12

Patents as a tool to encourage the production of healthier food

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Abstract

The need to supply consumers with healthier food and beverages constitutes an urgent priority as many people in both industrialized and developing countries struggle with obesity and other non-communicable diseases (NCDs) caused by the consumption of unhealthy products.

This chapter makes the point that patents may contribute to fighting such illnesses. Three proposals are put forward. The first and second proposals give healthy food inventions a preferential treatment with a view to speeding up or facilitating their patenting process. The third proposal would consist of excluding from patentability certain food inventions if it is proven that the relevant products or processes are harmful to human health.

Such proposals would comply with the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement and are in line with the general aim of the patent system, namely encouraging (before) and rewarding (later) the creation of inventions really useful to society.

1. Introduction

Could patents contribute to incentivizing companies to manufacture and market healthier foodstuffs and beverages? How could the patent system be amended to enable such a contribution and thus play a role in the fight against diseases caused by the consumption of unhealthy food? More generally, is the patent system suitable for carrying out such tasks? In this chapter I will try to answer these questions. In doing so I will put forward three proposals.

As is well known, the need to supply healthy food and beverages[1] constitutes an urgent priority as many people in both industrialized and developing countries struggle with obesity and other NCDs caused by the consumption of unhealthy products. Such need has been stressed in several international fora such as the 2004 World Health Organization (WHO) Global Strategy on Diet, Physical Activity and Health, the 2011 United Nations (UN) Political Declaration on NCDs and the WHO Global Action Plan for the Prevention and Control of NCDs 2013–20.[2]

Some recent data clarifies why it is important to take action urgently. Obesity worldwide has more than doubled since 1980. In 2014, more than 1.9 billion adults were overweight. Of these over 600 million were obese. That means that 39 per cent of adults were overweight in 2014 and 13 per cent were obese. Most of the world's population live in

1 Hereinafter, I will use the general term 'food' to refer to both food and beverages.

2 WHO Global Strategy on Diet, Physical Activity and Health (2004), WHA57.17; *Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases*, GA Res 2, UN GAOR, 66th session, 3rd plenary meeting, UN Doc A/Res/66/2 (2012); WHO Global Action Plan for the Prevention and Control of NCDs, Resolution WHA66.10 endorsed by the 66th WHO World Health Assembly.

countries where being overweight and obesity kill more people than being underweight. And 42 million children under the age of five were overweight or obese in 2013.[3]

It is also well known that obesity increases the risk of NCDs, such as coronary heart disease, stroke, high blood pressure, diabetes, cancer (including endometrial, breast and colon cancer), cholesterol, liver and gallbladder disease, infertility and mental health conditions. NCDs kill 38 million people each year worldwide, and an unhealthy diet is the main risk factor. Also, 2.8 million people die yearly as a result of diet-related NCDs.[4]

Obesity and other illnesses derived from the consumption of unhealthy food also entail high economic costs for societies and cause reduced work productivity.

This chapter will make the point that using the patent system and, in particular, amending certain of its substantial and procedural rules, may be one of the answers to the above problems. Indeed, I believe that patent law, far from being neutral, should deal with these issues and be capable of pushing food companies into manufacturing healthier products. This belief can be echoed in the words of the former Director General of the World Trade Organization (WTO) Pascal Lamy: 'the international intellectual property system cannot operate in isolation from broader public policy questions, such as how to meet human needs as basic as health [and] food …'.[5] It should also be remembered that the right to health, which includes the right to consume healthy food, is protected as a fundamental and human

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3 WHO, Media Centre, Obesity and Overweight, January 2015, <http://www.who.int/mediacentre/factsheets/fs311/en> accessed 18 November 2015.

4 Such data have been presented by Paolo Vergano at the 2015 Summer Academy in Global Food Law and Policy on 22 July 2015, in Bilbao, Spain <http://www.albertoalemanno.eu/academy> accessed 18 November 2015.

5 Pascal Lamy, WTO Director General, talk given at the World Intellectual Property Organization (WIPO) Conference on IP and Public Policy Issues, Geneva, 14 July 2009, see <https://www.wto.org/english/news_e/sppl_e/sppl131_e.htm> accessed 18 November 2015.

right by international and regional provisions, such as the 1948 Universal Declaration on Human Rights: 'everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food …'.[6] The European Union (EU) is also particularly keen to protect people's health. Indeed, the EU Charter of Fundamental Rights reminds us that 'a high level of human health protection shall be ensured in the definition and implementation of all the Union's policies and activities'.[7]

2. Food-related patents: some examples

The proposals I will highlight seem to be timely as food and beverage-related patents are increasingly applied for and/or granted around the world, especially in the USA. An examination of several databases has revealed the existence of many patents related to new and improved foodstuffs.

Take, for example, the US Patent No 5260087 covering an invention entitled 'Fat and egg yolk substitute for use in baking and process for using substitute'.[8] As is explained in the patent's specification, fats and eggs produce desirable taste and sensory qualities in the baked goods, but also contribute much fat and cholesterol to the baked items. The main purpose of this invention is to provide a low-fat compound which can be used in baking cookies and cakes as a substitute for fats and egg yolks, while still producing the desired product taste and sensory qualities. Such an invention further aims to provide a very low fat compound and a method of using it that will not only produce a tasty and tender baked item, but will also contribute to increased item shelf life.

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6 Article 25.

7 Article 35.

8 The patent application was filed with the USPTO in July 1992 and the patent has therefore expired.

The US patent No 8647696 is also relevant.[9] The invention comprises a shelf-stable and low fat food containing gas bubbles. The applicant notes in the specification demonstrate the food industry's need to meet low fat targets while keeping the taste of the product as appealing as possible:

> Particularly in the West, obesity is a major cause for concern. Health conscious consumers are increasingly looking for products that have low fat and calorific content. However, they are often not prepared to accept healthier alternatives that have poor (or even different) taste and/or texture to the traditional products. Thus, food manufacturers face the problem of making low fat alternatives to some of the consumers' favourite products such as desserts, cooking sauces and salad dressings that not only taste as good but that also give the same texture and sensation in the mouth when eaten. Fat plays an important role in giving products their distinctive texture as well as taste. Although fat can be removed and/or substituted to produce a healthier product, if it does not have the same organoleptic properties as the equivalent 'full fat' alternative it may not meet with customer acceptance.

Analogous concerns are expressed in the description of the US patent 6485775 covering a starchy food-based fine particle useful as a fat substitute in a variety of food products:

> For many years, doctors have recommended low fat diets. Accordingly, the food industry has directed substantial effort at finding fat substitutes which demonstrate the taste and mouth feel characteristics of fats without their detrimental properties … Potato granules and flakes are commercially available sources of dehydrated potato product having known characteristics. However, they have not been used as a fat

[9] The application was filed with the USPTO on 9 December 2009 and the patent was granted on 11 February 2014.

mimetic. There is a need for an inexpensive fat mimetic which does not have the detrimental effects of fat on the consumer.

A similar invention is described in the international patent No WO 2013162802 A1, which refers to fat particle compositions containing salt, dough and baked-dough articles made therefrom, and related methods.[10] The specification explains that:

> ... these fat particles can be used to prepare dough formulations that meet the desire of being more healthful than previous dough formulations due to a reduced sodium content, optional more healthful fat content (e.g., low trans fats or low saturated fats), or both … These days, consumers, regulators, and food companies desire to lower total sodium content in food products … Fats typically used in these types of dough products are triglyceride-based fats that commonly contain a fairly high level of saturated fats and trans fatty acids. Due to a present trend toward healthier dough and bakery products, there is demand for products that contain healthier fats (i.e., having a reduced amount of saturated fats and trans fatty acids) without sacrificing taste and baking performance of the dough. In view of the foregoing, alternative fat compositions that are low in saturated and trans fatty acids are very desirable . . .

The above are just a few examples of patents that protect healthier food products or processes. They show the interest of certain sectors of the food industry in fighting obesity and related illnesses by developing improved foodstuffs and accordingly meeting the concerns of an increasingly conscious category of consumers aware of the risks stemming from the consumption of highly fatty and calorific products.

3. Proposals to amend patent regimes to incentivize the production of healthy foodstuffs

[10] This international patent application was filed through the PCT route on 22 March 2013.

The trend of healthy food patenting is certainly a positive step for the purpose of enhancing consumers' health. The fact that food companies spontaneously feel the need to come up with healthier products, even where prompted by the mere desire to pursue commercial profits, is not only a trend that should be praised, it should also be incentivized.

That is why I propose to utilise and amend patent regimes and procedures with the specific aim of encouraging the production of healthier foodstuffs. The first and second proposals are 'positive' as they aim at speeding up or facilitating the patenting process for foods that are considered, and proven to be, healthy.[11] The third proposal would instead consist of excluding from patentability inventions related to food if it is proven that the relevant products or processes contain unhealthy ingredients. It is therefore a 'negative' proposal. As noted by Friedrich-Karl Beier back in 1972, if the aim of the patent system is to stimulate inventions that are useful to people, then 'two conclusions should be self-evident: first, inventions that are of no use or even damaging to society should not be patented, and, second, inventions that are of special and particular utility … for society should be patentable and even enjoy preferential treatment'.[12]

Fast-track procedures for patent applications related to healthy food

[11] Not so different from the proposals highlighted by Estelle Derclaye in relation to environmentally sound inventions in 'Should Patent Law Help Cool the Planet? An Inquiry from the Point of View of Environmental Law: Part 2' (2009) *International Energy Law Review* 229–37.

[12] Friedrich-Karl Beier, 'Future Problems of Patent Law' (1972) 3(4) *International Review of Industrial Property and Copyright Law* 423–50, 441 and 443 (also wondering: 'should we not accord preferential treatment to inventions that are of special significance for society, examine them more quickly, publish them earlier, and protect them more broadly?').

The first proposal would consist of setting up a fast-track procedure for patent applications covering foodstuffs that contain macronutrients such as proteins, vitamins, iodate or other healthy ingredients so as to provide an expedited examination of the relevant patentability requirements. The target is to incentivize the production of healthy food. This seems to be in line with the aim of the patent system, which is to encourage and reward the making of inventions useful to society.

As a general remark, the idea that certain socially useful technologies should be given priority and special treatment is not new. Several national medicines regulators already provide an accelerated review process for the most important drugs. The US Food and Drug Administration is one of these. It has indeed expedited its review process for medicines that treat serious or life-threatening diseases.[13]

'Speedy' patent procedures are already available in several countries and can be used for any kind of technology: the European and the UK patent offices are good examples.[14] The US Patent Office also has in place a three-track prioritized examination system that allows applicants in any field of technology to choose between three examination procedures: prioritized examination, normal examination and delayed examination. Such accelerated proceedings produce certain advantages as they permit applicants to begin

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13 Fast-track, Accelerated Approval and Priority Review, US Food and Drug Administration: see <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm358301.pdf> accessed 18 November 2015.

14 The EPO has an accelerated examination procedure in place that anyone can use at no additional cost. The UK Patent Office offers three different types of accelerated examination. The first two types, Combined Search and Examination and Early Publication, are available to anyone upon request. The third one is Accelerated Search and Examination, which aims at issuing a search report within four months of the application.

licensing their inventions sooner, thus reducing the time to reach the market and accordingly speeding up the dissemination of the relevant products.

Fast-track patent procedures have also been, or are currently being offered, in relation to specific sectors, for example, in the field of green technologies: pioneering countries have been the USA,[15] the UK, Australia, South Korea, Israel, Canada and Japan.[16] These programmes have been set up with a view to reducing the time needed for an application regarding environmentally sound technologies, permitting 'green' applicants to obtain patents sooner and thus encouraging further innovation in this socially relevant field.[17] Indeed, for industries where there is a very urgent need for the development of new technologies, like the renewable energy sector, delay hurts both inventors and the public.[18]

Reserving accelerated procedures to socially important inventions does not constitute an absolute novelty either. In 1959 US patent provisions already included an exception to the examination order, clarifying that applications could be assessed out of turn if 'the inventions are deemed of peculiar importance to some brunch of the public service and the head of some department of the Government requests immediate due action for that

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15 The USPTO Green Technology Pilot Program closed in early 2012.

16 The first country to launch this programme was the UK in May 2009; see Press Release, UK Intellectual Property Office, 'UK "Green" Inventions to Get Fast-Tracked through Patent System', see <http://webarchive.nationalarchives.gov.uk/20140603093549/http://www.ipo.gov.uk/about/press/press-release/press-release-2009/press-release-20090512.htm> accessed 18 November 2015. See also Eric Lane, *Clean Tech Intellectual Property: Eco-marks, Green Patents, and Green Innovation* (Oxford University Press 2011) 218–26.

17 Amanda Patton, 'When Patent Offices Become Captain Planet: Green Technology and Accelerated Patent Examination Programs in the United States and Abroad' (2012) 3(3) *Intellectual Property Brief* 30.

18 Sarah Tran, 'Expediting Innovation' (2012) 36 *Harvard Environmental Law Review* 123, 139.

reason'.[19] Similar procedures are now offered in other countries as well. The Australian Patent Office, for example, has in place an 'expedited examination' system that allows patent applications to be assessed more rapidly if the commissioner believes that it 'is in the public interest' or that 'there are special circumstances that make it desirable'.[20] The Japanese Patent Office (JPO) has also operated since 1986 an accelerated examination programme, amended in 2004, which applies inter alia to socially relevant inventions, such as earthquake disaster recovery technology.[21]

Also in light of the above, I believe that introducing fast-track procedures for socially relevant inventions like healthy foodstuffs would not be 'revolutionary'. There would be no need for big procedural changes. Applicants that ask for the proposed fast-track would just need to mention in the application that their products or processes contain healthy ingredients.[22] And patent examiners should be tasked with confirming this. It is important

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19 See 37 CFR §1.102 (1959); Patents, Trademarks, and Copyrights, Republication of Regulations, 24 Fed reg. 10,332, 10,340 (22 December 1959) (recording 37 CFR §1.102 (1959)).

20 Patent Regulations 1991 (Cth), reg. 3.17(2)(a)–(b) (Australia).

21 The other categories of inventions admitted to the Japanese programme are now: (i) working-related applications; (ii) internationally filed applications; (iii) applications filed by small and medium-sized enterprises, individuals, universities, public research institutes etc; (iv) green technology related applications; and (v) Asian business location law related applications. See the Outline of Accelerated Examination and Accelerated Appeal Examination (Patents), JPO (23 July 2004), Outline of Accelerated Examination and Accelerated Appeal Examination (Patents), JPO (23 July 2004), see <http://www.jpo.go.jp/torikumi_e> accessed 18 November 2015).

22 A similar feature is shared by fast-track procedures adopted in the field of green technologies by the UK, Australia, South Korea, Japan, Israel and Canada. Simple statements by applicants are here sufficient, and patent offices do not require them to provide particular evidence to show the 'environmentally friendliness' of their inventions. See Antoine Dechezleprêtre, 'Fast-Tracking Green

that applicants should not bear the burden of proof that the invention is healthy: otherwise, food companies or individual inventors may be discouraged from innovating in this socially important sector.[23]

As has already been proposed in relation to fast-track procedures for green patenting,[24] it would be wise to devise this fast-track procedure in the context of an international treaty. A treaty that could serve this purpose is the Patent Cooperation Treaty (PCT),[25] which assists applicants in obtaining patent protection internationally for their inventions and helps offices with their decisions to grant or refuse the patent. An international harmonization of fast-track procedures would help in overcoming the difficulties stemming from differences between national fast-track procedures. Such differences may indeed make participation in multiple fast-track programmes expensive and lengthy, as applicants who wish to protect their inventions in several jurisdictions would have to comply with different procedural rules. An international harmonized fast-track programme, with similar rules and requirements, would instead reduce burdens on applicants and thus speed up and make cheaper the patenting process for healthy foodstuffs. It would also boost participation. Additional burdens on applicants should also be avoided, such as conducting prior art

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Patent Applications – An Empirical Analysis', International Centre for Trade and Sustainable Development paper No 37 (ICTSD 2013) 3–4.

23 A similar proposal and argument have been put forward in the field of environmentally sound technologies: see Estelle Derclaye, 'Intellectual Property Rights and Global Warming' [2008] 12(2) *Marquette Intellectual Property Law Review* 264–95.

24 Eric Lane 'Building the Global Green Patent Highway: A Proposal for International Harmonization of Green Technology Fast Track Programs' (2012) 27(3) *Berkeley Technology Law Journal* 1119, 1147–50.

25 Patent Cooperation Treaty, agreed at Washington on 19 June 1970, amended on 28 September 1979, modified on 3 February 1984 and on 3 October 2001 (as in force from 1 April 2002).

searches and analysis, which are usually requested when it comes to patenting ordinary inventions. In this way the entire process would be accelerated.[26]

Exempting healthy food and beverage patent applications from paying fees

The second proposal would consist of exempting applicants for healthy food patents from paying patent procedure fees, or at least significantly reducing them. Again, applicants should mention the healthiness of their products and processes in the application and patent offices should confirm that the inventions in question are healthy. As with the proposal for fast-tracking, highlighted in the previous section, this proposal would aim at encouraging and facilitating patent protection, and production, of healthy foodstuffs.

Indeed, patent fees may sometimes be unaffordable, especially for small and medium-sized enterprises. Take the large number of fees required by the European Patent Office: filing fees, search fees, fees per designated state, fees per claim over ten claims, examination fees and a fee for the patent grant and printing. US patent procedures are also very expensive. Indeed, applicants there must carry out a pre-examination search of all prior art, including previous patents and patent applications, and non-patent documentation, which can easily cost thousands of dollars in fees.[27]

Excluding unhealthy food from patentability

[26] The above suggestions build upon analogous ones put forward with reference to fast-track programmes for green technologies based inventions. See Lane (n. 24 above) 1160–70.

[27] Tran (n. 18 above) 141.

The third proposal would consist of excluding from patentability food products and processes that contain an excessive amount of unhealthy ingredients or components such as salt, fat and sugar. Specific and clear thresholds identified by health specialists should be introduced in order to guide both applicants and patent examiners – and the latter should confirm that the relevant invention is harmful to consumers.

This proposal may be particularly useful in countries that have recently experienced, or might experience in the future, an upsurge in the filing of patent applications related to unhealthy food. China seems to have recently witnessed such a trend, as has been noted by the Task Group of Patent Examination Cooperation Center of the Chinese Intellectual Property Office, which has found that several patents have been granted to food possibly harmful to consumers' health. This has occurred despite the fact that China has recently passed nearly 800 laws and regulations to protect food safety and the health and life of domestic consumers.[28]

The proposal could be implemented by introducing an ad hoc exclusion from patentability of inventions harmful to human health. This type of new category could be inserted in patent laws such as the TRIPS Agreement[29] and the European Patent Convention (EPC),[30] right next to the exclusion from patentability of surgical, diagnostic or therapeutic

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28 China Intellectual Property, updated 13 July 2011, see <http://ipr.chinadaily.com.cn/2011–07/13/content_12895645.htm> accessed 18 November 2015.

29 The TRIPS Agreement is one of the WTO Agreements, Annex 1C *Marrakesh Agreement Establishing the World Trade Organization*, opened for signature 15 April 1994, 1867 UNTS 3 (entered into force 1 January 1995).

30 Convention on the Grant of European Patents, opened for signature 5 October 1973, 1065 UNTS 199 (entered into force on 7 October 1977).

methods,[31] which also protects public health, although in another fashion (basically by preventing the monopolization of medically important methods).[32]

Alternatively, we could support a broad interpretation of those provisions that prohibit the patenting of inventions contrary to '*ordre public'* and morality. Many jurisdictions have introduced such a ban, availing themselves of the relevant TRIPS clause (Article 27.2).[33] The EPC also states that 'European patents shall not be granted in respect of … inventions the commercial exploitation of which would be contrary to "ordre public" or morality' (Article 53-a). The US has not incorporated a statutory ban in this regard, but inventions that are considered immoral seem to be excluded from patentability under a judge-made moral utility doctrine.[34]

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[31] Article 27(3) TRIPS allows countries to exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals. Likewise, Article 53(c) EPC states that 'European patents shall not be granted in respect of . . . methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body.'

[32] US patent law permits patenting of medical methods but denies a remedy for its infringement, therefore nullifying the right in so far as there is no enforceability.

[33] Article 27(2) TRIPS provides that countries may exclude from patentability 'inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment'.

[34] The moral utility doctrine dates back to *Lowell v Lewis* in 1817, 15 F Cas, 1018, 1019 (US Court of Appeals 1817) (the judge held in this case that 'the law will not allow the plaintiff to recover, if the invention be of mischievous or injurious tendency' and gave the examples of inventions aimed at poisoning people, promoting debauchery and facilitating private assassinations). The doctrine in question was also invoked to refuse patents for inventions related to gambling devices (see, for example, *Reliance Novelty Corp v Dworzek* 80 F 902, 904, ND Cal 1897, invalidating the patent for 'lack of utility'). Yet, such a doctrine has not been invoked to invalidate patents in recent years, prompting several commentators to hold that it is a dead doctrine. See Margo A Bagley, 'Patent First,

It could indeed be argued that inventions related to unhealthy food, whose consumption may cause obesity and other diseases, should be excluded from patentability on these grounds. I am aware that this exception has often been interpreted by courts and patent offices, especially in Europe, in a very narrow way.[35] Yet, the subject matter seems here to be particularly alarming and thus capable of being caught by the provision at issue.[36]

Ask Questions Later: Morality and Biotechnology in Patent Law' (2003) 45(2) *William and Mary Law Review* 469–547.

[35] See the decisions of the EPO in a string of cases concerning the patentability of biotechnological inventions: e.g. (i) *Transgenic Animals/*HARVARD, Board of Appeal of the EPO, Decision of 6 July 2004, T 315/03*;* (ii) T 356/93 *Plant Cells/PLANT GENETIC SYSTEMS*, OJ EPO 1995; (iii) *Howard Florey/Relaxin* [1995] EPOR 541. The literature on the morality and *ordre public* exception in the biotech sector is extensive: see inter alia Sigrid Sterckx (ed.), *Biotechnology, Patents and Morality* (Ashgate, 2000); Sivaramjani Thambisetty, 'Understanding Morality as a Ground for Exclusion from Patentability under European Law' (2002) *Eubios Journal of Asian and International Bioethics* 12, 48–53; Aurora Plomer, *Stem Cell Patents: European Patent Law and Ethics Report* (2006), see <http://www.nottingham.ac.uk/~llzwww/StemCellProject/project.report.pdf> accessed 18 November 2015; Tine Sommer, 'Interpreting Ordre Public and Morality in a Patent Law Context: Which is the Correct Approach?' (2007) *Bio-Science Law Review* 62–74; Sigrid Sterckx, 'The European Patent Convention and the (Non-)patentability of Human Embryonic Stem Cells' (2008) *Intellectual Property Quarterly* 478; Aurora Plomer and Paul Torremans (eds), *Embryonic Stem Cell Patents: European Patent Law and Ethics* (Oxford University Press, 2009); Oliver Mills, *Biotechnological Inventions: Moral Restraints and Patent Law* (Ashgate, 2010); Enrico Bonadio, 'Biotech Patents and Morality after Brüstle' (2012) *European Intellectual Property Review* 433–43.

[36] See the EPO proceedings G 2/06, Comments by the President of the European Patent Office (Alain Pompidou), 28 September 2006, p. 14 (noting that Article 53(a) EPC constitutes a blanket clause, which ensures the incorporation of fundamental ethical and legal principles in patent law, framed as to accommodate future developments).

If such applications are filed in Europe, patent offices could rely on the costs/benefits analysis criterion used by the European Patent Office (EPO) in some cases, including *Onco Mouse Harvard*. In the final decision of that saga, the EPO confirmed the validity of a patent related to a mouse that had been genetically engineered to develop cancer and could be used for anticancer research. It examined, on the one hand, the advantages for the treatment of cancer and, on the other, the environmental risks that could stem from the use of the said invention, and concluded that the benefits overwhelmed the costs.[37] In contrast, a patent examiner or judge tasked with assessing a food invention extremely harmful to consumers' health would probably weigh the possible costs (increased chances of obesity and other NCDs) and benefits (e.g. keeping the taste of the product as appealing to consumers as possible) in favour of the former – and thus refuse the patent. A similar outcome was reached by the EPO in *Upjohn*, where a patent application related to a transgenic mouse into which a gene had been inserted so that it would lose its hair was rejected. The invention aimed at testing products to treat human baldness and wool production techniques: the EPO again used a utilitarian approach and weighed up costs (animal suffering) and benefits (research to cure hair loss and improved wool manufacturing techniques), but in this case the former obviously outweighed the latter, so the invention was deemed immoral and thus not patentable.[38] A parallel could therefore be drawn between this decision and the case of unhealthy food inventions.[39]

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[37] See again the decision *Transgenic Animals*/*HARVARD* (n. 35 above), which confirmed the validity of the patent by relying on a costs/benefits analysis (paras 9.1–9.7 and 13.2.1–13.24). See also Guy Tritton, *Intellectual Property in Europe* (Sweet & Maxwell 2008) 135–36.

[38] European Patent Application No 89913146.0, filed on 17 November 1989, refused on 25 July 1993.

[39] The utilitarian approach is not accepted by all scholars, though. Other commentators prefer the so-called 'deontological approach', according to which inventions are considered contrary to public policy and morality even though they bring more benefits than disadvantages. In other words, the fact that an

Also, the letter of the relevant TRIPS provision should militate in favour of a broader interpretation of the *ordre public* and morality clause, so as to apply it to food products and processes which are scientifically proven to be harmful to human health. Indeed, Article 27(2) of the TRIPS Agreement expressly specifies that human health falls within the category of interests protected by the morality and public policy clause.[40] Even before TRIPS the expression '*ordre public*' had been interpreted as including a large range of public policy grounds, and in particular any matter in the general interests of the state and society:[41] and there is little doubt that the fight against obesity and other diseases caused by the consumption of harmful foodstuffs amounts to a strong interest of the state and society. Secondly, the proposal to exclude from patentability unhealthy food also seems in line with the very purpose of patent law, which is to incentivize the realization of inventions that are really useful to societies, not products or processes harmful to people's health.

Additional proposals?

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invention produces real or potential benefits cannot 'neutralize' immoral aspects stemming from the exploitation of the same: see Sigrid Sterckx (n. 35 above) 487–90 and 494. The application of the deontological criterion to unhealthy inventions would again make such subject matter unpatentable on morality and *ordre public* grounds.

40 See n 33 above.

41 This interpretation was given by a UK committee when attempting to implement the requirements of the 1963 Convention on the Unification of Certain Points of Substantive Law on Patents for Invention (Strasbourg Convention 1963). See Committee to Examine the Patent System and Patent Law, *The British Patent System: Report of the Committee to Examine the Patent System and Patent Law* (The Stationery Office, 1970) 68 [242].

The above could be stand-alone proposals, but they could also be 'merged'. The first and second proposals, for example, could be linked, so that applicants for healthy foodstuffs would not be required to pay fees for accelerated examination procedures. Also, countries particularly keen on protecting and promoting food security and good nutrition could provide a mix of 'positive' and 'negative' measures and cumulatively: (i) set up a fast-track patent procedure for healthy food applicants; (ii) exempt such applicants from paying the relevant fees (or greatly reduce them); and (iii) exclude from patentability unhealthy foodstuffs.

Other proposals could be made with a view to amending patent regimes and encouraging the dissemination of healthy foodstuffs: namely extending the term of protection.[42] The idea underlying this proposal is to provide extra years of patent protection in order to strongly encourage the making of healthy food products and processes. Such a proposal would probably be compliant with TRIPS as this treaty only requires states as a minimum standard to provide 20 years of protection counted from the filing date.[43] That means that countries can offer inventors a longer term of protection if they so wish, as is also confirmed by TRIPS itself, which leaves WTO countries free 'to implement in their law more extensive protection'.[44] Yet, despite its formal compliance with TRIPS, I would not recommend such a proposal to be implemented. Indeed, extending the term of protection beyond the 20-year barrier would have undesirable anti-competitive effects by delaying the entrance into the public domain of socially relevant inventions.

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[42] A similar proposal was mentioned in the early 1990s with reference to environmentally sound technologies by Nicola Atkinson and Brad Sherman in their article 'Intellectual Property and Environmental Protection' (1991) *European Intellectual Property Review* 165–70, 170; see also Derclaye (n. 11 above) 232.

[43] Article 33 TRIPS states that 'the term of protection available shall not end before the expiration of a period of twenty years counted from the filing date'.

[44] Article 1(1).

4. Objections and counter-arguments

That said, one may note that the three proposals suggested in this chapter, by requiring that food inventions should be treated differently (more favourably in the first and second proposals and less favourably in the third one), provide a discriminatory treatment in favour of, or against, the food industry. This situation would therefore discriminate against other fields of technology and thus violate the TRIPS anti-discrimination rule: 'patents shall be available and patent rights enjoyable without discrimination as to . . . the field of technology'.[45]

One may also argue that the proposals would make patenting procedures and related litigation in court rather cumbersome. They would first introduce difficulties for patent examiners and judges, that is in confirming that the relevant invention is either healthy (first and second proposals) or harmful to human health (third proposal). Fast-track procedures, in particular, would make the whole patenting process even more complicated and expensive to handle for patent offices, also taking into account that giving priority to certain inventions would require extra efforts from offices. All this would therefore amount to unreasonable conditions on the acquisition and maintenance of the patent, again, contrary to the TRIPS

[45] Article 27(1). Both negative and positive discrimination may be deemed inconsistent with this provision. As has been noted, 'a law that unjustifiably favors patentees in one field of technology over all other fields can be just as discriminatory as a law that unjustifiably disadvantages patentees in one field of technology relative to all other fields': see Maria Victoria Stout, 'Crossing the TRIPS Nondiscrimination Line: How CAFTA Pharmaceutical Patent Provisions Violate TRIPS Article 27.1' (2008) *Boston University Journal of Science and Technology Law* 177–200, 182; see also Carlos Correa, 'Public Health and Patent Legislation in Developing Countries' (20) 3 *Tulane Journal of Technology and Intellectual Property* 7.

Agreement, which requires, as a condition of the acquisition or maintenance of intellectual property (IP) rights, countries' 'compliance with *reasonable* procedures and formalities' (emphasis added).[46]

Yet such objections would be weak for the following reasons.

Discrimination v differentiation

I do believe that the proposals in question do not constitute a discriminatory treatment either against or in favour of the food industry. Far from constituting a discriminatory treatment, these proposals boil down to a lawful differential treatment that is necessary to meet a socially sensitive objective in a specific sector, namely the protection of human health.

As far as the first and second proposals are concerned, as it is accepted that patent law gives incentives to come up with new technologies, there is no reason in principle why public policy should not try to give greater incentives to develop specific products or processes that are considered particularly beneficial to society.[47] Take the example of accelerated procedures in the field of green-technologies that – as we have seen – have

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[46] Article 62(1). This provision has been interpreted by the WTO Panel in *Canada–Term of Patent Protection*, WT/DS170/R, Report of 5 May 2000. The Panel held that some Canadian patent law provisions (which required applicants to resort to delays such as abandonment of the application, reinstatement, non-payment of fees and non-response to a patent examiner's report) would be inconsistent with the general principle that procedures should not be unnecessarily complicated as expressed in inter alia Article 62.1 TRIPS Agreement (paras 6.117–6.119 of the report).

[47] Daniel Alexander, 'Some Themes in Intellectual Property and the Environment' (1993) 2(2) *Intellectual Property and Environment* 113–30, 116. The third proposal highlighted in this chapter also aims (at least indirectly) at encouraging the production of healthier food. Indeed, if food companies are aware that harmful food cannot be patented, they will probably switch to less harmful ones.

already been adopted in several jurisdictions. These have never provoked objections regarding possible discriminatory treatment over other fields of technology that do not have access to a similar preferential track (back in 1972 Rudolp E Blum made the point that a special status should be granted to inventions concerned with the protection of the environment, praising in particular the USA and Japan for granting such inventions a privileged and accelerated treatment).[48] It would thus be difficult to claim that the first proposal put forward here, which shares similar features and is also meant to meet socially relevant targets, is discriminatory. The incentive-related argument could again be relied on to justify and legitimize fee waivers (or reductions) for patenting healthy food. It should also be noted that such a preferential scheme is not completely new, at least in the scripts of IP scholars: already in 1972 Freidrich-Karl Beier noted that 'in the future, other possibilities for preferential treatment of socially important inventions might be adopted, such as reducing fees for the application, grant and maintenance of patents'.[49]

The distinction between unlawful 'discrimination' and lawful 'differential treatment' in the field of IP rights has already been stressed by the WTO Panel in *Canada—Patent Protection for Pharmaceutical Products*: the principle of discrimination – the Panel held – 'does not prohibit bona fide exceptions to deal with problems that may exist only in certain product areas'.[50] This finding sanctioned the lawfulness of certain Canadian exceptions to

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48 Rudolf E Blum, 'The Threat to Our Environment and the Protection of Industrial Property' (1973) *Industrial Property* 243–49, 248–49.

49 Beier (n. 12 above) 445.

50 Panel Report, *Canada–Patent Protection of Pharmaceutical Products*, WTO Doc WT/DS114/R, 17 March 2000, [7.92].

patents under Article 30 TRIPS that de facto targeted the pharmaceutical sector.[51] Yet, the 'spirit' of this finding could be relied on to also support a broad interpretation of *ordre public* and morality clauses such as the TRIPS and EPC ones, if not to create an ad hoc exclusion from patentability of unhealthy foodstuff (see above the first 'negative' proposal): indeed, excluding from patentability inventions harmful to humans could amount to a bona fide public health measure aimed at discouraging the development and dissemination of harmful food and accordingly defeating or at least mitigating serious extenuating circumstances.

No *discrimination* then, just lawful *differentiation*. Several other scholars have highlighted the need to consider the latter (as opposed to the former) as legitimate. For example, with particular reference to the pharmaceutical field, Frederick Abbott pointed out that, if specific rules applicable only to pharmaceutical patents are necessary to address important public interests such as the protection of public health, 'this does not constitute "discrimination" against the field of pharmaceutical technology. It constitutes recognition of legitimate public interests in differential treatment.'[52]

Thus, when it comes to devising IP, and specifically patent legislations, governments should be able to adopt measures on public interest grounds – such as the proposals put forward in this chapter – to meet specific concerns in certain fields. This can also be inferred by Article 8 TRIPS: '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

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51 The exceptions were the so-called 'regulatory review provision' (s. 55.2(1) of the Canadian Patent Act) and the 'stockpiling provision' (s 55.2(2) of the Canadian Patent Act): both exceptions allowed general drug manufacturers to override, in certain situations, the rights conferred on the patentee.

52 Frederick Abbott, 'Compulsory Licensing for Public Health Needs: The TRIPS Agenda at the WTO after the Doha Declaration on Public Health', Occasional Paper No 9 (Friends World Committee for Consultation, February, 2002) 49–50.

technological development' (emphasis added). Analogous provisions can be found in bilateral investment and free-trade agreements, such as amongst others the Comprehensive Economic Partnership Agreement (CEPA) between the EU and a group of Caribbean countries (CARIFORUM): 'an adequate and effective enforcement of intellectual property rights should … allow the EC Party and the Signatory CARIFORUM States to protect *public health* and *nutrition*' (emphasis added).[53] The references in the above legislative texts to 'sectors of vital importance' and in particular 'public health' and 'nutrition' are indeed to be interpreted as allowing states to take public interest measures in specific policy areas.[54]

Differentiation and the refusal of the neutrality principle

If proposals like the ones put forward in this chapter were eventually implemented, this would probably confirm that patents and inventions are not all 'equal' from a social utility perspective. Indeed, a patent covering a new and innovative bottle opener cannot be

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53 Economic Partnership Agreement between the CARIFORUM states, on one side, and the European Community and its member states, on the other, (CEPA) signed in Bridgetown (Barbados) on 15 October 2008, OJ 2008 L 289/I/3.

54 Marco Ricolfi, 'Is there an Antitrust Antidote against IP Overprotection within TRIPs?' (2006) 10 *Marquette Intellectual Property Law Review* 305, (noting that 'when problems exist only in certain product areas, and these involve important national public policies under Article 8(1), even measures or rules operating selectively may be TRIPs-compliant'). It should moreover be stressed that the protection of the public interest is one of the objectives pursued by the TRIPS Agreement, as confirmed by Article 7: 'the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation … in a manner conducive to social and economic welfare'. The importance of protecting public health within TRIPS has also been stressed by the Doha Declaration on the TRIPS Agreement and Public Health, adopted by the WTO Ministerial Conference on 14 November 2001 (WT/MIN(01)/DEC/2).

compared, say, to an anti-retroviral drug: everyone agrees that saving human lives is more socially important than finding easier ways of opening bottles. Patent legislators and judges would rather accept that difference and refuse to support what has often (and wrongly) been accepted in the past, that is a (by now) anachronistic and aseptic principle of neutrality of patents and of equal treatment of all inventions. This is also what several economic circles believe: as the journal *The Economist* has recently put it in an article highly critical of the current excesses of the patent system, differentiation between patent rights 'for different sorts of innovation' are possible and would be welcome.[55]

According to the neutrality principle, based on the laissez-faire model of modern capitalistic systems,[56] patent law should only concern itself with granting a monopolistic right without assessing whether inventions, for example, are socially meritorious, jeopardize the environment or are harmful to human health which result in patent law becoming 'technology neutral' and meaning that the 'wrong' kind of technologies might attract patent protection,[57] for example, a particularly harmful food manufacturing process. Such a principle, which excludes value judgements in IP matters and treats all subject matter equally,[58] has more in common with copyright law, as it would be unfair to subject the granting of copyright protection to judges' subjective assessments regarding artistic and social merit.

Yet, extending this principle to patent law is wrong. An interesting point to note is that 'despite patent law's apparent neutrality, it [patent law] carries the seed of differentiation

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55 'A Question of Utility' *The Economist* (London, 8–14 August 2015) 45.

56 Atkinson and Sherman (n. 42 above) 169.

57 Estelle Derclaye, 'What Can Intellectual Property law Learn from Happiness Research?' in G Dinwoodie (ed.), *Methods and Perspectives in Intellectual Property* (Edward Elgar, 2013) 13.

58 Estelle Derclaye, 'Patent Law's Role in the Protection of Environment – Re-assessing Patent Law and its Justifications in the 21st Century' (2009) *International Review of Intellectual Property and Competition Law* 249–73, 254.

and can therefore allow for special treatment'.[59] First, we have seen that many jurisdictions already incorporate provisions – for example, the exclusion from patentability of inventions that are contrary to *ordre public* and morality as well as of surgical, diagnostic and therapeutic methods – which inject into patent laws social considerations and concerns and therefore legitimize differential treatment. The incorporation of public interest-focused provisions into patent statutes is not even a novelty of recent times. The first UK Patent Statute of 1623 already stated that a patent could only be granted if it was 'not contrary to law or mischievous to the State'.[60] This provision was confirmed in the UK Patent and Design Act of 1883[61] and in the Patent Act 1949 (when the predecessor of the current Patent Act already excluded from patentability inventions contrary to morality and 'well-established natural laws').[62]

That the neutrality principle is weak can be also inferred by looking at the IP clause of the US Constitution, which stresses that the reason why IP rights are granted is to promote the 'Progress of Science and Useful Arts'.[63] The rationale behind this clause is to promote the development of useful inventions by offering inventors monopolistic rights for a limited period of time. Yet, according to many commentators, the meaning of 'progress' (also) within that IP clause is not neutral. As has been noted, progress is not an end in itself, but

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59 Derclaye (n. 58 above) 251.

60 Statute of Monopolies, s 6. See Derclaye (n. 58 above) 258.

61 S 86 of this Act gave power to the Comptroller General of the Patent Office to reject a patent application if 'the use would, in his opinion, be contrary to law or morality'.

62 S 19 of this Act provided refusal of patents '(1) if it appears to the comptroller in the case of any application for a patent—(a) that it is frivolous on the ground that it claims as an invention anything obviously contrary to well-established natural laws; or (b) that the use of the invention in respect of which the application is made would be contrary to law or morality'.

63 S 1(8) of the US Constitution.

rather an intermediate step towards other social goals.[64] It should also include the improvement of human life, which in turn includes the general concept of well-being.[65] That inevitably entails that inventions of highly social utility that are meant to deliver humanity greater benefits (like healthy foodstuff) fulfil that constitutional bargain better than inventions of little social value.[66]

Proposals that aim at providing a differential and more socially oriented legal treatment have also been put forward in relation to an IP right 'close' to patents, namely the plant variety rights protection that countries are required to adopt under TRIPS.[67] It has indeed been proposed that such a system could be designed by introducing an additional condition, the so-called 'value for cultivation and use' requirement (VCU).[68] Detailing the VCU requirement would then be left to national governments and would ensure that the developers of new plant varieties contribute to certain national priorities. For example, for a new variety to acquire protection, VCU might require applicants to demonstrate their socio-

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64 Beier (n. 12 above) 423 and 444 (stressing that 'the assumption that all technological advances are beneficial to humanity and that progress need only be accelerated for everything to turn out well – this belief has largely disappeared by now. It has yielded, although still not universally, to the view that mankind and its social needs should come first and that science and technology must orient themselves toward human needs.'); Atkinson and Sherman (n. 42 above) 169.

65 Derclaye (n. 23 above) 268.

66 Sarah Tran (n. 18 above) 36; Derclaye (n. 57 above) 14.

67 See Article 27(3)(b). While this provision mandates countries to provide for the protection of plant varieties, it also allows them to choose the specific form of protection: either the patent system or an effective *sui generis* system (or a combination of them). According to several commentators, countries have freedom to devise the *sui generis* system according to their needs: see D Leskien and M Flitner, 'Intellectual Property Rights and Plant Genetic Resources: Options for a Sui Generis System', Issues in Genetic Resources No 6 (Intellectual Plant Genetic Resources Institute, 1997).

68 Leskien and Flitner (n. 67 above) 54–55.

economic or environmental benefits, such as how it might benefit small farmers in terms of enhancing productivity or requiring fewer external inputs.[69]

The paradox of the neutrality principle

The neutrality principle of patents should also be rejected because of the paradox it creates.

For example, what if a patent office were to grant a patent in relation to an invention, say, covering a food product that contains a huge amount of saturated fat, sugar or salt? If we accept the neutrality principle, the patent would certainly be valid. Yet, due to increased awareness on the part of a number of legislators around the world keen to protect people's health, the consumption of such a product could be prohibited in some countries or at least severely restricted by regulatory bodies, in order to avoid, for instance, consumption by children in schools (poor eating habits developed at an early age can lead to a lifetime of serious health consequences and school is where young people spend most of their time and where they lay the foundations for healthy habits).

The paradox therefore lies in the fact that in such circumstances public authorities – patent offices and regulatory bodies – would send contradictory messages.[70] On the one hand, by granting patents they encourage and reward the making of inventions harmful to consumers and, on the other, by introducing strict regulatory measures they ban or limit the consumption of products incorporating such inventions. This inconsistent outcome comes from the very essence of the neutrality principle, according to which each area of the law has

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69 Graham Dutfield, *Intellectual Property, Biogenetic Resources and Traditional Knowledge* (Earthscan, 2004) 62.

70 Derclaye (n. 11 above) 231 (highlighting this paradox in the field of anti-global warming technologies).

a different and separate function to pursue and, accordingly, it is wrong for these functions to be confused and conflated.[71]

The rejection of the neutrality principle would eliminate this paradox and inconsistency and make patent law and food law compatible with each other and complementary (such a result probably being achieved by the implementation of the third proposal highlighted in this chapter, especially in countries that experience an upsurge in the filing of patent applications for unhealthy food). In actual fact, patent law, by excluding harmful food from patentability, might be more beneficial than food law, as the former would aim at discouraging the production of unhealthy products rather than merely restricting their consumption, which has been the aim of many regulatory measures under recent food legislation but which may also cause negative externalities: for example, a fat tax introduced by Denmark in 2011 to fight obesity and related diseases (hitting meat, pizza, butter, cheese, milk, oil and processed food if the product contained more than 2.3 per cent saturated fat) was later scrapped as it was perceived as regressive and as triggering cross-border trade.[72]

Other arguments and counter-arguments in relation to the third proposal

One may also note that excluding the patentability of unhealthy food products and processes would allow any food operator to develop and sell at a lower price products incorporating

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71 Atkinson and Sherman (n. 42 above) 169.

72 On the nature and impact of fat taxes see Alberto Alemanno and Ignacio Carreno, 'Fat Taxes in the European Union: Between Fiscal Austerity and the Fight against Obesity' (2011) 4 *European Journal of Risk Regulation* 571–76.

such inventions because of the absence of monopolies granted by patents. Paradoxically, this would therefore increase the dissemination of harmful foodstuffs.[73]

This argument seems weak, however. The argument that granting patents that protect controversial inventions might have the effect of reducing the availability of the relevant goods is not really convincing. First, this is not always necessarily the case. Indeed, when a patented invention is commercially successful and socially desirable, this may well trigger a rapid and massive dissemination of the product, regardless of whether the patentee keeps the price low or high. Second, the extent the invention is used should not really influence how patent law regulates patentable or unpatentable subject matter, especially when public authorities do not want to encourage research in controversial fields such as the development of unhealthy foods. As has been correctly pointed out, 'if the moral worth of an invention is debatable, then the degree in which it is exploited should not temper the law's attitude to it'.[74]

Another argument that may be used to oppose the third proposal revolves around the *ordre public* and morality clause contained in several patent legislations. As already highlighted, such a provision excludes from patentability inventions whose exploitation is contrary to public policy and accepted principles of morality. Yet such exploitation – as made clear in TRIPS and the EPC, for example – is not deemed immoral or against *ordre public* simply because it is prohibited by local laws or regulations.[75] A similar provision is contained in the Paris Convention: 'the grant of a patent shall not be refused and a patent shall not be invalidated on the ground that the sale of the patented product or of a product obtained by

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[73] A similar argument was presented by the patent owner in the *Transgenic Animals/HARVARD* opposition (n. 35 above).

[74] Thambisetty (n. 35 above) 48–53.

[75] Article 27(2) TRIPS and Article 53(a) EPC.

means of a patented process is subject to restrictions or limitations resulting from the domestic law'.[76] These rules basically entail that an inventor would still be able to get a patent from a patent office even where the regulatory body of that country prohibits the exploitation of the relevant product or process. The rationale is that, if it is the case that further evidence is later brought that convinces the regulatory body to lift the ban, the still valid patent would then become exploitable.

Yet, such rules and rationale would not fit well with the patenting of a foodstuff that is undisputedly considered unhealthy. Take a food invention containing a hugely excessive amount in fat, saturated fat, salt or sugar. Pursuant to the above mentioned rules, that invention would still be patentable even when, as is highly likely, the consumption of the relevant product or process is severely restricted on food safety grounds. Yet, in this case chances are slim that regulatory bodies might be convinced by new evidence about an alleged lack of harmful effects.

It would therefore be recommendable to modify the above TRIPS, EPC and Paris Convention provisions. That could be done by specifying that, where the ban or restriction of the exploitation of a product or process is based on clear and indisputable scientific evidence (such as in the case of food containing an excessive amount of fat, saturated fat, salt or sugar), countries would still be able to exclude that invention from patentability on *ordre public* or morality grounds. Such a legislative move would again make patent law and food law align in pursuit of the same goal.

Finally, it could be argued that the third proposal might not be good and effective because – it could be stressed – what is harmful to human health is not the occasional consumption of, say, foodstuffs containing an excessive amount of transfat or sugar. Rather, it is the continued and systematic consumption of such food that would be harmful. In other

[76] Article 4-*quarter*.

words, we should not talk about *unhealthy food*, but just about *unhealthy diets*. However, this argument also seems weak. A product or process should be deemed unpatentable – I believe – because of its inherent capability to harm people's health, no matter what amount is necessary to actually cause such harm. If we were to accept that it is only the abuse of a certain invention that triggers its unpatentability on *ordre public* or morality grounds, the result would be absurd. For example, an extremely polluting exhaust pipe for cars might attract patent protection on the assumption that its occasional use by a car driver would not have hugely negative effects on the environment (such effects would only materialize in case of cumulative use by a broad category of users). Yet, what should be taken into account for the purposes of deciding whether an invention must be excluded from patentability again is not *how much* the relevant product or process is used, but its inherent ability to harm people, the environment and other public goods.

Unreasonable and cumbersome proposals?

I also believe the three proposals in question do not create unreasonable conditions on the acquisition of patents on food related inventions. They therefore do not run contrary to TRIPS.[77]

First, they would not place excessively heavy burdens on patent offices and applicants. The objection that patent offices and judges would be ill-equipped to verify whether the relevant food product or process is healthy or harmful (a task beyond the skills of patent officers) could be overcome. For example, patent officers could be partnered with experts, such as professors and specialists in food safety, who could be questioned about technical issues. The idea of getting experts involved in patent procedures is indeed not new,

[77] Article 62(1).

as some patent offices already rely on them, for example, when dealing with biotechnological inventions.[78] The latest developments in food safety and nutritional science would also help overcome the scientific uncertainties that have for a long time surrounded the distinction between healthy and unhealthy foods. Indeed, efforts have recently been made by regulators to devise an appropriate categorization system that allows for the differentiation of foods that are high in fat, saturated fat, salt or sugar. The UK Food Standards Agency has, for instance, developed a nutrient profiling model as a tool for categorizing foods for children on the basis of objective criteria and, in particular, their nutrient content.[79] This model, which has been adopted by the UK media and communications regulator Ofcom to regulate the advertising and promotion of foods to children, uses a simple scoring system that recognizes the contribution made by beneficial nutrients that are important in a child's diet (i.e. protein, fibre, fruit and vegetables, and nuts) and penalizes foods with ingredients that children should eat less of (saturated fats, salt and sugars).

Also, the fact that applicants would obtain an expedited examination and would not be required to pay fees to patent their healthy food inventions does not make the first and second proposals described in this chapter unfeasible. It could indeed be said that examining patent applications – which involves a significant amount of work by examiners – quickly or without charging fees would make the whole procedure cumbersome and thus unreasonably difficult to manage. Yet, I believe such an objection could be overcome by re-emphasizing that these procedures are aimed at pursuing an overriding public interest, hence rendering rather weak any allegation that the system would be unfeasible (and anyway understaffed

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78 Enrico Bonadio, 'Patents and Morality in Europe' in I Calboli and S Ragavan (eds), *Diversity in Intellectual Property – Identities, Interests, and Intersections* (CUP, 2015).

79 See the UK Food Standards Agency webpages at <http://www.food.gov.uk/northern-ireland/nutritionni/niyoungpeople/nutlab/#.Ugn2GVMgYfo> accessed 19 November 2014.

patent offices could be supplemented by hiring more experts in the specific field). As has been noted in relation to US fast-track procedures for green technologies, requiring extra fees for receiving the accelerated review would upset 'the balance of the constitutional patent bargain by over-burdening the parties most likely to promote "the Progress of Science and Useful Arts" (Section 1(8) if the US Constitution)'.[80]

Conclusion

This chapter has highlighted a serious problem of contemporary society – namely the obesity and other NCDs caused by the consumption of unhealthy food – and how such problem may be tackled by also relying on patent regimes.

I do believe that the patent system could play a positive role in this specific regard, by encouraging (not mandating) food companies and inventors to produce and bring to market healthier foodstuffs. I am indeed convinced that patent law has the potential to modify behaviours to promote good corporate and scientific conduct.[81] Conversely, I oppose views that consider the patent system as neutral to, and insulated from, any public policy considerations including human health. In other papers, I have made the point that public policy and morality related concerns are actually *embedded in* and *permeate* the patent system and that the latter should therefore serve as a social filter.[82] In other words, patent law cannot be considered in a vacuum nor can it neglect considerations and concerns related to

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80 Tran (n. 18 above) 128.

81 Brad Sherman, 'Regulating Access and Use of Genetic Resources: Intellectual Property Law and Biodiscovery' (2003) *European Intellectual Property Review* 301–08.

82 Bonadio (n. 78 above). See also Angus J Wells, 'Patenting New Life Forms: An Ecological Perspective' (1994) *European Intellectual Property Review* 111–18.

products and processes whose exploitation poses serious threats to society,[83] such as the diseases caused by the consumption of unhealthy food. Conversely, patent law should be considered as the servant of public policy and be justified by the benefits it is capable of bringing.[84] This is even more so if we look at the general purpose of the patent system, that is, to incentivize (before) and reward (after) the making of inventions useful to our society. The proposals put forward in this chapter serve that purpose: that is, they would aim to push research and development in the food industry towards healthier paths – and would do so by stretching the capacity of the patent system to respond to new public policy challenges and to be complementary to another area of law, namely food law.

By either facilitating and speeding up the patenting process of healthy food or by excluding harmful ones from patentability, the implementation of these proposals would send clear messages that: (i) inventions which are of a greater social value, like healthy foodstuffs, should be patented faster and more cheaply and thus reach markets more quickly; and (ii) patenting 'anything under the sun which is made by man'[85] would not be possible anymore.[86]

Also, the proposals put forward in this chapter are in line with some recent studies, such as the 'happiness and IP' related research carried out by Estelle Derclaye: this scholar rightly noted that if we want patents and related rights to be legitimate, we need to go further and base patent regimes on stronger universal values and goals.[87] In other words, patent law should focus more on 'needs', not 'wants', and therefore encourage investments in

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83 Thambisetty (n. 35 above) 48–53.

84 Alexander (n. 47 above) 113.

85 *Diamond v Chakrabarty* 447 US 303 (1980).

86 In fact the above statement by the US Supreme Court in *Diamond v Chakrabarty* does not completely reflect the reality of the patent system as, in the USA (and in many other jurisdictions), a number of inventions are excluded from patentability on many grounds including public interest grounds.

87 Derclaye (n. 57 above) 528.

necessities, not luxuries.[88] It should be used not only for merely economic purposes but also as a tool to regulate the impact of technology on the environment or health.[89] The argument that IP law should take into account sustainable development is not new and has recently been put forward by other academics such as Henning Grosse Ruse-Khan,[90] as well as Lionel Bently and Brad Sherman.[91] The latter scholars in particular noted that:

> there is no reason why the patent system, as a regulatory tool, should only be used in the pursuit of economic ends, nor any reason why 'external' factors such as … health should not fall within the core remit of the patent system … arguments of this nature are beginning to have an influence on patent law, particularly in relation to … food security.[92]

As shown above, I also believe that the proposals put forward in this chapter would not place excessively heavy burdens on patent offices. The assessment of the harmfulness or healthiness of products or processes does not seem an insuperable obstacle. Integrating

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88 Derclaye (n. 57 above) 532 and 536 (also noting that 'technology, and thus patents and related rights, can bring happiness in the sense that they correspond to needs. For example, with technology, inventors can enable food security, invent new pharmaceuticals, create non-polluting, renewable energy, and facilitate sustainable production of goods and services.').

89 Derclaye (n. 58 above) 269.

90 Henning Grosse Ruse-Khan, 'The Concept of Sustainable Development in International IP Law – New Approaches from EU Economic Partnership Agreements?' in Annette Kur and Vytautas Mizaras (eds), *The Structure of Intellectual Property Law: Can One Size Fit All?* (Edward Elgar, 2011) 308–42, 322 (highlighting 'the promotion of creativity, innovation and competitiveness as a *means* of achieving the goal of sustainable development' and noting that 'the protection of IP is no end in itself, but merely an (important) tool for achieving those means').

91 Lionel Bently and Brad Sherman, *Intellectual Property Law* (Oxford University Press, 2014) 381.

92 Ibid. 381.

technical experts into patent examiners' teams would help in confirming whether a food related invention carries the health benefits claimed in the application.

The proposed fast-track procedure for patenting healthy food may also be promising. A quick look at the data gathered with reference to the accelerated programmes already implemented in some countries in the field of green technologies is quite telling: the time taken to grant patents in this sector has been cut by between 42 per cent and 75 per cent, with the shortest time to grant being delivered by the UK (75 per cent).[93] If such programmes work for green technologies, there is no reason why similar systems could not work for healthy food. As stressed by the former Undersecretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office (USPTO), David Kappos, 'we're already experimenting with various ways of enabling applicants to receive accelerated review of technologies in areas that are priorities … like green technology … and we'll be considering accelerated reviews in other categories of innovation that are also vital to our national interests'.[94]

Obviously, the proposals in question are not being put forward as the only solution to combatting obesity and other illnesses caused by consumption of unhealthy foods. Yet, they may be part of a wider global and national answer aimed at fighting such diseases, including tax incentives for the production of healthier food.

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93 These data are accessible at the WIPO website: see <http://www.wipo.int/wipo_magazine/en/2013/03/article_0002.html> accessed 18 November 2015.

94 David Kappos, Public Meeting on Enhanced Examination timing Control Initiative 9 (20 July 2010), see <http://www.uspto.gov/web/offices/com/sol/og/2012/week52/TOCCN/item-252.htm> accessed on 18 November 2015.