection of public health. In addition, plain packaging would appear to be unlikely to satisfy the necessity test for a further reason. As shown above, there might indeed be other means of attaining the same public health objective that would be more effective and less restrictive of IPRs, such as educational campaigns, health information and warnings as well as advertising restrictions.

Finally, it is not an easy matter to meet the second condition of Article 8(1) – i.e. consistency of the measure in question with TRIPs. Thus a Panel's decision finding generic packaging is contrary to TRIPs cannot be ruled out.

Nevertheless, states willing to adopt plain packaging may overcome the abovementioned difficulties if they succeed in proving (a) the existence of the causal link between this marketing restriction and the protection of public health (e.g. by relying on studies confirming that this measure would make cigarette boxes less attractive to consumers and health warnings and information more visible and accordingly increase the incidence of smoking cessation); and (b) that there exists no less trade-restrictive means of achieving the chosen policy goal. In addition, states should also prove that plain packaging is compliant with TRIPs. In this respect, particular weight should be attached to both Article 8.1 TRIPs and paragraph 4 of the 2001 *Doha Declaration on the TRIPS Agreement and Public Health*. In particular the latter reproduces the spirit of the former by stressing that "*the TRIPs Agreement does not and should not prevent members from taking measures to protect public health*"[5].

Plain packaging is a thorny issue that is likely to keep busy IPRs and WTO specialists as well as academics in the years to come.

3 For a first analysis of the compatibility of plain packaging with the trademark-related provisions of the TRIPs Agreement see Benn McGrady, "TRIPs and Trademarks: The Case of Tobacco", 3(1) *World Trade Review* (2004), pp. 53–82.

4 See Nuno Pires de Carvalho, *The TRIPs Regime of Patent Rights* (The Hague: Kluwer 2005), pp. 119 *et sqq*.

5 The *Doha Declaration on the TRIPS Agreement and Public health* was adopted on 14 November 2001 by the WTO Ministerial Conference. States seeking to adopt plain packaging should also stress that each country has the right to decide the level of health protection that it considers appropriate in a given situation, as it was stated by the WTO Panel in *EC – Asbestos*, see *European Communities – Measures Affecting Asbestos and Asbestos-Containing Products*, Report of the Appellate Body, WTO Doc. WT/DS135/AB/R, 5 April 2001, at para. 168.

As shown above, the tobacco industry is particularly keen to emphasize both the futility of plain packaging for reducing smoking rates and its incompatibility with TRIPs provisions on trademarks. Clearly, major tobacco companies fear to lose a powerful means of communication between themselves and their consumers and are afraid that what they see as a serious curtailment of their trademark and goodwill-related rights could hit their flourishing businesses hard and decrease cigarette sales. Indeed, it is a fact that sales of tobacco products continue to rise worldwide. For example, some figures revealed that tobacco sales in UK rose to £11.3 billion in 2009, an increase of 3.3 % on the previous year[6]. Moreover, the World Health Organization found that the developing world tobacco consumption is rising by 3.4 % per year[7].

On the other hand, those who support plain packaging stress its enormous potential in the fight against tobacco-related diseases and defend its legality and conformity with WTO law and particularly with international provisions protecting trademarks. In their eyes, plain packaging is both useful and lawful.

Given the high economic stakes related to the introduction of plain packaging and the impact that such measure could have on tobacco consumption, it is not unlikely that any state that adopts such a marketing restriction will expose themselves to a WTO dispute settlement proceedings. Needless to say, such actions might be triggered by countries particularly keen in protecting their tobacco majors. Yet, the outcome of such a dispute would be uncertain and – as is often the case – technical expertise is likely to make the difference. What is the impact of plain packaging on consumer's choice and tobacco consumption? There does not seem to be any definitive answer yet.

6 See News.Scotsman.com of 21st February 2010.

7 See the relevant smoking statistics available on the Internet at <http://www.wpro.who.int/media_centre/fact_sheets/fs_20020528.htm> (last accessed on 7 July 2010).

Nanotechnology

This section is meant to give readers an insight into the emerging field of nanotechnologies and risk regulation. It informs and updates readers on the latest European and international developments in nanotechnologies and risk regulation across different sectors (e.g., chemicals, food, cosmetics, pharmaceuticals) and policy areas (e.g., environmental protection, occupational health and consumer product, food and drug safety). The section analyzes how existing regulatory systems deal with new kinds of risks and reviews recent regulatory developments with a focus on how best to combine scientific freedom and technological progress with a responsible development and commercialization of nanotechnologies.

Nanomaterial Safety: The Regulators' Dilemma

*Nico Jaspers**

I. Introduction

Nanotechnologies have been hyped as bringing about another industrial revolution. But they have also caused concern about their potential adverse effects on human health and the environment, misuse for military purposes, and excessive corporate control of intellectual property. Policy-makers find themselves in the difficult position of promoting the development of nanotechnologies while at the same time securing public trust in their safe commercial application. Having invested enormous financial resources into nanotechnology research and development,[1] policy-makers often struggle to convince an increasingly informed – and sometimes sceptical – public that existing regulatory frameworks are sufficiently able to address potential risks related to nanotechnologies. In most cases, this is not for lack of want or interest, but due to the challenge of framing "nano" for regulatory purposes. Regulators face a dilemma: they have to ensure the safety of nanotechnology applications without being able to state exactly what nanotechnology is.

* London School of Economics, United Kingdom. Please send inquiries to n.jaspers@lse.ac.uk.

1 Cientifica, "Nanotechnology Takes a Deep Breath … and Prepares to Save the World!", Cientifica Report (2009).