

# Introduction: setting the scene

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*The New Intellectual Property of Health* provides the first legal and policy analysis of the intellectual property (IP) aspects of a rapidly growing category of regulatory measures affecting the presentation of certain health-related goods as diverse as tobacco, alcohol, unhealthy foods, baby formulas and pharmaceuticals. By unearthing a possible tension between these measures and IP regimes, it explores how to balance the legitimate interests of governments to promote public health with the protection of IP assets. The breadth of the analysis, however, goes beyond providing a mere assessment of the compatibility of these innovative measures with IP rights as enshrined in international, European and domestic regimes as well as investment treaties. The rapid diffusion of these measures across jurisdictions calls for some redefinition of the nature of rights offered by IP legislations, especially in relation to trademarks and, in particular, for a new balancing of IP rights protection with the promotion of public health. Indeed, while these measures carry the promise to enhance public health protection, they require the development of some innovative uses of IP protection.

Plain packaging of tobacco products, as recommended by the Guidelines to the 2005 Framework Convention on Tobacco Control, pioneered by Australia in 2011 and subsequently adopted by Ireland,<sup>1</sup> the UK<sup>2</sup> and France,<sup>3</sup> epitomizes the emergence of this new category of IP-restrictive measures pursuing a public health objective. It shows how governments

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<sup>1</sup> The Public Health (Standardised Packaging of Tobacco) Act 2015 was signed on 10 March 2015. The text is available at <http://www.irishstatutebook.ie/eli/2015/act/4/enacted/en/pdf>.

<sup>2</sup> The Standardised Packaging of Tobacco Products Regulations 2015 No 829 was voted on 16 March 2015. The text is available at <http://www.legislation.gov.uk/ukxi/2015/829/contents/made>.

<sup>3</sup> The Décret No 2016-334 du 21 mars 2016 relatif au paquet neutre des cigarettes et de certains produits du tabac. The text is available at <https://www.legifrance.gouv.fr/eli/decret/2016/3/21/AFSP1603141D/jo>.

can severely restrict the freedom of certain manufacturers to use brands and packaging space to convey messages to consumers. While by far the most controversial, plain packaging does not exhaust the category of measures analysed in this volume. A wider range of packaging and brand-related measures, such as information schemes (e.g. labelling, warnings), presentation requirements (e.g. various forms of standardized packaging) and restrictions on sale (e.g. point-of-sale visual display ban), are increasingly adopted by governments well beyond tobacco.

While generally the common objective of most of these measures is to better inform consumers about the characteristics of the goods at stake, they often aim at dissuading people from actually consuming them. And they do so by minimizing the impact of trademarks and other packaging elements (also protectable by copyright and design rights) on the overall aspect of the product. In their pursuit of public health targets, regulatory bodies are thus determined to restrict the ability of manufacturers in the industries in question to promote and market their goods as they wish and make the products appealing to consumers by using IP-protected eye-catching words, logos or ornamental features on the pack.

Pharmaceuticals are no exception to the above trend. However, IP-restrictive measures applied to these products are generally not to discourage their consumption but to provide clearer, and possibly not misleading, information about their characteristics. But more regulatory requirements are currently under consideration. Some of them may inter alia compel manufacturers of medicines to flag up active ingredients on a significant portion of the surface of the packaging with equal prominence to the brand name. Another proposal is to prohibit the use of the same umbrella brand for different drugs so as to ensure that medicines are taken safely and correctly.<sup>4</sup>

As the space available to manufacturers to present their products on packs is progressively shrinking, brands and IP-protected packaging elements in general are set to come under attack across an increasing number of industries. Such a regulatory trend may spread soon to more industries and hit further products whose use may be harmful and addictive, such as cosmetics and gambling-related products including games and slot machines.

Academic attention is increasingly focusing on several high-level disputes that have confirmed the tension between the public health

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<sup>4</sup> See, for example, the Australian proposal to compel pharmaceutical companies to indicate active ingredients on a significant part of the packaging of medicines with equal prominence to the brand name. On this proposal see Blum, Chapter 4 of this volume.

objective pursued by those IP-restrictive measures and the interests of private companies to fully use their IP assets. The recent decisions of the High Court of Australia (which found the legislation on plain packaging compliant with the Australian Constitution),<sup>5</sup> of an arbitration court under the Hong Kong–Australia Bilateral Investment Treaty (BIT) (which dismissed, on procedural grounds, the action brought by Philip Morris Asia against the same measure) and of the High Court of England and Wales<sup>6</sup> exemplify this trend. The same goes for the decision of the arbitration court established under the Uruguay–Switzerland BIT, concerning a challenge to a series of Uruguayan tobacco control measures mandating minimum size (80 per cent) and content (including pictorial images) of pack warnings as well as the mandatory use of just one kind of tobacco packaging from a brand family.<sup>7</sup> More rulings are expected to determine the legality and therefore the future of such a measure and other space-appropriation measures. The most relevant decision set to be delivered by a World Trade Organization (WTO) panel (following the TRIPS-based complaints brought by Ukraine, the Dominican Republic, Honduras, Cuba and Indonesia)<sup>8</sup>. Most of these cases, and their impact on both public health and IP rights and assets, are thoroughly discussed by the contributors to this volume.

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<sup>5</sup> In August 2012 the Australian High Court confirmed that the measure did not amount to an expropriation of the tobacco companies' (intellectual) property and is thus compliant with the Australian Constitution (*JT International SA v Commonwealth* [2012] HCA 43). For a comment of the decision, see Jonathan Liberman, 'Plainly Constitutional: The Upholding of Plain Tobacco Packaging by the High Court of Australia' (2013) 39(2) *American Journal of Law and Medicine* 361–81; Sam Ricketson, 'Plain Packaging Legislation for Tobacco Products and Trade Marks in the High Court of Australia' (2013) 3(3) *Queen Mary Journal of Intellectual Property* 224–40.

<sup>6</sup> On 19 May 2016 this court found the British regulations on standardized packaging proportionate and compliant with intellectual property regimes (*British American Tobacco & others v Department of Health* [2016] EWHC 1169 (Admin)). The proceedings were started by several tobacco companies to challenge such legislation. As the decision occurred while this volume was in press, it contains only a few, brief references to the judgment's main findings.

<sup>7</sup> This ruling also occurred while this book was in press. Hence, the volume only contains a few short references to the decision's main findings.

<sup>8</sup> See Davison, this volume, Chapter 6.

## THE LEGAL ISSUES

The implementation of this new category of regulatory requirements aimed at protecting public health raises significant challenges for IP regimes. This is true insofar as they tend to limit the ability of IP holders to fully exploit their IP portfolio. In particular, this set of regulatory requirements raises three major issues:

- (i) the nature of rights offered by IP legislations, especially in relation to trademarks;
- (ii) the balancing of IP rights protection with the promotion of public health; and
- (iii) the relationship between IP law and the protection of fundamental rights.

### **On the Nature of IP Rights**

The question of whether IP laws offer their owners just a *negative* right to prevent third parties from exploiting the protected asset or also a *positive* right to use it is not a new one, having been intensely debated for decades. The issue has also been fiercely discussed amongst IP scholars when debating whether biotechnological inventions deserved to enter into the realm of patentable subject matter.<sup>9</sup> The scholars who push the 'negative right' approach point to the letter of many IP legislations including the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS), which clearly shows that no right of use is offered to IP owners. Yet this approach is far from being accepted by all commentators, especially as far as trademarks are concerned. Those who oppose it argue that, while IP regimes do not expressly recognize a positive right to use the protected asset (e.g. a trademark), their spirit, including that enlightening the TRIPS Agreement, is to allow the use of them. They therefore push for a purposive interpretation of such provisions and stress that the negative right to exclude third parties from exploiting the brand is meant to create a 'space' where trademark owners are able to use their signs. Registration of trademarks would therefore be the *means* to reach the final *end*, that is, the opportunity to use the brand.

This debate is key to the discussion revolving around the legality and policy viability of the regulatory measures analysed in the volume.

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<sup>9</sup> See inter alia Peter Drahos, 'Biotechnology Patents, Markets and Morality' (1999) 21(9) *European Intellectual Property Review* 441–49.

Should one accept that IP rights only confer a negative right, most of these controversial measures – by not affecting such a right – would be compliant with IP laws. On the other hand, should the positive right argument be preferred, the measures in question would probably conflict with IP regimes as they would nullify or greatly affect that right. The upcoming decision of the WTO Panel in the current dispute over Australian plain packaging is set to shed light on the issue.

### **Balancing IP Rights Protection with the Promotion of Public Health**

The question of how to balance IP rights protection with the pursuit of a legitimate interest such as public health is a sensitive one. The record of IP protection suggests that strong protection of IP rights may interfere inter alia with public policies aimed at guaranteeing access to medicines, especially in developing and least developed countries. The WTO and its member states have tried to address such a tension by introducing new mechanisms, such as parallel imports and compulsory licences of patents.

However, the IP/health balancing exercise analysed in this book presents different facets. Some contributors explore if and to what extent measures aimed at discouraging the consumption of unhealthy products or at giving consumers correct information about certain health-related products can be reconciled with legal provisions protecting IP assets, especially trademarks. Are such measures necessary and proportionate? Are they justifiable from a public health perspective? These are the questions this book wants to answer.

As mentioned, particular attention is devoted to the impact of the measures in question on trademarks owned and used by tobacco, alcohol, food and medicine manufacturers and their ability to fully use them. As is well known, brands have become ubiquitous in our lives as we are constantly exposed to signs, logos and slogans. It can be affirmed that we *eat* brands every day<sup>10</sup> and are influenced by the sociality attached to them.<sup>11</sup> The main function of trademarks is to distinguish branded products and services from those of their competitors. Yet, according to many commentators as well as to the courts, brands also aim at promoting the consumption of products and, in some cases, glorifying them. Even when just affixed to packaging, trademarks are there to help

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<sup>10</sup> Rebecca Tushnet, 'Gone in Sixty Milliseconds: Trademark Law and Cognitive Science' (2008) 86 *Texas Law Review* 507–688.

<sup>11</sup> Franck Cochoy, 'Tobacco, Packaging, and the Economics of Surprise: History and Stories', paper presented at the Contraband Tobacco Workshop, held at the London School of Economics on 17 October 2014.

sell the goods. In other words, they are a means of increasing the overall size of the market by inviting consumers to buy the relevant product.

Given this additional (and no longer neglectable) function of trademarks, it is understandable why governments want to restrict the ability to fully use them on the packaging of harmful products such as tobacco, alcohol and unhealthy food: their clear aim being to discourage the consumption of these products. It is also understandable why public authorities want to regulate the use of brands on pharmaceutical packaging, that is in order to give patients accurate information about the characteristics of the products and avoid consumers being mistaken about the correct use of medicines. Yet, there is an increasingly hot debate on whether the measures in question strike a fair balance between the various interests and rights at stake, including the interests of trademark owners in using their signs for distinctive purposes and the right of governments to prevent uses of brands which mislead consumers about health consequences or promote harmful products. Some contributions will delve into and expand on these intriguing issues.

### **IP Law and the Protection of Fundamental Rights**

The question of whether this category of measures violates fundamental rights, such as the right to (intellectual) property and commercial free speech, also calls for close scrutiny.

It is undisputed that IP rights can nowadays also be considered as fundamental rights, as confirmed by the European Union (EU) Charter of Fundamental Rights (Article 17(2)) and the case law of the European Court of Human Rights. One question worth discussing is therefore whether states are given a broad enough margin of appreciation in deciding if these fundamental rights can be restricted in order to promote public health.<sup>12</sup> The compatibility of this set of regulatory requirements with fundamental rights heavily depends on how the positive/negative rights debate will eventually be solved. Should the negative rights approach prevail, no interference would take place, while the recognition of some positive nature to IP rights is likely to strengthen the argument

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<sup>12</sup> In the British proceedings brought by tobacco companies to challenge the local regulations introducing standardized packaging the High Court has held that margins of appreciation are wide. They substantially limit and restrict the use of trademarks – it was noted – but they do so for entirely proper and legitimate reasons, by striking a fair balance between the right to property and opposing public health interests and rights (*British American Tobacco & others v Department of Health* [2016] EWHC 1169 (Admin)).

raised by the opponents of these measures. Even where such an interference is affirmed, it remains to be seen whether that is justifiable and proportionate: again we encounter a balancing exercise between the public interest in health and the private economic interests of IP owners. On the one hand, the opponents of the regulatory measures in question argue that a governmental decision to interfere with fundamental rights, and accordingly not to compensate the IP rights holders for the loss of their ability to affix brands or use other IP assets on their packaging, can be deemed as either manifestly arbitrary or unreasonable. Yet such arguments may be countered by stressing that paying compensation out of public funds to these businesses would be unreasonable, especially considering that those funds would be used to further promote products which harm or confuse the very people who consume them.<sup>13</sup>

## IP REGIMES AND NON-IP LEGISLATIONS

IP rights do not exist in a vacuum. It would therefore be a mistake to examine them in isolation from other important branches of law, like health and safety regulation, food law and tobacco control legislation (amongst others). These bodies of law inevitably overlap with IP law by constraining the ability of IP owners to fully use their intangible assets.

Take, again, the food industry. Under EU food law,<sup>14</sup> for example, it is not possible to incorporate into registered trademarks words, logos or other health or nutrition claims that are not listed by the European Union based on generally accepted scientific evidence. If a food company wishes to use an unlisted claim, it can apply to have it included in an approved list. The ability of food companies to exploit their IP assets is therefore restricted by non-IP food-related provisions.

This is not the only example of non-IP legislation restricting the ability of IP owners to fully exploit their assets.<sup>15</sup> Competition law regimes in several jurisdictions have the same restrictive effect on the full use of IP

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<sup>13</sup> Jonathan Griffiths, 'On the Back of a Cigarette Packet: Standardised Packaging Legislation and the Tobacco Industry's Fundamental Right to (Intellectual) Property' (2015) *Intellectual Property Quarterly* 343–69.

<sup>14</sup> See EU Regulation 1924/2006 on nutrition and health claims made on foods, OJ 2006 L 404/9-25. On the intersection between EU food legislation and trademarks regimes see Carreno – Laurenzi, this volume, Chapter 5.

<sup>15</sup> Limitations of IP holders' ability to exploit their assets are also provided in IP statutes or treaties, often to protect public interests. Take as example the bans on the patentability of inventions which are against public policy or morality (e.g. Article 27.2 TRIPS; Article 53(a) European Patent Convention) and of

assets. Take the so-called pay-for-delay agreements, a form of patent dispute settlement agreement in which a generic manufacturer acknowledges the patent owner and agrees to refrain from marketing its generic product in exchange for a consideration: such agreement may often be considered as accords which unlawfully restrict trade (especially under EU and US laws).<sup>16</sup>

While several legal regimes, such as a competition law, may limit the use and full enjoyment of IP assets, also in the name of public health protection, the question is whether the very same proprietary IP law regime – and its ability to interoperate with food, health and safety laws – could be used to further such an important public interest. The last part of the volume, in particular, attempts to verify whether IP rights such as certification marks, geographical indications and patents may adequately supplement domestic food safety standards. It is suggested that a good use of certification marks and geographical names may provide higher than minimum standards of health and safety. This is because they can potentially facilitate the choice of products whose health-promoting qualities might be of interest to the consumer and therefore facilitate her purchase decision. Likewise, this part of the volume also explores whether patents could be used to encourage food companies and innovators to produce and bring to market healthier products.

## THE STRUCTURE OF THE BOOK

The volume is structured in three parts.

Part 1 focuses on the major policy and legal issues, including the nature of the rights offered by IP rights (especially trademarks) as well as their relationship with fundamental rights. It also expands on the intersection between trademark law on the one hand and food law and pharmaceutical law on the other.

Chapter 1, authored by Alberto Alemanno, provides a systematic account and analysis of the emergence of a new category of IP-restrictive regulatory requirements pursuing public health objectives, as epitomized by plain packaging. After examining the rationale underpinning this set of requirements – which he traces back to the deliberate alteration of

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surgical, therapeutic or diagnostic methods (e.g. Article 27.3(a) TRIPS; Article 53(c) European Patent Convention).

<sup>16</sup> On these agreements see, amongst many academic works, Rudolph J R Peritz, 'An Essay, Taking Antitrust to Patent School: The Instance of Pay-for-Delay Settlements', (2013) 58 *Antitrust Bulletin*.

choice architecture vis-à-vis the consumer – the chapter introduces the major legal and policy issues posed by the adoption of these measures.

In Chapter 2, Enrico Bonadio introduces the reader to the sensible debate about the nature of trademark rights. In particular, he discusses whether trademark registrations offer their owners exclusively negative rights to *prevent* unauthorized exploitation of their brands or also positive rights to *use* the asset. After presenting the arguments on both sides of the debate, he concludes that the TRIPS Agreement and the Paris Convention afford only negative rights to trademark owners, which makes the measures discussed in this volume lawful and IP compliant. To reach this conclusion, he highlights the difference between the concepts of *registration* and *use* of trademarks.

In Chapter 3, Matthew Elsmore discusses the clash between the protection of tobacco trademarks and governments' public health targets. In doing so he examines the right to commercial free speech and the right to health under the EU Charter of Fundamental Rights. He concludes inter alia that insufficient attention has been given to freedom of expression (of trademarks) by EU institutions when drafting the directive harmonizing the law of registered trademarks.

Jeremy Blum addresses, in Chapter 4, the tension arising out of the imposition of regulatory requirements restrictive of trademarks on pharmaceutical products. He highlights and criticizes some Australian proposals which would trigger a new level of regulatory control over the labelling of medicines. He focuses, in particular, on the possibility of imposing an obligation to indicate active ingredients on a significant part of the packaging of medicines with equal prominence to the brand name; as well as the proposal to ban umbrella trademarks. The aim of the proposed measures is to prevent consumers from inadvertently taking multiple doses of the same active ingredient. While this is a legitimate objective, he highlights the concerns about the impact of these measures on manufacturers' ability to fully use their brands on the packaging.

Ignacio Carreño and Eugenia Costanza Laurenza focus, in Chapter 5, on a recent trend which sees food business operators trademarking words and symbols related to nutrition and health. They discuss the extent to which EU food legislation limits companies' freedom to affix such trademarks on their products and packaging. By focusing on the interface between EU food law and EU trademark law, this chapter explores whether the legitimate interests of governments to protect the public from regular exposure to misleading nutrition and health claims and food manufacturers' interest in exploiting their IP assets are duly balanced.

Building on this foundation, Part 2 provides readers with a timely set of analyses of the major disputes. It also offers several case studies

revolving around the compatibility of the regulatory requirements examined in the book with several legal regimes, including international IP law as well as investment treaty law protecting IP.

In Chapter 6, Mark Davison examines the Australia plain packaging dispute by focusing on the WTO TRIPS provisions invoked by the applicants against the plain packaging scheme. He accompanies readers on a very interesting journey through the most important claims against the Australian tobacco control measure that allegedly contravenes the TRIPS Agreement. The focus is on whether such a regulatory scheme can be considered justifiable under such a treaty. He concludes that this measure does not violate the TRIPS Agreement.

Althaf Marsoof shares and discusses, in Chapter 7, the latest developments occurring in Sri Lanka in respect of tobacco packaging regulation. He considers in particular the reaction of Sri Lankan courts when the legality and constitutionality of these regulatory measures were challenged. He notes that local judges have impliedly held that trademark registrations also confer a positive right to use the brand. He then speculates on whether a plain packaging regime is consistent with the Sri Lankan Constitution and proposes a potential compromise – the removable trademark – should the measure be found unconstitutional.

Andrew Mitchell and Valentina Vadi look at whether plain packaging and other domestic measures affecting IP may violate investments treaties' provisions on expropriation or fair and equitable treatment. In Chapter 8 Andrew Mitchell presents and analyses the IP-related issues of two major challenges to tobacco packaging measures brought under international investment law. He focuses on the claim brought by Philip Morris Asia Limited against the Australian plain packaging measure under the bilateral agreement between Australia and Hong Kong and the action started by other tobacco majors against the above-mentioned Uruguayan tobacco control measures which affect brands. These two disputes reveal areas of uncertainty and debate concerning the relationship between trademark protection and international investment agreements.<sup>17</sup> In turn, Valentina Vadi examines, in Chapter 9, some investor–state arbitrations concerning the protection of pharmaceutical patents as investment assets and critically assesses their potential impact on public health. She argues that arbitrators should not put an excessive emphasis on the private interests of patent owners, but adequate consideration should also be given to the pursuit of public health targets. Indeed, she is concerned that an overprotection of pharmaceutical patents may have a negative effect on the public health policies of the host state and in

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<sup>17</sup> As the chapter has been authored before the final decisions (which occurred while the book was being finalised), no reference to the rulings are contained therein.

general that the mere possibility of a dispute with a powerful pharmaceutical company can exert a chilling effect on governments' decisions to regulate in the health sector.

Part 3 looks into future developments aimed at reconciling the tension existing between the public health measures negatively affecting IP regimes and their legitimate public objectives. Its chapters explore whether workable solutions can be found to find a balance between IP protection and the promotion of consumers' health, such as the use of certification marks and GI schemes as well as amendments to food-related patent regimes and procedures.

In Chapter 10 Margaret Chon and Maria Therese Fujiye present certification marks as a form of social marketing that may effectively counter the pervasive and powerful for-profit marketing activity that typically bombards consumers on a daily business. Although critical towards certain weaknesses of this IP right, the authors stress its potential ability to provide additional information to consumers in the form of certifications and related marking of goods and services circulating in global markets. In their opinion, these marks may provide alternative approaches to the mandatory disclosures and labelling discussed in this volume.

Chapter 11, authored by Irene Calboli, focuses in turn on geographical indications to assess whether they may play a positive impact on the production of 'healthy' products. While geographical names do not promote healthy products per se and at times identify products whose excessive consumption may be harmful to health (like wine and cheese), they could provide consumers with a body of information that could assist them in making healthier choices. Likewise, they could serve as factors to motivate GI producers to maintain or develop healthier production practices as a means to increase consumer demand for their products.

Finally, in Chapter 12, Enrico Bonadio argues that patents could be used to contribute to fighting obesity and other non-communicable diseases caused by the consumption of unhealthy foods such as products high in fat, sugar and salt. To achieve this end, he puts forward three proposals. The first and second proposals give healthy food inventions preferential treatment with a view to speeding up or facilitating the patenting of foods that contain healthy ingredients. The third proposal consists of excluding from patentability food inventions if it is proven that the relevant products or processes are harmful to human health.

The aim of this volume is thus to nurture an urgently needed debate on how to think more creatively about the interface between intellectual property rights and public health objectives. *The New Intellectual Property of Health* intends to be an initial contribution to that debate.