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# The Legal Notion of Abuse of Patent Rights

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The patent system has reportedly been subjected to various misuses in the past decades. Evergreening, exclusive and limited licensing of diagnostic tests and the destruction of generic medicines are only a few of the instances discussed in literature. Additionally, certain phenomena have also been reported to distance the system *as a whole* from its intention: incentivising innovation. Here, the keywords are anti-commons, patent thicketing, patent trolling, etc.. In international law, the TRIPs ceilings debate mainly roots in developmental grounds, but also on examples such as these.
The hypothesis is that the flexible nature of the patent system should be strong enough to cope with most situations. In this context, this paper will analyse an additional legal tool that could serve to flexibly deal with possible negative uses of patent system: the notion of abuse of rights. Abuse of rights classically means that a right holder may not make use of his right in an illegitimate manner. The aim is to analyse what this notion entails concretely and what it could mean in/to patent law. After this, we proceed by testing it upon two instances reported to be abuses of the system: the evergreening of patents and medicines in transit-case. Finally, this analysis and its results are being put against the background of the TRIPs-ceilings debate. Here, the thesis is advanced that a good faith interpretation imposes certain ceilings on WTO member states already, and that a contrary application may constitute an abuse or rights.

# Contents

# Introduction

The patent system has been subject to intense criticism over the past decades[1]. Phenomena such as patent thicketing[2], patent trolling[3], the theory of anti-commons[4] and more generally the quality of patents[5] as well as the strategic use of the system[6], have all created doubt on the system's health. These instances also form part of the motivation to claim maximum standards of protection or 'ceilings' at the international level - in the TRIPs Agreement. Although much of today's criticism seems to have somewhat lost its breath and often lacks empirical evidence[7], some aspects remain valid.

A distinction can be made here between the different kinds of criticism or reported misuses of the system. One can group them according to who or what is affected. Then, depending on the category into which a specific instance falls, the appropriate remedy will (have to) differ. In a typology of possible 'patent failures', one could thus envisage three categories:

- uses of (a) patent(s) considered abusive towards a specific user or group of users (e.g. certain licensing practices);
- uses of (a) patent(s) that would go against the rationale of the patent system itself (incentivising innovation); and
- uses of (a) patent(s) that would go against higher ends (e.g. access to medicines, human rights, benefit of society as whole).[8]

[1] To cite but a few: Bessen, J. and Meurer, M.J., *Patent Failure* (Princeton University Press, New Jersey, 2008); and Jaffe, A.B.; and Lerner, J., Innovation and its Discontents: How Our Broken Patent System is Endangering Innovation and Progress and What to do About It (New Jersey: Princeton University Press, 2004).

[2] E.g. Shapiro, C., 'Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting', in A.B. Jaffe, J. Lerner and S. Stern (eds.), *Innovation Policy and the Economy*, vol. 1 (MIT Press, Cambridge US, 2001).

[3] E.g. Reitzig, M.G., Henkel, J., and Heath, C., *On Sharks, Trolls, and Other Patent Animals - 'Being Infringed' as a Normatively Induced Innovation Exploitation Strategy*, 2006, available online at: http://www.ssrn.com/ (last visited 22 March 2009).

[4] Heller, M.A., and Eisenberg, R.S., 'Can patents deter innovation? The anticommons in biomedical research', *Science* 280 (1998), pp. 698-701.

[5] On the patent quality debate, see e.g.: Wagner, R.P., 'Understanding Patent-Quality Mechanisms', *University of Pennsylvania Law Review* 157 (2009), pp. 2135-2157; Hirschey, M.; and Richardson, V., 'Are Scientific Indicators of Patent Quality Useful to Investors?', *Journal of Empirical Finance* 11/1 (2004), pp. 91-107; Hall, B. (et al.), 'Prospects for Improving U.S. Patent Quality via Post-grant Opposition', *NBER Working Paper* N° W9731 (2003); King, J.L., 'Patent Examination Procedures and Patent Quality', in W.M. Cohen and S. Merrill, *Patenting in a Knowledge-based Economy* (Washington: National Academies Press, 2003).

[6] Schilling, M., Strategic management of technological innovation (McGraw-Hill, New York, 2006).

[7] In the context of biotechnology, see for instance: Caulfield, T. Cook-Deegan, R., Kieff, F. and Walsh, J., 'Evidence and anecdotes: an analysis of human gene patenting controversies', 24 *Nature Biotechnology* 9 (2006), p. 1091.

[8] Needless to say here that some instances can fit into more than one category at the time; but this does not strongly affect our analysis.

Whereas the first category of our typology is usually left to the challenge of third-parties, the second and third bring expectations for state-driven actions or redress. The patent system however strongly relies upon the challenge of private actors, i.e. competitors. Patent offices are overloaded with work and do often not check whether the patentability requirements are being met before issuing the patent. The Swiss and Belgian patent office for instance do not check the novelty requirement. The burden of control is systematically moved away from the state, the patent office. Furthermore, with post-grant issues like licensing schemes, the patent office cannot intervene anyway.

In this context, third-party actors are thus called upon but often seem to lack the instruments to tackle the problems. This is true especially in relation to instances that show in the post-grant phase only and which are outside of the realm of competition law. They also seem to lack the instruments to tackle patents beyond the technical analyses of the patentability requirements. Only rarely indeed, can they challenge patents on more fundamental grounds. One isolated example of such a possibility is the exception of 'ordre public'[9] and 'morality'[10] – a possibility to challenge the patentability and thus validity of patents.[11] Apart from this, one will however have a difficult time finding ways to tackle (uses of) patents that go against the rationale of the system or other higher ends. These grounds alone will not suffice. Technical grounds must be present as well, and these may be hard to find.

There appears to be a necessity for flexible legal provisions that enable private actors to protect themselves from patent abuses, but also enable them to play a more active role in order to assure the effectiveness of the system to society at large. This paper therefore proposes the introduction of the notion of abuse of rights into the patent system[12], both as a flexible mechanism to tackle certain

[9] This concept is generally linked to safety issues. As with the morality exception, the ordre public exception mainly emerged under the European patent swstem(s). The Technical Board of Appeal of the European Patent Office established the principle that claimed subject matter that is likely to seriously prejudice the environment should be excluded from patentability for being contrary to the *ordre public* (Technical Board of Appeal of the European Patent Office, *Plant cells/PLANT GENETIC SYSTEMS*, 21 February 1995, T 356/93, Official Journal of the European Patent Office (1995) 545, § 18). Obviously, issues of biosafety and biodiversity immediately come to mind (See for instance: G. VAN OVERWALLE, *Influence of Intellectual Property Law on Safety in Biotechnology*, in World Congress on Safety of Modern Technical Systems, Saarbrücken 2001, TÜV-Verlag, pp. 664–670). Yet it remains to be seen to what extent patent examiners actually *can* assess safety.

[10] The concept of morality – under European patent case-law - is a belief about whether a certain behaviour is right or wrong, based on the totality of norms that are deeply rooted within European society and civilization (see Technical Board of Appeal of the European Patent Office, *Plant cells/PLANT GENETIC SYSTEMS*, 21 February 1995, T 356/93, Official Journal of the European Patent Office (1995) 545, § 6).

[11] Under international patent law, countries can chose whether or not to implement such an exception into their patent laws (Article 27 § 2 TRIPS Agreement).

[12] The matter has not yet been subject to thorough analysis in patent law, although the matter has been addressed in relation to copyrights and trademarks. A Ph.D. dissertation on the matter exists in relation to trademarks (E. Wiedmann, Der Rechtsmissbrauch im Markenrecht, 2002, available online at: http://deposit.ddb.de/cgi-bin/dokserv?idn=96472118x&dok_var=d1&dok_ext=pdf&filename=96472118x.pdf (last visited 15 April 2011)); and a 1998 publication addresses abuse of rights in relation to copyrights (C. Caron, *L'abus de droit et droit d'auteur*, Paris, Litec, 1998).

instances and as a screening mechanism for eventual changes in the positive law. Abuse of rights, known from other fields of law, simply states that although one exercises legally obtained rights, one is not entitled to do so in an illegitimate way. It is essentially a post-grant tool, since it only plays once (patent) rights have been established. However, its ability to be used to tackle (post-grant) a number of abuses rooting in pre-grant phase needs to be investigated.

This paper therefore discusses where, in the typology of cases and available remedies, the said notion can bring an added value. First, the concept in general will be described, then analysed as to its applicability in patent law. After this, its usability in practice is being tested in two case-studies. These cover each of the three above described categories, and have been chosen because no strong remedy is reported to be available so far.

First, we test the case of what is called the *evergreening of patents*. Evergreening can be described as the situation where shortly before a patent expires, one re-applies a slightly different version of the invention to restart another 20 years of protection for what in fact is the same subject matter. Whereas the case described here below is a typical post-grant issue, this one is rather 'borderline'. The evergreening of patents mainly roots in a failure to prevent too small amendments to existing inventions to be (re-)granted a patent. This case study is chosen to see how and whether abuse of rights could be construed to cover abuses rooting in the pre-grant phase.

The second step entails an analysis of the notion of abuse of patent rights on the case of *medicines in transit*. Having benefited from strong media attention, this is the case of medicines on the way from and to developing countries that were stopped at the Dutch borders, on the basis of local patent infringement. They were seized there and finally either sent back to the country of origin or destroyed. Although produced in a country where there was no patent protection for these medicines, and although being on the way to another country where the medicines were not patented, shipments were stopped for violation of the patent law of the transit-country. The matter was debated in the access to medicines context. Later, the discussion was even continued at the WTO. More than any other case study, it shows the intrinsic linkage between patent and international trade law.

Each case study will be conducted along the following scheme/set of questions:

- Is there a need for additional legal tools in this specific case study?
- Can the abuse of rights notion apply here in practice and is it efficient?
- What does this teach us in relation to international obligations and the ceilings debate?

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See also: J. Götz, ‚Zum Rechtsmißbrauchseinwand im Markenrecht', in: Erdmann, Willi/Gloy, Wolfgang/Herber, Rolf, *Festschrift für Henning Piper*, München, 1996, p. 563; and H. Helm, 'Die bösgläubige Markenanmeldung', *GRUR* 1996, 593.

The last question will be discussed in a separate chapter. The prior two will be at the centre of each case-study.

# I. Abuse of rights

*Generally speaking*, abuse of rights as a legal concept is well-known. It means that although in theory someone might be acting within the scope of what is legally permitted (as a 'right'), the law is infringed nonetheless because a specific situation turns out to render the chosen action to be (legally) unacceptable. A *right* is used, but in an *illegitimate* ('abusive') way[13]. Without the application of the abuse of rights theory, said behaviour could not or only with great difficulty be challenged. Abuse of rights thus frames the general 'substance over form' debate. It can be considered a counterweight of flexibility to/in positivistic legal systems. An often mentioned danger of the notion lies in granting too much discretionary power to judges and (hence) providing too little legal security.

*Concretely speaking*, its application is different from one field of law to another. In this section – since it introduces the later investigation of abuse of rights in patent law – we look at abuse of rights in civil law and where possible at abuse of *ownership* rights, and then dedicate a section to its content on the international regulatory level.

## A. Domestic approaches

In most legal systems, the notion roots in the more general notion of 'good faith'. In common law systems, it is linked to 'equity[14]'. We concentrate on the classical and narrow 'abuse of rights' doctrine. To this purpose, we next look at how abuse of rights is being applied in the civil law of a number of countries. We briefly address the Belgian legal system – the authors' native country - the French - where the notion of 'l'abus social' appears particularly interesting in light of instances going against a given rights' rationale - the German - a country with a strong positivistic legal system – and the Swiss - a country with a clear and specific provision on the matter.

In Belgium, the notion ('Rechtsmisbruik') in civil law roots in the general obligation to good faith: "*Alle overeenkomsten, …, moeten te goeder trouw worden ten uitvoer gebracht*"[15]. As we will see below, this is the case in most jurisdictions. The narrower notion of abuse of rights does not however have a particularly long history in Belgium. Although it first appeared in the early

[13] Definitions diverge. Each Legal system more or less works with its own.

[14] Define

[15] Article 1134 § 3 of the Belgian Civil Code.

20th century, 'modern' abuse of rights[16] was only established in the 1980s[17]. It is nonetheless considered to be a general principle of law today.[18]

Abuse of rights has been interpreted by Belgium's highest court[19] in several cases. It has most recently been defined as the exercise of one's right(s) obviously/evidently[20] going beyond the normal exercise of that right by a careful and concerned[21] person.[22] On this basis, numerous applications of it can be described. It has for instance been exemplified by the exercise of right with the only aim to cause harm to third parties. Similarly, it covers the exercise of a right whereby the right holder deliberately chooses the option that is the most disadvantageous to others, amongst options equally beneficial to him. Furthermore, it has also been applied to the case where one exercises a right without reasonable and sufficient interest, especially when the disadvantage that is hereby caused to others is disproportional to the benefit obtained by the right holder.[23] Finally, it is used when a right holder in the exercise of his rights, created reasonable expectations in relation to third parties; but then does not honour these. The notion has also been applied to cases where the right is being used against the rationale of the right or its social or economic aim.[24] It is thus not limited to what one calls the 'intention de nuire'; the intention to cause damage.

In the analysis of abuse of rights, Belgian judges must take into account all of the circumstances of the case[25], whereas it can be an acceptable legal ground even in cases where the right finds its origin in the law itself[26]. Importantly, the sanction in civil law cases such as abuse of ownership rights is not the loss of right. Abuse of rights is sanctioned by obliging a 'normal' exercise of the right and/or by an obligation to repair the caused damages.[27]

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[16] Meaning it was decoupled from extra-contractual liability ('haftplicht' or 'onrechtmatige daad' – Article 1382 BW).

[17] Hof Van Cassatie/Cour de Cassation, 19 september 1983 (A.C. ,1983-1984).

[18] T. Strubbe, *Rechtsmisbruik in contractuele aangelegenheden*, Universiteit Gent, 2009, at p. 4.

[19] 'La Cour de Cassation' (French); 'Hof van Cassatie' (Dutch).

[20] Hard to translate. The Dutch wording says 'kennelijk'.

[21] In the original Dutch : 'voorzichtig en bezorgd'.

[22] Hof Van Cassatie/Cour de Cassation, 8 February 2001 (A.C. 2001, nr. 78); Hof Van Cassatie/Cour de Cassation, 1 February 1996 (A.C. 1996, nr. 66); Hof Van Cassatie/Cour de Cassation 21 Hune 2000 (A.C. 2000, nr. 392 (gerechtelijk rechtsmisbruik)); Hof Van Cassatie/Cour de Cassation, 11 june 1992 (A.C. 1991-92, nr. 534) ; Hof Van Cassatie/Cour de Cassation, 10 September 1971 (A.C., 1972, 42).

[23] Hof Van Cassatie/Cour de Cassation, 18 June 1987 (A. C., 1986-1987, 1441); Hof Van Cassatie/Cour de Cassation, 19 September 1983 (A.C. ,1983-1984, 53-54).

[24] M. Van De Putte and G. Van Malderen, 'Contracten of Verbintenissen uit overeenkomsten in het algemeen', in Van De Putte, M., and Van Malderen, G., *Verbintenissenrecht*, Brugge, Die Keure, 1996, at p. 20.

[25] Hof Van Cassatie/Cour de Cassation, 17 May 2002, (XX). Also: Hof Van Cassatie/Cour de Cassation, 15 March 2002, C.01.0225.F (XX).

[26] Hof Van Cassatie/Cour de Cassation, 22 September 2008, *Rechtskundig Weekblad*, 2010-2011, at p. 1345: "*7. Misbruik van recht kan voorhanden zijn, ook al raakt het bedoelde recht de openbare orde of is het van dwingend recht*". Also: Hof Van Cassatie/Cour de Cassation, 10 June 2004 (AR C.02.0039.N, A.C., 2004, N° 315).

[27] Hof Van Cassatie/Cour de Cassation, 5 March 1984 (A.C. 1983-84, nr. 374).

In France, the notion of abuse of rights ('Abus de droit') appears similar to its Belgian cousin. Rather than in good faith, it however roots here in Article 1382 of the French Civil Code - the gerenal provision on extra-contractual liability: "*Tout fait quelconque de l'homme, qui cause à autrui un dommage, oblige celui par la faute duquel il est arrivé à le réparer*".

Abuse of rights in France has been developed in jurisprudence to cover two settings: 'l'abus-social' and 'l'abus-intention-de-nuire'.[28] The latter is the classical case, where one uses his right with the only benefit of causing damages to others. It also covers the use of a right in the most damaging way to others with equal benefit to the right holder. It is linked and limited however to intentionally causing harm. The prior - l'abus social - covers the case where a right is being exercised in a way contrary to its rationale or aim.[29] In practice, this has for instance been applied to cover the case where the right to come out on strike is being exercised without aiming at better working conditions, but instead at triggering political changes.

As is the case in Belgium, the notion of abuse of rights ('Rechtsmissbrauch') is being deducted in Germany from the principle of good faith. This is implemented in 242 of the German civil code ('Bürgerliches Gesetzbuch'): "*Der Schuldner ist verpflichtet, die Leistung so zu bewirken, wie Treu und Glauben mit Rücksicht auf die Verkehrssitte es erfordern*". Freely translated into English, it states that one has to fulfil one's obligations in the manner required by the principles of 'Treu und Glauben' (good faith), taking into account the 'Verkehrssitte' (customs). Best known application of abuse of rights is the so-called Schikanenverbot[30], as embodied in Article 226 of the German Civil Code: "*Die Ausübung eines Rechts ist unzulässig, wenn sie den Umständen nach nur den Zweck haben kann, einem anderen Schaden zuzufügen*". Freely translated, this provision states that a right cannot be exercised when – according to the circumstances – this can only have the purpose to cause damages to others.[31] This is the classical 'intention de nuire'. Literature reports that in Germany also, the notion of abuse of rights can be broad enough to encompass cases

[28] Cass. req., 3 August 1915, pourvoi no 00-02378

[29] L. Josserand, *De l´esprit des droits et de leur relativité: Théorie dite de l´abus des droits*, 2nd edition, Paris, 1939.

[30] On the matter: K. Huber, *Ueber den Rechtsmißbrauch*, Bern, 1910; E. Betti, 'Der Grundsatz von Treu und Glauben in rechtsgeschichtlicher und vergleichender Betrachtung', in: Loehlein, R., (Eds.), *Studien zum kausalen Rechtsdenken. Eine Festgabe zum 80. Geburtstag von Rudolf für Müller-Erzbach*, Rudolf, München, 1954; K. Ballerstedt, ‚Zur Systematik des Mißbrauchsbegriffs im GWB', in: *Festschrift für Wolfgang Hefermehl zum 70. Geburtstag*, 1976, pp. 37-68; E. Zeller, *Treu und Glauben und Mißbrauchsverbot*, Zürich, 1981; P. Mader, *Rechtsmißbrauch und unzulässige Rechtsausübung*, Wien, 1994.

[31] Other examples are Paragraph 320.2 of the BGB: *"Ist von der einen Seite teilweise geleistet worden, so kann die Gegenleistung insoweit nicht verweigert werden, als die Verweigerung nach den Umständen, insbesondere wegen verhältnismäßiger Geringfügigkeit des rückständigen Teils, gegen Treu und Glauben verstoßen würde";* or Paragraph 1020 of the BGB: „*Bei der Ausübung einer Grunddienstbarkeit hat der Berechtigte das Interesse des Eigentümers des belasteten Grundstücks tunlichst zu schonen. Hält er zur Ausübung der Dienstbarkeit auf dem belasteten Grundstück eine Anlage, so hat er sie in ordnungsmäßigem Zustand zu erhalten, soweit das Interesse des Eigentümers es erfordert*".

where the right is being used against its rationale[32] or its social function ('soziale Funktion')[33]. Finally, such limitations to ownership rights are being recognised also outside of the abuse of rights context. An interesting analogy can for instance be drawn from the German Constitutional Court's decision in *Clinical Trials I* – a case interestingly covering patent issues. At stake here was the research exemption in patent law[34]. This exemption allows third parties to use a patented invention for research purposes, without having to reward the patent holder or ask for his permission. As it however limits the patent holders' intangible (patent) ownership right, it was claimed that the exemption breaches the constitutionally guaranteed right to property of Article 14 § 1 of the German Constitution.[35] The court decided that as the rights enshrined in Article 14 § 1 are to be assessed taking into account public welfare ('Gründe des Gemeinen Wohls'), they can, however only proportionally, be limited to the benefit of society as a whole. The research exemption, the Court went on, is to be considered such a legitimate limitation of property rights. An unlimited patent protection would not be justified, especially taking into account the freedom of research ('Forschungfreiheit') and the ('Sozialbindung des Eigentums'). [36]

An interesting country in the abuse of rights context, finally, is Switzerland. The Swiss Confederation uses the concept in a slightly different form from both countries discussed above . It has a specific 'abuse of rights' provision in its Civil Code, explicitly including the notion in the good faith concept. Article 2 § 2 of the Swiss Civil Code ('Handeln nach Treu und Glauben' – good faith) states: "*Der offenbare Missbrauch eines Rechts findet keinen Rechtsschutz*". Freely translated, this states that the obvious abuse of a right will not enjoy legal protection. The provision has lead to a more dominant notion of abuse of rights than is the case for instance in France[37]. On its basis, specific cases however turn out similarly as in the other countries mentioned above. Also, in Switzerland, the notion is broad enough to cover instances where a right has been used against its rationale[38]. [39]

[32] BGHZ 3, 94, 104.

[33] Palandt/Heinrichs, § 242 BGB, Rn. 38.

[34] See: Cottier et al, Patents and the Research Exemption: Regulatory Competition or Harmonization in International Law, forthcoming 2011 – on file with author.

[35] Patent rights had been ruled as part of Article 14 § 1 and hence a form of personal property in a prior decision by the Constitutional Court (Bundesverfassungsgericht, *Akteneinsicht in Patentuteilungsverfahren*, BGHZ 18, 81, p. 95).

[36] Federal Court of Justice (Bundesgerichtshof), 10th Civil Senate, Clinical Trials I, 11 July 1995, X ZR 99/92, GRUR 1996, 109.

[37] P. Ancel, G. Aubert, and C. Chappuis, L'abus de droit: comparaisons franco-suisses: actes du séminaire de Genève de Mai 1998, Saint Etienne: Publications de L'université de Saint Etienne, 2001, at p. 26.

[38] Ibid, at p. 25.

[39] In general, see: E. Zeller, Treu und Glauben und Rechtsmissbrauchsverbot Prinzipiengehalt und Konkretisierung von Art 2 ZGB, Zürich: Schulthess, 1981.

## B. In international law

In the public actors' relationship[40], abuse of rights is exclusively based upon the principle of good faith[41]. Good faith is one of the most important principles of international law. Treaties must be executed and interpreted - *pacta sunt servanda* - in good faith - *bona fides*. We read it in of the Vienna Convention on the Law of Treaties:

> "*Every treaty in force is binding upon the parties to it and must be* ***performed*** *by them in good faith*" (emphasis added).[42]

> *"A treaty shall be* ***interpreted*** *in good faith"* (emphasis added).[43]

Hereby, according to O'Connor, the indispensable functions of the notion of good faith are:

> "*(a) The addition of good faith (****honesty, fairness and reasonableness****) as an integral part of the rule pacta sunt servanda. Good faith must be observed in all obligations connected with treaties (negotiations, formation, performance). (b) Good faith must be observed* ***in the exercise of legal rights****. (c) The conflict of equal rights must be reconciled by the application of good faith. (d) The application of good faith to doubtful obligations or to obligations which are difficult to charaterize precisely in legal terms, to give definition to these obligations. This function may result in the creation of a new legal rule where the morel content of good faith, in a legal context, appears to demand articulation"* (emphasis added).[44]

Subsequently, the same author defines good faith in international law as:

> "*…a fundamental principle from which the rule pacta sunt servanda and other legal rules distinctively and directly related to honesty, fairness and reasonableness are derived, and the application of these rules in determined at any particular time by* ***the compelling standards of honesty, fairness and reasonableness prevailing in the international community at that time***" (emphasis added).[45]

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[40] In the private actors' relationship, one may wonder to what extent provisions such as Article 17 of the European Convention on Human Rights in fact establish abuse of rights as a principle in international law - "*Nothing in this Convention may be interpreted as implying for any State, group or person any right to engage in any activity or perform any act aimed at the destruction on any of the rights and freedoms set forth herein or at their limitation to a greater extent than is provided for in the Convention*". Opinions vary.

[41] E.g. - R. Kolb, *La bonne foi en droit international public*, Geneva, Presses Universitaires de France, 2000.

[42] Article 26

[43] Article 31 of the Vienna Convention on the Law of Treaties: "*A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose*" (emphasis added).

See also: International Court of Justice, *North Sea Continental Shelf*, 1969.

[44] J.F. Connor, *Good Faith in International Law*, Aldershot, Dartmouth Publishing, 1991, at p. 124.

[45] Ibid.

Good faith has been interpreted in the context of international trade law specifically – by the WTO Dispute Settlement Body[46] – including in the context of the TRIPs Agreement. WTO law, according to Panizzon, uses the corollaries of pacta sunt servanda, abuse of rights and legitimate expectation alongside good faith.[47] Pannizon however shows that the Appellate Body, the appeal instance, tends to prefer a literal and textual interpretation. We come back to this later.[48]

Abuse of rights, to come back to our subject, is only a specific application of good faith. Whereas good faith is usually used in the interpretation of legal provisions, abuse of rights is used in relation to the exercise of rights. To say it clearer: good faith can be both an interpretive and a substantive tool to solve cases, whereby abuse of rights is an example of the latter. Also in international law, abuse of rights requires the *existence* of a right or a competence and the *exercise* thereof in an abusive manner. This latter is present for instance when a state exercises a right in a manner that hinders another state to exercise its rights; or when a right is (intentionally) exercised against its aim.[49]

In the relationship between *private actors*, and in the context of intellectual property, abuse of rights IPRs/patents is mentioned in both the Paris Convention and the TRIPs Agreement. Sometimes, abuse here is actually only used as a word, rather than a concept.

The Paris Convention has specific provision refers to the abuse of intellectual property. Article 5A allows countries to grant compulsory licenses "*to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work*".[50] This provision allows countries to sanction and cure abuses with compulsory licenses, and explicitly mentions failure to work as a possible instance here. In case a compulsory license would not suffice to prevent or cure the abuse, then forfeiture of the patent is also allowed.[51] The relationship of this provision to the TRIPs provision on compulsory licenses is under debate[52], and the possibility to grant compulsory

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[46] For instance in WTO Panel, *United States – Continued Dumping and Subsidy Offset Act of 2000*,16 September 2002, WT/DS217, at 4.624: "*it is clear that an obligation of good faith pervades over the manner in which Members must conduct their affairs*".

[47] M. Panizzon, *Good Faith in the Jurisprudence of the WTO - The Protection of Legitimate Expectations, Good Faith Interpretation and Fair Dispute Settlement*, Zürich, Schulthess, 2006.

[48] Cross reference.

[49] M. Panizzon, *Good Faith in the Jurisprudence of the WTO - The Protection of Legitimate Expectations, Good Faith Interpretation and Fair Dispute Settlement*, Zürich, Schulthess, 2006, at p. 30-31. She also describes the third case of 'abus de pouvoir'.

[50] Article 5 A 2: "*Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work*".

[51] Article 5 A (3): "*Forfeiture of the patent shall not be provided for except in cases where the grant of compulsory licenses would not have been sufficient to prevent the said abuses*".

[52] See e.g.: B. Mercurio, and M. Tyagi, 'Treaty Interpretation in WTO Dispute Settlement: The Outstanding Question of the Legality of Local Working Requirements', *Minnesota Journal of International law* 19 (2010), pp. 275-326; and G. Van Overwalle, 'Regulating Protection, Preservation and Technology Transfer of Biodiversity Based Drugs' in I. Govaere; and H. Ullrich (eds), *Intellectual*

licenses only offers relief in a limited number of cases. It nonetheless at least shows that abuses of patent rights may be addressed under domestic law and that even revocation of the right may be used as a sanction thereto (if compulsory licenses do not suffice).

The TRIPs Agreement mentions 'abuse' at several occasions. First, it says that its member states may take 'appropriate measures' (cryptically however: 'consistent with the Agreement') to prevent the abuse of intellectual property rights by right holders.[53] This could be interpreted as allowing countries to work with the notion of abuse of rights, but may then also be interpreted as establishing a limitation thereto: 'consistency with the Agreement'. Second, members may specify licensing practices or conditions that may constitute an abuse of intellectual property rights. The abuse here is limited to the constellation of licensing practices having an adverse impact on competition. It is thus similar to the US Patent Misuse notion[54]. The provision however does not exclude a broader use. It only - explicitly but exemplary - mentions exclusive grant-back conditions, conditions preventing challenges to validity and coercive package licensing in this context.[55] Further, in Article 41 TRIPs we read as mentioned above[56] that enforcement procedures must be applied in such a manner as to provide for safeguard against their abuse[57] and that adequate compensations for defendants who were victim of abused enforcement procedures are allowed (yet not imposed).[58]

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*Property, Public Policy and International Trade* (Brussels: P.I.E. Peter Lang, College of Europe Studies, 2007).

[53] Article 8 TRIPs Agreement: "*1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement. 2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology*".

[54] Cross reference

[55] Article 40 § 2 TRIPs Agreement: "*Nothing in this Agreement shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market. As provided above, a Member may adopt, consistently with the other provisions of this Agreement, appropriate measures to prevent or control such practices, which may include for example exclusive grantback conditions, conditions preventing challenges to validity and coercive package licensing, in the light of the relevant laws and regulations of that Member*".

[56] Cross reference.

[57] Article 41 § 1 TRIPs Agreement: "*Members shall ensure that enforcement procedures as specified in this Part are available under their law so as to permit effective action against any act of infringement of intellectual property rights covered by this Agreement, including expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements. These procedures shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse*".

[58] Article 48 § 1 TRIPs Agreement: "*The judicial authorities shall have the authority to order a party at whose request measures were taken and who has abused enforcement procedures to provide to a party wrongfully enjoined or restrained adequate compensation for the injury suffered because of such abuse. The judicial authorities shall also have the authority to order the applicant to pay the defendant expenses, which may include appropriate attorney's fees*".

# II. Abuse of rights in patent law

A classical subject of abuse of rights cases are ownership rights. The notion is classically applied to limit the way one can use one's garden in relation to the neighbours. Much case law on the matter in fact developed from such cases. Patent rights being (intangible) ownership rights, the application of the notion in patent law should occur predictably smooth. In Germany for instance, patent rights are considered to be a form of personal property as guaranteed under Article 14 of the constitution.[59] Surprisingly, however, cases in patent law involving abuse of rights arguments are not known of so far. Only concepts similar to those being used in the US patent system can be found: patent misuse and inequitable conduct. The investigation on how abuse of rights would function in patent law therefore has to start from scratch, yet may rely on a strong potential for analogical applications from US doctrines. We therefore start off with these.

## A. Patent misuse

Patent misuse in the United States[60] cannot be used to start a case. It is merely an affirmative defence[61] and unlike abuse of rights, it is linked to competition effects of patents. It is a type of tool internal to patent law to tackle anti-competitive behaviour. Although a breach of competition law is not enough to invoke patent misuse, neither is it a requirement.[62] Patent misuse can be used to "*show that the patentee has impermissibly broadened the 'physical or temporal scope' of the patent grant with anticompetitive effect*"[63]. Patent misuse is there to "*prevent a patentee from using the patent to obtain market benefit beyond that which inheres in the statutory patent right*".[64] It has been recently confirmed in Federal Circuit jurisprudence that this should be interpreted narrowly[65], yet the notion of "*obtaining market benefit beyond that which inheres the statutory patent right*" does seem to leave some leeway to address more than pure competition issues[66]. Even then, however, it remains a mere defensive tool, and appears to be limited to "*a handful of specific practices by which the patentee seemed to be trying to 'extend' his patent grant beyond its statutory limits*".[67] A general application of the concept seems to have been excluded from the notion[68],

[59] Bundesverfassungsgericht, *Akteneinsicht in Patentzuteilungsverfahren*, BGHZ 18, 81, at p. 95.

[60] As first established in US Supreme Court, *Morton Salt Co. v. G.S. Suppiger Co.*, 314 U.S. 488 (1942).

[61] Affirmative defence in common law is when a defendant does not refute what the plaintiff claims, but reacts by invoking and exception or a counterclaim.

[62] *Kolene Corp. v. Motor City Metal Treating, Inc.*, 440 F.2d 77 (6th Cir. 1971).

[63] *B. Braun*, 124 F.3d, at 1426.

[64] *Mallinckrodt*, 976 F.2d, at 704.

[65] *Princo Corp. v. International Trade Commission and U.S. Philips Corp.* (Fed. Cir. 2010) (*en banc*).

[66] Saying that a limitation to anticompetitive effects is too narrow: R.J. Hoerner, 'The Decline (and Fall) of the Patent Misuse Doctrine in the Federal Circuit', 69 *Antitrust Law Journal* 669 (2001), pp. 669 – XX.

[67] *USM Corp. v. SPS Techs. Inc.*, 694 F.2d 505, 510 (7th Cir. 1982).

[68] *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340 (Fed. Cir. 1998).

while a number of cases are explicitly excluded from patent misuse under 35 U.S.C. 271 (D)[69]. Patent misuse will be sanctioned by the unenforceability of the patent until the misuse has stopped.

### B. Inequitable conduct

The US notion of 'inequitable conduct' can be inspiring to our study as well. Inequitable conduct in general means the failure of an applicant to exercise his duty of candour and good faith to the patent office; the USPTO.[70] This notion is thus closely linked to the idea of tackling abusive pre-grant behaviour. If a patent applicant has failed to provide certain prior art information or submitted false information to the patent office, the patent will be declared unenforceable. The patent cannot be declared *invalid* on this basis and it has in fact been *infringed*, yet inequitable conduct in the course of the procedure will make it *unenforceable*. Unlike with patent misuse, this will be permanent. Like with patent misuse, it is however only a defence mechanism. This means that the deterring effect on third-parties of the patent obtained in an abusive manner will to a large extent remain. Proof of inequitable conduct, finally, has been set quite strictly. A "*mere showing that art or information having some degree of materiality was not disclosed*", is not enough[71].[72]

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[69] 35 U.S.C. 271 (D): "*No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having done one or more of the following: (1) derived revenue from acts which if performed by another without his consent would constitute contributory infringement of the patent; (2) licensed or authorized another to perform acts which if performed without his consent would constitute contributory infringement of the patent; (3) sought to enforce his patent rights against infringement or contributory infringement; (4) refused to license or use any rights to the patent; or (5) conditioned the license of any rights to the patent or the sale of the patented product on the acquisition of a license to rights in another patent or purchase of a separate product, unless, in view of the circumstances, the patent owner has market power in the relevant market for the patent or patented product on which the license or sale is conditioned*".

[70] For recent jurisprudence in this context, see: US Supreme Court, *Aventis Pharma v. Amphastar*, 2008.

Literature, e.g.: T.F. Maffei, 'The Patent Misuse Doctrine: A Balance of Patent Rights and the Public Interest', 52 *J. Pat. Off. Soc'y* 178 (1970); J.B. Kobak, 'The New Patent Misuse Law', 71 *J. Pat. & Trademark Off. Soc'y* 859 (1989); R.C. Feldman, 'The Insufficiency of Antitrust Analysis for Patent Misuse', *Hastings Law Journal* 55 (2003), pp. XX-XX; J. Potenza, P. Bennett, and C. Roth, 'Patent Misuse - The Critical Balance, a Patent Lawyer's View', 15 *Fed. Cir. B.J.* 69 (2005-2006); D. McGowan, 'An Argument for Tailoring Patent Misuse Remedies', San Diego Legal Studies Paper N° 07-69 (2006); and D. McGowan, 'What Tool Works Tells Us About Tailoring Patent Misuse Remedies', 101 *Nw. U. L. Rev. Colloquy* 208 (2007).

Contra: M. Lemley, 'The Economic Irrationality of the Patent Misuse Doctrine', 78 California Law Review 6 (1990); J.D. Brinson 'Patent Misuse: Time for a Change', 16 Rutgers Computer & Technology Law Journal 357 (1990).

[71] *Exergen Corp. v. Wal-Mart Stores Inc. and S.A.A.T. Systems*, xx.

[72] Literature e.g.: B. Brown, 'Inequitable Conduct: A Standard in Motion', 19 *Fordham Intell. Prop. Media & Ent. L.J.* 593 (2009); C.A. Cotropia, 'Modernizing Patent Law's Inequitable Conduct Doctrine', 24 *Berkeley Tech. L.J.* 723 (2009); E. Peters, 'Are We Living in a Material World: An Analysis of the Federal Circuit's Materiality Standard under the Patent Doctrine of Inequitable Conduct', 93 *Iowa L. Rev.* 1519 (2008); K. Mack, 'Reforming Inequitable Conduct to Improve Patent Quality: Cleansing Unclean Hands', 21 *Berkeley Tech. Law Journal* 147 (2006); D. Hricik, 'Where the Bodies Are: Current Exemplars of Inequitable Conduct and How to Avoid Them', 12 Texas Intellectual Property Law Journal 287 (2004); L.A. Dolak, 'The Inequitable Conduct Doctrine: Lessons from Recent Cases', 84 *J. Pat. & Trademark Off. Soc'y* 719 (2002); S.D. Anderson, 'Inequitable Conduct: Persistent Problems and Recommended Resolutions'; 82 *Marq. L. Rev.* 845 (1998-1999).

## C. Abuse of patent rights

After having seen what is being used already, we now move to investigating our proposal: introducing the notion of abuse of patent rights. Going back to the categorisation we made in the introduction[73], and linking this to the country studies above[74], we now indeed have to check whether or not the notion of abuse of rights is usually broad enough to cover all the said cases:

- Can abuse of rights be used to tackle uses of a patent that are abusive towards a specific third-party?
- Can abuse of rights be used to address instances where a patent is being used against the rationale of the system?
- Can abuse of rights be used when a patent is being used against higher ends, i.e. the benefit of society as a whole?

The answers to all three questions a priori appears to be in the affirmative. The above discussed notions of abuse of rights in civil law slightly differ amongst the studied countries. Yet, it can be noted that whether it is derived from the provisions of good faith or from extra-contractual liability, abuse of rights covers cases where:

- third-parties are affected with or without an intention to cause damage; as well as
- cases where a right is being used against its rationale or its social function.

Whereas the notion may thus appear broad enough to cover the three groupings in most systems, it is however not clear whether it offers an adequate relief to each of them. Also, it may often appear difficult to prove when, for instance, a patent is being used in a way that goes against the rationale of the patent system, which aims at incentivising innovation. A specific issue of patent law finally shows in distinguishing the cases (and their effect) amongst whether the 'abuses' root in the pre-grant phase – before the actual grant of the right – whether they originate post-grant; or whether they are mixed. Consequently, three questions will be addressed in the discussion:

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Contra: M. Peters, 'The Equitable Inequitable: Adding Proportionality and Predictability to Inequitable Conduct in the Patent Reform Act of 2008', 19 *DePaul J. Art Tech. & Intell. Prop. L.* 77 (2009); M.F. Wasserman, 'Limiting the Inequitable Conduct Defense', 13 *Virginia Journal of Law and Technology* 7 (2008); G.E. Von Tersch, 'Curing the Inequitable Conduct Plague in Patent Litigation', 20 *Hastings Comm. & Ent. L.J.* 421 (1998); J.F. Lynch, 'An Argument for Eliminating the Defense of Patent Unenforceability Based on Inequitable Conduct', 16 *AIPLA Quarterly Journal* 7 (1989).

[73] CROSS REFERENCE.

[74] CROSS REFERENCE.

- Can the notion – in relation to abuse of the system's rationale or 'higher ends' – really be used in practice or would one stumble on the difficulty to bring evidence that is more than anecdotal or equivocal?
- For which cases is the usual remedy of abuse of rights – the curtailment/limitation of the use of the right – adequate and for which is it not? Or, alternatively, could the abuse of rights also lead to the revocation of the patent?
- Can the notion apply to both pre- and post-grant issues; and if so, which of both types of cases would it be able to tackle efficiently (in light of the above)?

A proof will often be difficult to provide for an abuse of the rationale of the patent system or of a use against higher ends. An example here could be the case of large-scope patents in a specific sector or sub-sector. The abuse would exist only if innovation – the overall objective of the patent system – would be discouraged or even hindered in that sector or sub-sector, and if this could was causally linked to the scope of that patent. This proof may be fairly hard to provide, yet not impossibly so. In other cases, it may even be easier. For the refusal to license a patented research tool under reasonable circumstances, it may be much easier to establish a prima facie use of a patent against its aim.

Secondly, *post-grant* issues are the 'natural habitat' of the abuse of rights notion. Before being able to abuse a right, one must have acquired it. Following the usual application of abuse of rights as discussed above, one could not count on the notion to be applicable to pre-grant abuses. However, the specific context of patent law, the emphasis on third-parties appeal and the lack of strong pre-grant checks by the institution granting the rights may require a broad interpretation of the notion to include such cases. Abuse of rights is applied differently in the field of law. It is essentially a flexible notion, and in patent law no prior jurisprudential guidance exists. One might argue that it is exactly there that the danger of the notion lies, and that legal security may be impeded – and I would agree up to a certain point. However, criteria on the matter have not yet been established in patent law. Doing so would change the situation. We do therefore not see a strong reason to refrain from establishing that abuse of patent rights allows tackling a right – once established – on the basis of abusive actions in the *pre-grant* phase. An asterisk must however be placed insofar as pre-grant issues are best tackled in the pre-grant phase, especially from a process economy point of view, and to avoid deterring effects of wrongly granted patents –. In this context, the abuse of rights here should only be a lifebuoy in case patent quality fails.

As to the sanction in relation to such pre-grant abuse cases, two possibilities emerge. First, the *limitation* of the right to stop the abuse may be interpreted broad enough to lead to a de facto revocation of the right. Classically, the sanction must be broad enough to stop the abuse. In the case of pre-grant abuse, this may well be a prohibition to further use the right. Here, the US patent misuse doctrine can serve as inspiration - although only applicable when one is sued for infringement. Patent misuse leads to the unenforceability of the patent, although it remains valid and may be enforced once the misuse

has stopped. Even more inspiring is the sanction imposed to 'inequitable conduct' during the prosecution of a patent. Here, the patent will remain unenforceable no matter what, because the abuse has occurred in the procedure to acquire the right. As a second option, the sanction of revocation may simply be set. Again, no specific guidelines exist and be set by the specific context of patent law. Moreover, the revocation of a right if the acquirement thereof has been subject to an abuse practice is classical. For instance, if a list or misinformation forms the basis of the transfer of ownership, it can be annulled within a certain time-period in most countries.

## III. Abuse of patent rights applied: Evergreening of patents

A situation often referred to as an abuse of the patent system is the so-called evergreening of patents. It can be described as follows: shortly before a patent expires, one re-applies a slightly different version of the invention to restart another 20 years of protection for what is in fact the same subject matter. Mostly, this scenario is encountered in the medicinal field: *"the evident commercial strategy of innovative drug companies to evergreen their products by adding bells and whistles to a pioneering product even after the original patent for that pioneering product has expired"*[75]. The evergreening of patents is not limited to this field, yet is particularly present here due to the increasing number of patentable drug properties. At most patent offices today, it is indeed not only possible to patent drug features such as primary uses, processes and intermediates, bulk forms, simple formulations, or compositions of matter as was the case in the 1980s. One can now also apply for the protection of (an expanding number of) uses, methods of treatment, mechanisms of action, packaging, delivery profiles, dosing regimens, dosing ranges, dosing routes, combinations, screening methods, chemical methods, biological targets, and fields of use.[76] A quote by the Supreme Court of Canada summarizes the matter best and quite cynically: *"surprisingly ... the substance omeprazole can exist in more than one crystal form"* [77].

In the evergreening scenario, competitors will thus not be able to place a generic version of the product on the market even after twenty years - as should be the case. The compromise that has lead to rewarding innovation with a time-limited monopoly is disregarded. The duration of a patent is extended by another 20 years, although innovation did not occur:

> *"In particular, strategy documents of originator companies confirm that some of them aimed at developing strategies to extend the breadth and duration of*

[75] Supreme Court of Canada, *Apotex Inc. and AstraZeneca v Canada*, 3 November 2006, 2006 SCC 49, at para. 39.

[76] Larson, E. (2001) 'Evolution of IPR and Pharmaceutical Discovery and Development', Paper presented at the Committee on Intellectual Property Rights in the Knowledge-based Economy, Stockholm.

[77] Supreme Court of Canada, *Apotex Inc. and AstraZeneca v Canada*, 3 November 2006, 2006 SCC 49, at para. 10.

*their patent protection. Filing numerous patent applications for the same medicine (forming so called "patent clusters" or "patent thickets") is a common practice. Documents gathered in the course of the inquiry confirm that an important objective of this approach is to delay or block the market entry of generic medicines"*[78].

Issues of evergreening exist on various levels. The first level covers non-legal, practical analysis and impact assessment issues. The second is about the legal basis to address the matter. The first level goes beyond the scope of this article, but is nonetheless worth mentioning. It brings about questions on how to distinguish real cases of evergreening from genuine innovation (a matter of case-to-case, non-legal analysis) and on the concrete realm and impact of the phenomenon (a matter of quantitative and qualitative patent data analysis). We only address the second level of issues here: legal matters.

The evergreening of patents essentially calls for *pre*-grant intervention: it should simply not happen. Patent officers must be able to assure the quality of the patents they grant. If an invention is evergreened, they have clearly failed their task. Pre-grant action avoids costs, uncertainty and unjustified monopolies. It however requires a system in which patent offices control the prior art strictly; where there is no so-called 'dilution of patentability requirements'[79]; where patent examiners have up-to-date and specific expertise; where their workload remains manageable in spite of a steadily increasing number of technologies applicable for protection; and where patent offices are free from national political interests. In today's patent reality, many cases slip through the mazes and the evergreening of patents is in practice most often addressed *post*-grant only. There, the phenomenon has been the subject of a number of prominent cases in the past decade. We next look at a number of diverging approaches.

### A. Available remedies

Third parties faced with patents suspected of evergreening have several options. Either they do not enter the field protected by the evergreened patent – the worst scenario – or they simply ignore the patent at stake and do enter the field. Two possibilities can be outlined:

1. The patent holder may only have been speculating on the deterrent effect of his patent. In the knowledge that it would not stand in an invalidity procedure, the patent holder would then simply not initiate an infringement procedure.
2. Or, an uncertain procedure starts. The patent holder will challenge the competitors or other third parties which ignored the patent. Here:

[78] EUROPEAN COMMISSION, *Competition inquiry into the pharmaceutical sector*, 8 July 2009, available at: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html (last visited 21 June 2011), at p. 10.

[79] This is claimed to have occurred over the past decades. For instance, it has been said that in biotechnology specifically, the criterion of non-obviousness or inventiveness has lost its relevance (S. Merrill,, R. Levin, M. Myers (eds), *A Patent System for the 21st Century*, Washington, DC, The National Academies Press, 2004, p. 3).

- A *patent law*-internal challenge will most likely bring an invalidity counterclaim. This may however not necessarily bring the patent owner to the losing camp. We will see below that the patentability requirements will not necessarily lead to invalidation. Inventiveness could be invoked, but this will depend on how this notion is applied in the given jurisdiction.
- Rather, *competition law* elements may in fact appear the most ready. Both unfair competition and the abuse of monopoly positions could be used to tackle the effects of an evergreening patent. Yet, one must then first fulfil their internal criteria of application (e.g. the proof of a dominant position), and it remains unclear to which extent the use of unfair competition is in fact allowed in relation to IP issues.
- Finally, the abuse of rights notion or – in the United States – the patent misuse or inequitable conduct doctrines could be used.

This last scenario is discussed in a separate section below. First, we look at how a number of countries have dealt with the matter within their patent law to then investigate whether competition law concepts can be used here.

### 1. Patent law

Inventors intending to evergreen their patent rights make use of the fact that, for patent law, inventions can be novel, inventive and industrially applicable (and hence patentable) without achieving substantial progress. Inventions must in fact not solve an existing problem or improve a given invention. There is no 'solving an unsolved problem' requirement. This allows, for instance, for the patenting of different processes leading to the same result. It is therefore in fact a legitimate feature of the patent system. Although not solving an unsolved problem a priori, these processes and methods nonetheless bring about progress. If used strategically however, the said mechanism can lead to situations such as the evergreening of patents.

For this reason, India decided to explicitly exclude new dosages and different forms of the same medicine such as capsules, tablets, syrups, and suspensions from patentability, as well as more generally every known substance which does not result *in the enhancement of the known efficacy thereof*.[80] Salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substances will be considered to be the same substance, unless they differ significantly in properties regarding efficacy. This is a purely pre-grant intervention, however also allowing later invalidity (counter)claims to be successful post-grant. Perhaps this is the most recommendable approach, yet as we'll see later, doubts as to the TRIPs compatibility of the measures arise[81].

Theoretically, the criterion of inventiveness should be flexible enough to cope with the matter, and offer a similar relief without countries having to fear for

[80] ADD

[81] Cross reference.

TRIPs compatibility. Yet, interpretations of this notion are often strict. Exceptionally, an inventiveness-based approach has been pursued in an Australian case – albeit by a lower court. Here, a patent application had been made regarding only to the dosage regimen of an already patented drug: whether or not the drug is taken weekly[82]. In the first instance decision to *Arrow Pharmaceuticals Limited v Merck & Co*[83], the judge revoked that patent[84]. Not excluding every new dosage regimen from patentability when it was the result of a newly discovered technical effect, or when the dosage regime was the key that unlocked the door to utility, the judge found none of these features in the situation under consideration. Although on appeal, the issue of inventiveness was not addressed (for procedural reasons), the reasoning for the judge's ruling in the first instance keeps its relevance.

Other courts in Australia have also used the criterion of 'inventions'. In the appeal to the said Merck case, 'invention[85]' or 'manner of manufacture' were at the centre of debate and finally formed the decisive reason to revoke the patent. It must however be said that this was closely linked to the factual situation at stake and (strangely) used to converge both elements of novelty and inventiveness:

> "*Thus, in substance, each claim relates to the use of a known substance with known properties for a known purpose in a known manner*[86]*…;… We see no invention in asserting that a patient is more likely to comply with a continuous weekly regime than with an intermittent regime involving periods of weekly administration and rest periods*".[87]

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[82] Federal Court of Australia, *Arrow Pharmaceuticals Limited v Merck & Co.*, 6 October 2004, FCA 1282, at para. 1: "*The case involves what would now colloquially be called an attempt to 'evergreen' a pharmaceutical patent*".

[83] Federal Court of Australia, *Arrow Pharmaceuticals Limited v Merck & Co.*, 6 October 2004, FCA 1282, available at: http://www.austlii.edu.au/au/cases/cth/federal_ct/2004/1282.html (last visited: XX).

[84] Federal Court of Australia, *Arrow Pharmaceuticals Limited v Merck & Co.*, 6 October 2004, FCA 1282, at § 125: "*there is no evidence to suggest that there is any inventive step in formulating a 70 mg tablet or the equivalent liquid*". And at § 124: "*I do not regard a choice between dosage regimes of a patented drug in the circumstances of this case as involving an inventive step sufficient to found a stand-alone patent. Ingenuity might be exercised, but not invention*".

[85] Defined in Australian patent law to mean: "*any manner of new manufacture the subject of letters patent and grant of privilege within section 6 of the Statute of Monopolies, and includes an alleged invention*" (Section 18(1)(a) of the Australian Patent Act) and interpreted in jurisprudence as follows:

"*Microcell, NRDC and Philips establish the following propositions: 1.The opening words of s 18(1) (' … a patentable invention is an invention that …') impose a threshold requirement that the 'patentable invention' be an 'invention', that is to say an 'alleged' 'manner of new manufacture' within s 6 of the Statute of Monopolies (Philips at 663). 2.That requirement will not be met if, on the face of the specification, the subject matter (a) lacks the necessary quality of inventiveness under the Statute of Monopolies (Phillips at 664) (b) is not new (NRDC at 262, Philips at 664) 3.A new use of an old substance is not an invention if its known properties make it suitable for that use – in such a case the new purpose is 'no more than analogous to the purposes for which the utility of the substance is already known' (NRDC at 262) 4.But there will be an invention if the new use consists in taking advantage of a hitherto unknown or unsuspected property of the substance (NRDC at 262)*". (Appeal in Merck at § 68).

[86] Federal Court of Australia, *Arrow Pharmaceuticals Limited v Merck & Co.*, 6 October 2004, FCA 1282, at § 81.

[87] Federal Court of Australia, *Arrow Pharmaceuticals Limited v Merck & Co.*, 6 October 2004, FCA 1282, at § 71.

In recent Canadian jurisprudence, we find a post-grant, yet patent law internal 'anti-evergreening' mechanism. Searching for a middle ground combining patent law and market access, it however appears unsuited to tackle the matter efficiently in our view. In *AstraZeneca v Canada*, the Canadian Supreme Court said the commercialization of generic medicines should be accepted insofar as they are not in the realm of the original patent. This mechanism shows substantial flaws. First, one wonders why patents are being allowed on additional characteristics in the first place, if they would not be enforceable in the end. Second, the factual situation of the case and the way the decision was linked to it makes the mechanism to be applicable in a limited number of cases only. AstraZeneca, an innovative drug company, held a patent over 'omeprazole' a 'protonpump inhibitor' marketed as 'Losec 20'. The patent was granted in 1989 to expire in 1999, yet AstraZeneca withdrew the medicine from the market in 1996. Remarkably, AstraZeneca, despite this withdrawal, applied for two additional patents, granted in 2002, over a different form of the same medicine, while still keeping the medicines off the market. It was mainly this lack of commercialization that led the Canadian Supreme Court to decide that the 2002 patents were irrelevant for the market authorization of the generic variant of the medicine, produced by generic manufacturer Apotex.[88] The only relevant patent was the one that expired in 1999, the Court ruled. If, however, the medicine had been commercialized, the approach might have appeared inefficient for tackling the evergreening of patents following that reasoning. A serious flaw indeed, since the only attempt at the 'evergreening' of a *non-commercialised* pharmaceutical to occur so far in Canada was the one in this case.[89]

## 2. Competition law

In the post-grant phase, classical elements to redress an abusive use of certain patents are to be found outside of patent, in competition law. We discuss below the European example to see whether abuse of dominant position and/or unfair competition is suited to address the matter of evergreening.

### a) Abuse of dominant position

Under EU law, a dominant position is reached when "*a position of economic strength enjoyed by an undertaking which enables it to prevent effective competition being maintained in the relevant market by giving it the power to behave to an appreciable extent independently of its competitors, customers and ultimately of consumers*"[90]. The main factors here appear to be the size of market shares,

[88] For instance in: Supreme Court of Canada, *Apotex Inc. and AstraZeneca v Canada*, 3 November 2006, 2006 SCC 49, at §§ 8 and 33.

[89] Further, a number of misinterpretations seem to lie at the basis of this decision. For instance, the Supreme Court seemed to assume that because no drug had been produced falling under the scope of the 2002 patents, Apotex could not copy anything other than the drug commercialized until 1996 ('Losec 20', covered by the patent that expired in 1999): "*As a practical matter, there was no AstraZeneca omeprazole product on the market after 1996 which Apotex could copy*" (Supreme Court of Canada, *Apotex Inc. and AstraZeneca v Canada*, 3 November 2006, 2006 SCC 49, at para. 33) This however fails to take into account that in order to obtain a patent, a drug must be disclosed so as to enable a person skilled in the art to run the invention. In general, moreover, the link between commercialization and copying is rather unclear.

[90] European Court of Justice, *United Brands*, February 1978, C 27/76.

economic weakness of competitors, and the control of resources and technologies. Abuses of dominant positions are ruled by the European Court of Justice (ECJ) as being objective concepts; the "*recourse to methods different from those which condition normal competition in products and services on the basis of the transactions of commercial operators*", resulting in the reduction of competition in a market already weakened by the company concerned.[91] Examples here include imposing unfair prices or other unfair trading conditions; limiting production, markets or technical development to the prejudice of consumers; applying dissimilar conditions to equivalent transactions with other trading parties; and imposing supplementary obligations which have no connection with the purpose of the contract.

Depending on what is considered to be the 'relevant market', a patent holder may be deemed to have a dominant position. However, a patent alone cannot lead to a presumption of a monopoly or dominant position. It is an ownership right. It is still the market deciding on whether or not there is a monopoly, and not the eventuality of patents. Patents in fact do not decide on markets per se. Yet, they do help shaping them.

If a dominant position would be established, the pertinent question in relation to evergreening is whether this scheme can, under given definitions, be construed as an abuse of such a position. Evergreening, the abuse of patent rights, may in our view indeed be called "*methods different from those which condition normal competition in products and services, resulting in the reduction of competition in a market*". It can lead to several factualities and results previously addressed and punished by the ECJ, in particular imposing unfair prices (the patent will bring (unjust) monopoly prices). In fact, the recent AstraZeneca case opened the door to a new type of cases of abuse of dominant position. For the first time, the Commission considered the misuse of regulatory procedures to obtain a pharmaceutical patent (more specifically, the SPC) through misleading information as an abuse of Art. 82 EC.[92] However, this matter remains linked to the notion of abuse of monopoly rights and a dominant position will thus not be easy to construe. More is needed than a single evergreening patent, when this is the subject at heart of the matter one wants to tackle.

### b) Unfair competition

The notion of unfair competition primarily aims at ensuring fairness in business operations and is meant to fulfil the need that all market participants should play in accordance with the same rules. Unfair competition is one the few competition law features to have entered into international law. Under Article 2.1 of the WTO TRIPS Agreement, which incorporates Article 10bis of the 1883 Paris Convention[93], unfair competition forms part of WTO law.

[91] European Court of Justice, *Hoffman –LaRoche*, 13 February 1979, C 85/76.

[92] Reference.

[93] The Paris Convention for the Protection of Industrial Property as of March 20, 1883, as revised at Brussels on December 14, 1900, at Washington on June 2, 1911, at The Hague on November 6, 1925, at London on June 2, 1934, at Lisbon on October 31, 1958, and at Stockholm on July 14, 1967, and as amended on September 28, 1979, (the 'Paris Convention').

Although under Article 10bis of the Paris Convention, the concept seems limited to direct and indirect (potential and future) competitive relationships, unfair competition notions essentially protect against unfair business practices and therefore not compulsorily call for a competitive relationship. The concept could equally be invoked to protect consumer's interests and those of the public or the economy at large. In the EU, unfair business-to-consumer practices can for instance be found in acts that are contrary to the behaviour of professional diligence and in behaviour that has an adverse impact on the economic activities of the average consumer (especially when this practice is misleading and aggressive).[94] Again, the evergreening of patents appears to fit the description, perhaps even more easily than that of abuse of monopoly rights. However, it is debated to what extent unfair competition can be invoked in patent law cases, since patent law would be the *lex specialis*.[95] Both would be mutually exclusive.

### B. Abuse of patent rights

Evergreening patents slip through the mazes of the legal net. They are hard to challenge since they move along the borderline between the legal and the illegal, yet, they are definitely illegitimate. This is exactly the type of case for which the notion of abuse of rights has been designed in other fields of law.

The evergreening of patents constitutes a case-study which could fit into each of the three groupings of our previously established typology of patent misuses[96], and thus upon each of the three elements that could constitute or border the abuse of patent rights notion:

- an abuse in relation to specific third-parties (e.g. competitors, consumers);
- an abuse in view of the rationale of the patent right and the patent system (by re-claiming 20 years of protection without having innovated); and
- an abuse possibly also against higher ends, because the society as whole would not benefit from that patent anymore. We think in particular of access to medicines and the human right to health. Both are reportedly favoured and hindered by the grant of patents, yet this balance may shift the wrong way if patent protection goes up to 40 years.

[94] Articles 5 to 9 of the Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market and amending Council Directive 84/450/EEC, Directives 97/7/EC, 98/27/EC and 2002/65/EC of the European Parliament and of the Council and Regulation (EC) No 2006/2004 of the European Parliament and of the Council (the 'Unfair Commercial Practices Directive').

[95] Hermann. Reference.

[96] Cross reference.

We have seen above that the notion of abuse of patent rights could be used to tackle (post-grant) abuses of the pre-grant phase. The abuse of patent rights notion offers the advantage that it could be used to require the revocation of the patent - something not possible under competition law. Moreover, when unfair competition cannot be used and the conditions for the abuse of dominant position are not fulfilled, it may be the only tool to tackle the matter post-grant. Since the abuse in fact happened pre-grant, this could - as explained above[97] - still justify cancellation of the patent and thus restore the situation where the evergreening patent simply does not exist (on top of eventual damages). This does not result in avoiding the patent to be granted, but can provide a further step forward to the actual situation.

The possibility to challenge evergreening on this basis could also serve as an additional deterrent. Deterring elements not to try evergreening a patent are only few. Worst case, the patent will not be granted. Once the patent has been granted, a deterring effect on competitors exists in the opposite direction, even if it is not clear that the patent would stand a validity claim. If the owner is confident enough, then he may even take other competitors to court for patent infringement if their products are too closely connected. The possibility of being confronted with an abuse of rights claim may change this, at least a little.

The abuse of rights thus provides a fundamental tool to actively challenge evergreening patents outside of the validity angle and outside of the competition law realm. Since both are often hard to impose, abuse of rights may have a potential here. Evergreening is however not the issue which most obviously calls for the introduction of abuse of rights, since it should ideally have been tackled by the patent office itself, by not granting evergreening patents. Despite their often dubious strength in eventual invalidity procedures, the mere existence of 'evergreening' patents will first discourage generic competitors from entering the market. At the very least, it will delay entry. In the United States, for instance, manufacturers of generic pharmaceutical products must notify the holder of the expiring patent that they will launch a certain product onto the market. Automatically and obligatorily informed, patent holders will then threaten eventual competitors with (and may even file a case on the basis of) the newly acquired 'evergreening' patents. This creates costs, uncertainty and has an unjustified deterring effect. Avoiding this, means avoiding that the patent is granted.

Furthermore, when one moves from the pre-grant to the post-grant stage, one also moves from scientifically trained patent examiners to legally trained judges or even juries (in the US for instance). It also increases and moves the costs away from the self-financed patent office and the patent applicant, to third-party competitors, who, in a way, are 'innocent bystanders'. An issue rooting in the pre-grant phase like the evergreening of patents, can therefore not *by choice* be moved to being addressed in the post-grant phase. *As a practical matter,* however, tools must be available to redress evergreening also post-grant. It is (only) here that the abuse of patent rights can come in.

[97] Cross reference.

# IV. Abuse of patent rights applied: transit of generic medicines

The year is 2009. Dutch border authorities stop, seize and destroy or send back shipments of medicines in transit in The Netherlands. The shipments are on the way from India to Brazil, Venezuela, Colombia, Peru or Nigeria. Neither in the producing country, nor in the receiving county, the medicines were subject to patent protection. In the Netherlands – the transit country – they were. Pharmaceutical giant Merck, one of the patent holders at stake, first requested the seizure of a shipment of the drug Losartan on the way from India to Brazil. This started a cascade of 19 similar cases. Whereas in the first case, the drugs were reshipped to India, in later cases the drugs were sometimes destroyed. It was also not always a mere private initiative. Although GlaxoSmithkline, for instance, first claimed its patent rights, the Dutch customs proceeded against its later withdrawal and sent to the criminal prosecutor in charge a case involving a shipment of Abacavir on route on behalf of UNITAID.[98]

The matter of the drugs in transit caught quite some attention in the past two years. From a patent law perspective – unless one challenges the very idea of granting patents for medicines in developed countries – this is a purely post-grant case. It is not rooted in the way the patent has been granted, but in the way it is being enforced. We are faced with a case where the patent is legal, the enforcement is within the legal framework; but the result appears illegitimate. At first glance, this seems to be another classical setting where the abuse of right notion could be useful.

## A. Laws and issues

The legal basis for these decisions was the Council Regulation (EC) n° 1383/2003[99], as incorporated into the Dutch Patent Act. This Regulation addresses customs actions against goods suspected of infringing certain intellectual property rights. It aims in particular at keeping off the market counterfeit and pirated goods, "*because of the considerable damage to law-abiding manufacturers and traders and to right-holders, as well as the deceiving and in some cases endangering effect to the health and safety of consumers*"[100]. It is explicitly mentioned that this should however be done without impeding legitimate

[98] F.M Abbott, 'Seizure of Generic pharmaceuticals in Transit Based on Allegations of Patent Infringement: A Threat to International Trade, Development and Public Welfare', *World Intellectual Property Organization Journal*, Vol. 1, pp. 43-50, 2009.

[99] Council Regulation (EC) No 1383/2003 of 22 July 2003 concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights, Official Journal L 196 , 02/08/2003, pp. 7 -14.

[100] Recital 2 Regulation 1383/2003: "*The marketing of counterfeit and pirated goods, and indeed all goods infringing intellectual property rights, does considerable damage to law-abiding manufacturers and traders and to right-holders, as well as deceiving and in some cases endangering the health and safety of consumers. Such goods should, in so far as is possible, be kept off the market and measures adopted to deal effectively with this unlawful activity without impeding the freedom of legitimate trade. This objective is consistent with efforts under way at international level*".

trade[101]. In general, the Regulation applies to goods which are entered for release for free circulation, export or re-export[102]. In Article 2 of the Regulation 'goods infringing an intellectual property right' means goods which infringe a patent under that Member States' law. If - goods are suspected of infringing an intellectual property right, the Regulation allows customs authorities to suspend the release of the goods or detain them for a period of three working days from the moment of receiving the notification by the right-holder. This is done in order to enable the latter to submit an application for action in relation to such goods[103]. Authorities shall suspend the release of the goods or detain them when an application for action has then been initiated[104], while a number of deterrents have been set in place to avoid a frivolous use of said custom measures. The claimant can be held liable and bear all costs if the goods in question are subsequently found not to infringe intellectual property right[105].

The essential question is thus whether or not the goods at stake infringe the patent. In the case mentioned above, the goods suspected of patent infringement were only in transit at the airport or at a seaport. The Regulation states that the law of the country where the goods are 'placed' shall apply when deciding whether or not an intellectual property right has been infringed.[106] Yet, is there a sufficiently strong territorial connection to the Netherlands, the Dutch market not being at stake, to suspect and decide upon patent infringement? Are the goods 'placed' in the country? Technically speaking, the medicines at stake do not enter The Netherlands or release for free circulation, export or re-export, as outlined under Article 1 of the Regulation. They are in transit. It is therefore doubtful whether the Dutch actions are in accordance with Regulation 1383/2003. However, the Regulation manages to surprise us again. Under Article 12, EU members may provide for a simplified procedure enabling customs authorities to have said goods abandoned for destruction, without there being any need to determine whether an intellectual property right has been infringed under national law – however subject to a number of conditions. This decouples the measures from the need to judging on patent infringement and thus from actually applying Dutch Patent Law. The question of territorial effect becomes less acute.

The Dutch Court deciding on the matter did not even need this latter argument in the end. It ruled on patent infringement, and decided on the basis of the unprecedented theory of 'manufacturing fiction[107]', deducted from Recital 8 of the Regulation: "*Proceedings initiated to determine whether an intellectual property right has been infringed,…, will be conducted with reference to the criteria used to establish whether goods produced in that Member State infringe*

[101] Ibid.

[102] Article 2 Regulation 1383/2003.

[103] Article 4 Regulation 1383/2003.

[104] Article 9, application for action according to Article 8 of Regulation 1383/2003.

[105] Article 6 Regulation 1383/2003.

[106] Article 10 Regulation 1383/2003.

[107] 'Vervaardigingsfictie', in the original Dutch.

*intellectual property rights*" [108]. According to the manufacturing fiction, use of a patent – and thus infringement – occurs as if the goods were manufactured in the Netherlands.[109] This ruling represents a very remarkable extra-territorial application of Dutch law, and has been strongly criticized.[110]

The Dutch decision is considered contrary to previous jurisprudence of the European Court of Justice ('ECJ'). In the *Montex* case, the European Court of Justice said that infringement cannot occur until there is evidence that goods would be placed into the EU stream of commerce.[111] The Dutch Court took the latter case into account, but said that this ruling only applied for the Trademarks Directive and not on the one at stake. The ECJ has not expressed a statement on the matter so far. It shows precisely where the weakness of the entire approach lies, and points at what went wrong with the Regulation. When one discusses patent infringement, one does not discuss counterfeit medicines – a threat to the right to health – since counterfeit could never be patent infringement[112]. Patent infringement can only occur if one is talking about *the same* substance. The situation is thus different from trademark enforcement. Both patent and trademark law are however dealt with under a single chapeau ('IPRs') and under a uniform rationale by the Regulation. When talking about patent infringement, one does not talk about "*endangering effect to the health and safety of consumers*"[113], which is what is done in the context of trademark infringement. The present case exemplifies the need for differentiation here.

From an international law perspective, many provisions are at stake. First, Article 5 of the WTO GATT Agreement; 'freedom of transit', has to be considered: "*There shall be freedom of transit through the territory of each contracting party, via the routes most convenient for international transit*"[114]. It is an essential principle to international trade, and its importance is self-explanatory. The definition within the provision of traffic in transit is the

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[108] Recital 8 Regulation 1383/2003: "*Proceedings initiated to determine whether an intellectual property right has been infringed under national law will be conducted with reference to the criteria used to establish whether goods produced in that Member State infringe intellectual property rights. This Regulation does not affect the Member States' provisions on the competence of the courts or judicial procedures*".

[109] Court of The Hague, *Sisvel v Sosecal*, 18 July 2009, C-311378.

[110] E.g. F.M Abbott, 'Seizure of Generic pharmaceuticals in Transit Based on Allegations of Patent Infringement: A Threat to International Trade, Development and Public Welfare', *World Intellectual Property Organization Journal*, Vol. 1, pp. 43-50, 2009.

[111] Montex (C-281/05) [2006] E.C.R. I-10881.

See T. Jeager, H. Grosse Ruse-Kahn, J. Drexl, R. M. Hilty, *Statement of the Max Planck Institute for Intellectual Property*, Competition & Tax Law on the Review of EU Legislation on Customs Enforcement of Intellectual Property Rights, available at: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1622619 (last visited 23 April 2011): "*The Preamble to the BMR should be clarified in line with the ECJ's case law as renouncing an applicability of the manufacturing fiction to genuine acts of transit*".

[112] In this sense also: F.M Abbott, 'Seizure of Generic pharmaceuticals in Transit Based on Allegations of Patent Infringement: A Threat to International Trade, Development and Public Welfare', *World Intellectual Property Organization Journal*, Vol. 1, pp. 43-50, 2009.

[113] Recital 2 Regulation 1383/2003.

[114] Article 5 § 2 GATT.

situation where "*only a portion of a complete journey beginning and terminating beyond the frontier of the contracting party across whose territory the traffic passes*"[115]. All charges and regulations imposed by contracting parties on traffic in transit shall be reasonable, taking into account the conditions of traffic[116]. It goes without further explanation that the present case bears the potential to strongly affect this principle. The second to be affected is the WTO TRIPs Agreement. It imposes a number of minimum enforcement mechanisms for IPRs, yet asks for guaranteeing that these rules:

- avoid becoming barriers to legitimate trade[117];
- contribute to the mutual advantage of producers and users of technological knowledge, and are in a manner conducive to social and economic welfare[118]; and
- provide for safeguards against their abuse[119].

The Agreements' enforcement rules mostly deal with goods that should be prevented entry into the channels of commerce.[120] Goods in transit are only addressed in a footnote to Article 51 – "Suspension of Release by Customs Authorities". Article 51 obliges WTO members to adopt procedures enabling a right holder – if he has valid grounds for suspecting that the importation of goods infringing his IPRs may take place - to lodge an application with the competent authorities for the suspension by the customs authorities of the release into free circulation of these goods. The footnote states that: "*It is understood that there shall be* ***no obligation*** *to apply such procedures to imports of goods put on the market in another country by or with the consent of the right holder, or to goods in transit*"[121] (emphasis added). From the wording 'no obligation' it would be deducted that there is a choice; that they *may* apply the procedures to goods in transit if they wish. This is debated. In any case, the right holder initiating the procedures must provide adequate evidence to establish a *prima facie* infringement[122].

The facts and laws described above now call for a number of answers. A number of different points must be looked at:

- the application of speedy procedures allowing the destruction of seized goods:
    - without the necessity even of proving IP infringement[123],

[115] Article 5 § 1 GATT.

[116] Article 5 § 4 GATT.

[117] TRIPs Preamble, § 2: "*measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade*".

[118] Article 7 TRIPs Agreement.

[119] Article 41 TRIPs Agreement.

[120] For instance, Article 41 TRIPs Agreement.

[121] Footnote 13 to the TRIPs Agreement.

[122] Article 52 TRIPs Agreement.

[123] Article 11 Regulation 1383/2003.

    - to goods in transit[124]; and
- the application of Dutch patent law to goods in transit; and
- the decision on patent infringement in relation to goods in transit on the basis of a manufacturing fiction – as if the goods were manufactured in the country of transit.

These rules and decisions - the Dutch decision and its foundation, the EU Regulation - must then be tested on a (minimal) number of legal rules and principles:

- the extraterritorial application of the law and the principle of independence of patents[125];
- the principle of freedom of transit[126] as mentioned; and
- (minimally) the TRIPs preamble and articles 7, 41 and 51 (including its footnote 13), as well as the Doha Declaration on the TRIPS Agreement and Public Health[127].

These rules are the expression of the fundamentals which are affected by the Dutch decisions: international trade, economic development of DCs and LDCs, and access to medicines/the right to health.[128] The answers may vary, but all rather point to a breach of international law by the Dutch authorities. However: how to interpret footnote 13 to the TRIPs Agreement? Its text is fairly clear: there shall be no obligation. This implies that there is a possibility. However one could also say that the terminology used - *"**It is understood** that there shall be no obligation"* (emphasis added) - means that it is so obvious ('that it is understood') that these rules are not adequate to goods in transit, that of course the rules do not apply ('there shall be no obligation'). Next, the context of the provision may offer strong arguments not to read the footnote as leaving a choice: freedom of transit of Article V GATT; prohibition to enforcement rules constituting barriers to legitimate trade, as in Article 41

[124] It must be said that "*In almost 90% of all cases, customs action was started whilst the goods concerned were under an import procedure. In 7% of the cases, goods were discovered whilst in transit. With regard to the amount of articles detained, 43% of these articles were under an import procedure and 42% were in transit. More than 80% of the goods stopped in transit concerned DVD/CD and cigarettes. In these cases transit meant mainly 'internal' transit"* (European Commission, Report on EU Customs Enforcement of Intellectual Property Rights; Results at the European Border, 2008, at p. 20, available at: http://ec.europa.eu/taxation_customs/resources/documents/customs/customs_controls/counterfeit_piracy/statistics/2009_statistics_for_2008_full_report_en.pdf (last visited 24 April 2011)).

[125] Article 4bis of the Paris Convention.

[126] Article 5 GATT.

[127] World Trade Organization, *The Doha Ministerial Declaration on the TRIPS Agreement and Public Health*, 14 November 2001, WT/MIN(01)/DEC/2, at § 4: "*...we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all*".

[128] To this is also to be added the rationale of the patent system itself: "*Thirdly, using patents to block, or delay, the provision of generic medication to ill people is unacceptable, because it violates the very foundations of, or justifications for, patent law. As shown by the quotation above, patents are intended to secure the public good, by enabling the production of, and trade in, useful goods*". (C.B. Ncube, 'Enforcing patent rights against goods in transit: a new threat to transborder trade in generic medicines', 21 *SA Mercantile Law Journal* 5 (2009), pp. 680-694).

TRIPs; and a necessity to interpret and implement the TRIPs Agreement in a manner supportive the right to protect public health and, in particular, to promote access to medicines for all (as enshrined in the Doha Declaration which – historically – was not yet enacted at the time the TRIPs Agreement was drafted). The latter reminds us that this case is not about counterfeit medicines. A context interpretation finally also leads us to think about the principle of independence of patents as enshrined in the Paris Convention. This establishes that patents shall not have effect outside of the country that has issued them, while this must be understood in an unrestricted sense[129]. Both principles of independence of patents and access to medicines in fact legitimize the international trade in the discussed medicines and can lead to the conclusion that the use of the Dutch enforcement mechanism is abusive; from an international law perspective.

In this light, may we say with Abbott[130] that the cases are an 'unreasonable' regulation imposed on a product with minimal jurisdictional contact with The Netherlands? We say yes, yet the answer is not given. Early 2010, India (joined by Brazil, Canada, Ecuador, China, Japan and Turkey) initiated a request for consultation at the WTO – the preparatory stage for the establishment of a WTO Panel to decide on the matter. The country claimed that Article V:1, V:2, V:3, V:4; V:5, V:7 and X:3 of the GATT 1994; Articles 1.1, 2, 28, 31, 41.1, 41.2, 42, 49, 50.3, 50.7, 50.8, 51, 52, 53.1, 53.2, 54, 55, 58(b), and 59 of the TRIPS Agreement, and Article 4bis of the Paris Convention of 1967; and Article XVI:4 of the WTO Agreement were breached by the Netherlands and the EU Regulation.[131] In a response to a joint letter from several NGOs on this case[132], WTO's Director General Pascal Lamy recognized that the issue and their letter "*rightly points out the strong determination of all WTO Members to promote access to medicines for all which was explicitly confirmed in 2001 when the Doha Declaration on the TRIPS Agreement and Public Health was adopted*"[133]. The European Union accepted the request for consultations in June 2010.[134] After two rounds of consultations, in July and September 2010, no further news has however been released on the matter[135].[136]

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[129] Article 4bis § 2 of the Paris Convention.

[130] F.M. Abbott, 'Worst Fears Realised: The Dutch Confiscation of Medicines Bound from India to Brazil', *Bridges* 1, February - March 2009, pp. 13-14.

[131] World Trade Organisation, *European Union and A Member State – Seizure of Generic Drugs in Transit, Request for Consultations by Brazil*, 19 May 2010, WT/DS409/1, IP/D/29, G/L/922.

[132] Joint letter from public health NGOs to Pascal Lamy, WTO Director General, 18 February 2009.

[133] See: http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds409_e.htm (last visited 16 April 2011).

[134] World Trade Organisation, *European Union and A Member State – Seizure of Generic Drugs in Transit, Acceptance by the European Union of the Requests to Join Consultations*, 18 June 2010,WT/DS408/8.

[135] P. Lamy, 4 March 2009, available at: http://www.keionline.org/misc-docs/seizures/dglamyresponse.pdf (last visited 12 April 2011).

[136] For a further analysis, we may – on top of literature cited before – recommend: S.P. Kumar, *Border Enforcement of IP Rights Against in Transit Generic Pharmaceuticals: An Analysis of Character and Consistency*, 2010, Available at: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1383067 (last visited 14 April 2011); and H. Grosse Ruse-Khan, 'A Trade Agreement Creating Barriers to International Trade; Acta Border Measures and Goods in Transit', Max Planck Institute for Research Paper Series No. 10-10, 2010.

## B. Abuse of patent rights

From an abuse of rights point of view, the matter appears to offer a good case study. It also introduces a new angle to the debate: the application of abuse of rights amongst treaty parties. Whereas indeed the enforcement of patents on goods in transit may be abusive amongst private actors, the above discussed obligations of international law involving EU Regulation, the Dutch judgement, and the active engagement of Dutch custom authorities may point - at an abusive use of the TRIPs enforcement provisions amongst WTO member countries as well. This conclusion leads us to analyse the application of the principle of good faith in international law, which will be discussed in the section below.[137]

The abuse of rights notion could have been an argument to tackle the procedures in the Netherlands. The request to seize and destroy goods in transit only – medicines on the way between countries where no patent protection was granted – may well be construed as an abuse of patent rights. As with the evergreening of patents, the case here could be based upon each of the three elements which we have identified to constitute the border of the abuse of patent rights notion:

- an abuse in relation to specific third-parties (e.g. producers of generic medicines, consumers);
- an abuse in view of the rationale of the patent right and the patent system[138]; and
- an abuse also against higher ends; access to medicines and the right to health.

Unlike with the evergreening of patents, we however are faced with a purely post-grant matter. Whereas abuse of patent rights thus was only recommended as a second-best solution in relation to evergreening, it is much more an adequate tool in the present constellation. The usual sanction, limitation of the right to a non-abusive exercise seems to perfectly fit the present case study. The patent cannot be enforced on goods in transit and these must continue on their way. What may be complicating the matter however is that we are not in a purely private actors' relationship. Enforcement procedures and border measures are subject to criminal law and may involve a criminal prosecutor. This is what happened with several of the seizures. In those cases, the private patent right holder is only one of the actors involved, and state authority back-up may hinder judges accepting the abuse of rights argument in court.

[137] Cross reference.

[138] In this sense: "*Thirdly, using patents to block, or delay, the provision of generic medication to ill people is unacceptable, because it violates the very foundations of, or justifications for, patent law. As shown by the quotation above, patents are intended to secure the public good, by enabling the production of, and trade in, useful goods.*" (C.B. Ncube, 'Enforcing patent rights against goods in transit: a new threat to transborder trade in generic medicines', 21 *SA Mercantile Law Journal* 5 (2009), pp. 680-694).

# V. Analysis in view of international law – Abuse of rights as a ceiling

A debate on possible counterproductive effects of patent protection is also very present at the international level. Here, less than on technical questions and specific examples, the debate is centred on whether – mainly in view of the relationship between economic development and access to innovation – minimum standards of protection as established in the TRIPs Agreement are not in fact too high. At least, the question is whether a limit should not be imposed as well: maximum standards of protection or so-called 'ceilings'. Since the WTO TRIPs Agreement, things have furthermore evolved. The minimum standards of the Agreement – already subject to strong controversy – have been further developed outside of the WTO framework. At the WTO, negotiations have difficulties to progress and developments within IP regulation are being bargained to concessions in other fields. Bilateral treaties, plurilateral treaties; free-trade agreements and investment protection agreements now form the core of the evolution in international IP lawmaking. The latest example is the plurilateral ACTA: the Anti-Counterfeiting Trade Agreement. All agreements and treaties have in common the aim to increase the level of protection in the countries concerned. In the case of developing countries, the matter is highly controversial. If the parties are developed countries only, then worries are expressed that an ever increasing level of protection may end up being counterproductive to the aim of the system, which is innovation. Also their access to protected products outside of an innovation angle is being debated; for instance in relation to access to medicines. This background has framed the ceilings debate.

It is often disregarded however that the TRIPs Agreement already offers certain ceilings to the levels of IP protection, and that the good faith/abuse of right doctrines come to support this, as we will discuss here below. First, a number of in-built limitations are explicitly found in the Agreement. Article 1§1 for instance allows WTO members to implement more extensive protection than it requires, yet it also limits this in saying that it may only be done provided that such protection does not contravene the provisions of the Agreement[139]. Now, amongst the "provisions of the Agreement" are those already discussed above[140] – e.g. Article 7, 8, 40.2, 41.1 –which for instance prohibit enforcement rules constituting barriers to legitimate trade[141]. Most importantly, there is Article 7.

[139] Article 1§1 TRIPs Agreement reads: "*Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice*".

[140] Cross reference.

[141] Article 41 TRIPs Agreement.

Unlike the General Agreement on Trade and Tariffs – another major pillar of the World trade Organisation – the TRIPs Agreement does however not have a general provision allowing flexibilities in relation to an explicit set of examples. We talk about Article XX GATT, whose chapeau is a clear expression of good faith. The question rises in this context whether this provision could be invoked in other Agreements of the WTO and hence in the TRIPs context.[142] This is subject to debate. However, the TRIPs Agreement has its Article 7, interpreted by the Appellate Body in *Havana Club* as imposing a duty on WTO member states to implement the TRIPs Agreement in good faith, and specifying what this means in the TRIPs context. Although not providing a list per se, Article 7 can thus fulfil a similar function as Article XX GATT. It reads:

> "*The* ***protection and enforcement*** *of intellectual property rights* ***should contribute to*** *the promotion of technological* ***innovation*** *and to the* ***transfer and dissemination of technology****, to the mutual advantage of producers and users of technological knowledge and* ***in a manner conducive to social and economic welfare, and to a balance of rights and obligations***" (emphasis added).

The Panel in *Havana Club* – taking a decision in first instance – makes an explicit mention to 'abus de droit' – abuse of rights - in this context:

> "*The Appellate Body in United States-Shrimps stated that this principle "controls the exercise of rights by states. One application of this principle, the application widely known as* ***the doctrine of abus de droit, prohibits the abusive exercise of a state's rights and enjoins that whenever the assertion of a right 'impinges on the field covered by [a] treaty obligation, it must be exercised bona fide, that is to say reasonably.***' *An abusive exercise by a Member of its own treaty right thus results in a breach of the treaty rights of the other members and, as well, a violation of the treaty obligation of the Member so acting." Members must therefore implement the provisions of the TRIPS Agreement in a manner consistent with the good faith principle enshrined in Article 7 of the TRIPS Agreement"* (emphasis added).[143]

Although the Panel here in fact defines abuse by abuse, *a useful approach*, and the Appellate Body did not go much into this issue in appeal; this it the most explicit definition we find in the TRIPs context: the prohibition of the abusive exercise of a state's rights – e.g. exercised in manner contrary to the bona fide, that is to say unreasonably[144]. This is a literal quote from the US-Shrimps

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[142] Hermann. Reference.

[143] WTO Panel Report, *US-Section 211*, 6 August 2001, WT/DS176/R, at 8.57.

[144] The standard of reasonableness, is also used in literature in relation to good faith in international law. As O'Connor demonstrates, good faith includes moral values. It includes fairness and reasonableness as its standards (J.F. Connor, Good Faith in International Law, Aldershot, Dartmouth Publishing, 1991, at p. 118).

case.[145] In fact, abuse of rights – outside of the TRIPs yet inside of the WTO context – can also be found in a number of other cases, which offer better guidance. Although good faith or abuse of rights was not decisive to the case as such[146], it was for instance said by the WTO Panel in the *US-Offset Act* case that good faith was affected because the object and purpose of the treaty[147] as a whole, or the treaty provision at stake, was defeated by the United States. Clear references to abuse of rights were hereby used:

> *„The obligation* ***to perform a treaty obligation in good faith means*** *that such obligations "must not be evaded by a merely literal interpretation". It means also that the parties "****must abstain from acts that are calculated to frustrate the object and purpose of the treaty****"* (emphasis added).[148]

> *„The European Communities, India, Indonesia and Thailand are of the view that it is implicit in the obligation to perform a treaty provision in good faith that the* ***parties "must abstain from acts that are calculated to frustrate the object and purpose of the treaty"****. As explained in the Complainants' submission, the CDSOA* ***frustrates the object and purpose*** *of Articles 5.4 and 11.4 because it encourages the opening of investigations and the imposition of measures in cases where the domestic industry is not interested in such measures.* ***For that reason, the CDSOA is incompatible with the obligation of the United States to comply in good faith with the requirements of those articles.*** *The US submission does not address this argument"* (emphasis added).[149]

The panel even said that abuse of rights is a fundamental international level principle "*requiring WTO Members to refrain from engaging in an abusive exercise of their rights*".[150]

In US-Shrimps[151], abuse of the exceptions of Article XX GATT was at stake. As mentioned, abuse of rights was confirmed as a principle emanating from good faith, and also confirmed as a principle used for WTO law here as well:

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[145] WTO Appellate Body, United States – Import Prohibition of certain Shrimp and Shrimp Products, 12 October 1998, WT/DS58/AB/R, at 158.

[146] WTO Panel, United States – Continued Dumping and Subsidy Offset Act of 2000,16 September 2002, WT/DS217, at 4.624: „*Therefore,* ***while there is no claim for an independent violation of the principle of good faith at issue here****, it is clear that an obligation of good faith pervades over the manner in which Members must conduct their affairs. Obligations cannot be fulfilled where the principle of good faith is violated*" (emphasis added).

[147] The ASCM Agreement.

[148] WTO Panel, United States – Continued Dumping and Subsidy Offset Act of 2000,16 September 2002, WT/DS217, at 4.676.

[149] Ibid, at 4.1048.

[150] WTO Panel, United States – Continued Dumping and Subsidy Offset Act of 2000,16 September 2002, WT/DS217, at 4.115.

[151] WTO Appellate Body, United States – Import Prohibition of certain Shrimp and Shrimp Products, 12 October 1998, WT/DS58/AB/R.

It was said that only this decision was the first to explicitly recognise abuse of rights as a notion in WTO law – Cottier and Schäfer, p. 65.

> "*The chapeau of Article XX is, in fact, but one expression of the* ***principle of good faith****. This principle, at once a general principle of law and a general principle of international law, controls the exercise of rights by states.* ***One application of this general principle, the application widely known as the doctrine of abus de droit,*** *prohibits the abusive exercise of a state's rights and enjoins that whenever the assertion of a right "impinges on the field covered by [a] treaty obligation, it must be exercised bona fide, that is to say, reasonably."* (emphasis added).[152]

The standard of abuse of rights – as also confirmed in the TRIPs context by the above quoted Panel in *Havana-Club* - thus appears to be that of *reasonableness*. If we apply this to our case studies; would it be reasonable for instance to exercise the right to border measures as has been done in the Transits-case by the Netherlands – the rights to do so stemming from a treaty imbedded in the World *Trade* Organisation, and against the background of the Doha Declaration[153]? Is it a good faith interpretation of the footnote 13 to the TRIPs Agreement[154]?

Arguably, the doctrine of abuse of rights comes in here to place a ceiling; to limit the way the right (possibly) derived from footnote 13 can be exercised. The object and purpose of the treaty[155], as expressed in its preamble and Article 7, would be defeated if the rights of the enforcement section came to be exercised in a manner creating barriers to legitimate trade – in fact blocking international trade – and going against the principles of access-to-medicines as explicitly stated in the TRIPs context with the Doha Declaration.[156] These may

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[152] WTO Appellate Body, United States – Import Prohibition of certain Shrimp and Shrimp Products, 12 October 1998, WT/DS58/AB/R, at 158.

The Appellate Body hereby provides following footnote (n° 156):

"B. Cheng, *General Principles of Law as applied by International Courts and Tribunals* (Stevens and Sons, Ltd., 1953), Chapter 4, in particular, p. 125 elaborates: … A reasonable and bona fide exercise of a right in such a case is one which is appropriate and necessary for the purpose of the right (*i.e.*, in furtherance of the interests which the right is intended to protect). It should at the same time be *fair and equitable as between the parties* and not one which is calculated to procure for one of them an unfair advantage in the light of the obligation assumed. A reasonable exercise of the right is regarded as compatible with the obligation. But the exercise of the right in such a manner as to prejudice the interests of the other contracting party arising out of the treaty is unreasonable and is considered as inconsistent with the bona fide execution of the treaty obligation, and a breach of the treaty. …(emphasis added)".

[153] The evergreening of patents, the second case study in this paper, however, is not so much an issue of ceilings. It may be a pitfall for efficient TRIPs compliant domestic regulation, and therefore nonetheless represents a framework to this context, but only indirectly. Both are abuses of the system, yet one – the transits case – is intrinsically linked to the international level and must therefore be tackled there. The evergreening of patents only is a malicious use of the patentability requirements. It brings the question to what extent the ever increasing drug features that turn to be patentable should be stopped, but does not bring a foundation for abuse of rights *at the international level*.

[154] Here much will depend upon whether the notion can be used *praeter legem*, *infra legem* or *contra legem*.

[155] Cf. *US-Offset Act*: the object and purpose of the treaty as a whole, or the treaty provision at stake, was defeated.

[156] World Trade Organization, *The Doha Ministerial Declaration on the TRIPS Agreement and Public Health*, 14 November 2001, WT/MIN(01)/DEC/2, in its relevant parts:

"*4. We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of*

arguably be the "*compelling standards of honesty, fairness and reasonableness prevailing in the international community at that time*".[157] As said by the Panel in Havana Club:

> "*An abusive exercise by a Member of its own treaty right thus results in a breach of the treaty rights of the other members and, as well, a violation of the treaty obligation of the Member so acting*".[158]

Furthermore, since Article 7 has explicitly been said in WTO jurisprudence to be an expression of good faith, one can argue that Article 7 provides the standard of good faith to be used for the sake of the TRIPs Agreement. An interpretation and application of the TRIPs' enshrined border measures that goes against the promotion of technological innovation and the transfer and dissemination of technologies, to the mutual advantage of producers and users of technological knowledge, or which is not conducive to social and economic welfare and to a balance of rights and obligations; could thus be called an interpretation in bad faith.

One cannot therefore say that increasing the level of IP protection or enforcement to *x, y or z* is allowed under the TRIPs Agreement. In fact, one should say that it is not. Ceilings may arguably be enshrined into the TRIPs Agreement already, especially in contexts such as access-to-medicines, or in the general context of the economic development of the poor(est) countries. These ceilings come in through the interpretation of the provisions in good faith - in accordance to Article 7. One specific ceiling is hereby to be found in the abuse of rights doctrine: a substantive part of WTO law and the TRIPs Agreement.

## Conclusion

The notion of abuse of rights can be a useful tool to tackle a number of cases reported to be undesired in patent literature. Its flexible nature perfectly matches that of the patent system itself. Not all issues can however be addressed by this notion and not all issues – although in theory challengeable from this angle – need the abuse of rights notion. Cases rooting in post-grant issues which can satisfactorily be addressed by competition law, for instance,

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*WTO members' right to protect public health and, in particular, to promote access to medicines for all.*

*In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.*

*5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:*

*In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles*".

[157] Cf. J.F. Connor, *Good Faith in International Law*, Aldershot, Dartmouth Publishing, 1991, at p. 124.

[158] WTO Panel Report, US-Section 211, 6 August 2001, WT/DS176/R, at 8.57.

do not need the notion. Abuse of rights is thus only aimed at filling a gap of lacking means for legal challenge.

Abuse of rights does not usually lead to the revocation of the right at stake. This would however be necessary in the case of evergreening patents. Whereas the notion could be used for abuses rooting in the pre-grant phase, the usual remedy would thus not be appropriate in these cases. Additionally, it would come too late. Abuse of rights therefore mainly is a tool to address post-grant abuses, in cases where competition law does not intervene. Nonetheless, a patent law specific tailoring of the notion and its sanction seems to be possible.

The notion of abuse of rights could indeed be designed rather largely in patent law, although the danger of this concept lies in a possible arbitrary use. It may increase the number of cases and thus create costs, yet if properly defined, the notion should help private actors to better contribute to the systems' balance. In this context, it appears broad enough to address both instances where a patent is being used in a way contrary to the system's rationale, and where a specific behaviour of a patent holder is considered abusive towards a specific (third) party without necessarily having to challenge the rationale of the patent system. Eventually, it could also be invoked when a patent is being used against a higher end.

The transit of medicines case exemplifies a theoretically *legal but illegitimate* enforcement - the classical subject matter of abuse of rights. The study on the evergreening of patents shows that this in fact must be tackled pre-grant, but that in practice it amounts to post-grant action. Here, abuse of rights is useful.

For international law, the case studies can serve as background information to the ceilings debate. Abuse of rights can be used a mechanism used to screening for the necessity for changes in the positive law. The case study on medicines in transit in fact showed the need for a ceiling in this respect specifically. The possibility to use the notion of abuse of rights also brings a further tool to deal with a number of cases in a TRIPs compliant manner - it offers an additional and underused flexibility. Finally and most importantly, an interpretation of the TRIPs Agreement in good faith, may mean that certain interpretations leading to a ever higher level of protection constitute an abuse of rights. It may mean that ceilings are silently present in the Agreement already; that abuse of rights – as a substantive rule – is a ceiling to the TRIPs Agreement.