

DECLARATION ON PATENT PROTECTION

Regulatory Sovereignty under TRIPS

PREFACE

As a framework regulation for innovation markets, the patent system needs to be tailored to the innovation process, which it is supposed to serve, and to the competitive environment, within which it must operate. In order to ensure an efficient functionality of the patent system as an innovation policy tool, patent rights ought to be defined, justified and continually reconsidered by reference to their socio-economic benefits and costs.

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Sovereign states should retain the discretion to adopt a patent system that best suits their technological capabilities as well as their social, cultural and economic needs and priorities, with the proviso that the exercise of such discretion must remain within the boundaries of international law. Taking into account the customary principles of interpretation of international law, this Declaration seeks to shed light on these boundaries. The purpose is to clarify the policy space that the 'Agreement on Trade-Related Aspects of Intellectual Property Rights' (TRIPS Agreement) leaves to national legislators and judicial authorities with regard to the implementation and administration of their patent systems.

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This is of particular importance when it comes to accommodating the law to changed circumstances. We emphasise four key premises in this regard.

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First, states are faced with historically unprecedented numbers of patent filings and grants. Besides creating backlogs at patent offices, this phenomenon leads to patent thickets, legal interdependencies, market entry barriers, royalty stacking and increased litigation, all of which ultimately generate impediments to research and commercial applications. As a result, the costs of monitoring patents rise, legal certainty decreases, and the economic freedom of market participants becomes unduly limited. This affects consumer welfare and distorts competition. Furthermore, the overall social benefits of innovation are reduced while an imbalance emerges between those able to cope with the resulting insecurities and related costs, such as multinational enterprises with their own patent departments, and those who cannot, such as small and medium sized enterprises or individual inventors.

Second, new technologies and business practices challenge the traditional paradigm of patent protection developed during the industrial revolution. Biotechnology, business methods and computer science, as well as standard-setting, strategic patenting and non-practising entities all affect the functioning of the patent system as a regulatory institution.

Third, the role of patents in corporate management has changed. Patents are increasingly used as strategic assets to influence the conditions of competition rather than as a defensive means to protect research and development outcomes. The issue is less whether, in any given case, the patent does or does not serve a pro-innovation purpose (such as attracting venture capital or preserving the freedom to operate as opposed to blocking competitors or launching nuisance lawsuits). What matters is that the shift of the patent from a right of defence to a commercial tool affects the manner in which the right to exclude operates in practice.

Fourth, in many jurisdictions, in particular in those of industrialized states with highly developed economies and advanced technological infrastructures, there has been a gradual shift of balance in the patent regime towards right holders both by reducing the burdens for patent applicants (expanded scope of patentable subject matter, lower eligibility standards, reduced fees) and by extending the rights of patent holders (longer patent term, harsher sanctions for infringements, strengthened modalities of private and public enforcement). In turn, countervailing rights aimed at protecting the public interest in free competition and third parties' freedom to operate are rarely introduced or extended.

This evolution is complicated by two further developments. On the one hand, issues of global governance arise as patent offices reinforce international cooperation. On the other hand, the patent system faces increasing friction with ancillary public policy goals, such as protecting the environment, preserving biodiversity or ensuring affordable access to medicines.

When the world's major patent systems first developed into their present form, nation states were able to engage in the regulatory design process under conditions of high sovereign autonomy. Over the past decades, this autonomy has been progressively eroded. Today, states face a legal and institutional regime consisting of multilateral, regional and bilateral agreements, which are becoming increasingly complex and set more and more limits to their regulatory freedom.¹

As a result, the ability of states to maintain a proper balance between the need for protection of knowledge goods in global markets, the freedom to regulate national or regional innovation markets, and the policy space for pursuing diverse public interest goals risks becoming unduly constrained. This Declaration seeks to clarify some of the regulatory options states still retain under international law, in particular the TRIPS Agreement.

¹ See also the Principles for Intellectual Property Provisions in Bilateral and Regional Agreements, available at http://www.ip.mpg.de/en/pub/news/fta_statement.cfm.

CONSIDERATIONS

General Principles

The patent system's primary regulatory purpose is to prevent the market from failing to produce technical knowledge at adequate levels. The overriding rationale is that, absent patent protection, there may be insufficient incentives to invent (*i.e.* to invest in research and development) and to innovate (*i.e.* to exploit the commercial opportunities a new invention makes possible), because others cannot be excluded from appropriating the benefits without sharing the costs. Patents have also been regarded as serving a number of other objectives, such as attracting foreign investment, facilitating technology transfer and dissemination, supporting domestic industries, generating trade gains or avoiding trade losses. Yet, the impact of patents on the level of innovation strongly depends on the level of technological and economic development, prevailing in the country where they are granted.

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A suboptimal innovation rate may have a number of causes, but it is not necessarily proof of a market failure that can be attributed to absent or insufficient patent protection. Patents as such do not create innovation incentives. They respond to incentives that result from market opportunities, which patentees may or may not capture by virtue of their exclusive rights. Patents thus enable right holders to monetise given market opportunities without interference by others. However, they entail no entitlement for the patentees to be actually compensated for their efforts or to obtain any given return on their investments.

The proper functioning of the patent system depends on the existence of open and effective competition on the market. Patent protection must not interfere with dynamic competition as a decentralised discovery procedure for innovation opportunities, and as a price-setting mechanism for innovation rewards.

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The patent system's overall acceptance rests on a delicate interplay of privileges and responsibilities. As a regulatory institution, its operation must also accommodate other public policies and interests, such as environmental protection, biological diversity, health care (including managing the risks of pandemics), nutrition, food security, technological and scientific progress, education and security.

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The establishment of (see *infra* paras 9 *et seq.*), and limitations to (see *infra* paras 20 *et seq.*), patent protection are thus two sides of the same coin, both committed to promoting competition in innovation while at the same time ensuring that other socio-economic interests are duly safeguarded. As integral elements of patent governance, limitations are crucial to the overall balance of the system of protection – not merely an option that may be used *ad libitum*.

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On that note, Articles 7 and 8 of the TRIPS Agreement recognize that the patent system is embedded in a framework of policy controls. Within the ambit of these provisions, states should possess a high degree of discretion in regulating domestic innovation markets while pursuing public interest goals.

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Even if the measures adopted in connection with the exercise of that discretion curtail the exclusive rights of the patent holder as mandated by Article 28 of the Agreement, that does not make them ‘incompatible with the provisions of the Agreement’ (cf. Article 8(1) and (2)), as long as they are reasonable and necessary in the light of the objectives pursued and the interests involved. In this connection, it bears emphasising that Article 1(1) of the TRIPS Agreement expressly grants WTO Members the freedom to determine the appropriate method of implementing the provisions of the Agreement in their own legal systems and practice.

Differentiation Since it is not the patent but the market that creates innovation opportunities and provides for innovation rewards, patent protection must be neutral in its effects on competition. Both insufficient and excessive protection prejudice the operation of the market. Underprotection undermines the incentives to exploit innovation opportunities. Overprotection compromises other market participants’ freedom to operate and compete on the merits. In either case, the patent system causes a distortion of competition in that it prevents an efficient allocation of market revenues according to the competitive performance of market actors.

Every technology is more or less unique with regard to its exposure to market failure, its susceptibility to patent protection, and its socio-economic implications. It follows that the demand for legal protection, and the effects of that protection on both the operation of competition and the attainment of other public policy goals (see *supra* para. 3), may differ according to the technology at issue. The need to grant protection and the modalities of such protection may also differ accordingly.

Measures to accommodate these differences cannot be considered contrary to Article 27(1) of the TRIPS Agreement. While that provision prohibits discrimination as to the field of technology, it does not prevent states from treating different situations differently. Differentiation that serves to level the actual conditions of competition across all fields of technology is not discriminatory but rather the opposite. It constitutes a necessary response to the diversity of technologies and, consequently, a *conditio sine qua non* for an intrinsically balanced system of protection that remains neutral in its effects on competition.

Differentiation may relate to the requirements of patentability, patent eligibility and disclosure (see *infra* paras 12 *et seq.*), to the exclusion of subject matter from patentability, as well as to the scope of protection (see *infra* paras 17 *et seq.*). With specific regard to limitations of protection as set out in Articles 30 and 31 of the TRIPS Agreement (see *infra* paras 21 *et seq.*), the non-discrimination principle does not apply at all. Contrary to what a WTO’s DSB panel mistakenly assumed (cf. WT/DS114/R of 17 March 2000), the Agreement does not subject these provisions to Article 27(1) of the Agreement. The principle of *in dubio mitius* precludes an interpretation to that effect. When designing exceptions and compulsory licences, states thus remain free to discriminate with regard to the field of technology, provided that such action is reasonable in the light of other public policy goals.

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Patentability, Disclosure

Patent protection is only available for ‘inventions’ (see *infra* para. 10). Certain inventions may be excluded from protection because they do not constitute ‘patentable inventions’, such as those whose commercial exploitation is in conflict with *ordre public* or morality. Patentable inventions may otherwise be denied protection because they do not fulfil the ‘requirements of eligibility’ (see *infra* para. 11), including the disclosure prerequisites (see *infra* para. 12).

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Article 27(1) of the TRIPS Agreement requires states to provide patent protection for ‘any inventions [...] in all fields of technology’. In the absence of codified or customary international consensus, states have latitude in which to define these terms. They are not required to provide protection for subject matter that they classify as discoveries rather than inventions, such as, arguably,

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- biological material, *e.g.* genes, native plant traits or certain microorganisms, including their components and derivatives;
- biological processes;
- new forms, properties or uses of known inventions (see also *infra* para. 11).

By the same token, states are not required to provide patent protection for inventions that they do not consider to be of a technical nature, such as, arguably, business methods or computer programs.

Article 27(1) of the TRIPS Agreement does not prevent states from limiting the availability of patent protection to ‘technical’ inventions. Indeed, most jurisdictions have traditionally defined inventions as comprising ‘technical aspects’, solving a ‘technical problem’ or exhibiting a ‘technical effect’.

Article 27(1) of the TRIPS Agreement requires states to provide protection for any inventions that are not *a priori* excluded from patentability, provided that they are ‘new, involve an inventive step and are capable of industrial application’. States enjoy considerable discretion in implementing these requirements. They may, for example, deny product and/or process patents for

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- biological material, even if it has been isolated and purified;
- new forms of known products or substances, such as variations in chemical composition (‘derivatives’);
- new properties or uses of known products or substances, such as second or further medical uses of pharmaceutical substances;
- selections of elements or segments from a known group or class of patented compounds (‘selection inventions’).

If states grant protection to new properties, uses or derivatives of known substances, they are not prevented from doing that only under qualified conditions, such as enhanced efficacy or reduced side-effects of that substance. In any case, protection should only be available for the newly discovered form, property or use, but not in relation to the substance as such, since a product patent would arguably be unavailable for lack of novelty. Similarly, states may condition the patentability of isolated biological material on their having undergone a structural change (*e.g.* by genetic engineering) that altered their functions or their interaction with other substances.

According to Article 29 of the TRIPS Agreement, patent protection may only be granted if the invention has been disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. That person must be able to carry out the invention without any additional information other than that provided in the patent application. This provision means that different modalities and thresholds of disclosure may need to be applied depending on the technology at issue. For example, patent applications concerning computer programs may require the disclosure of the source code, and those concerning biotechnological inventions may require the deposit of biological material.

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When an invention is not effectively disclosed within the meaning of Article 29 of the Agreement or when the application relates to unspecific or speculative embodiments of the invention, the grant of a patent may not only harm innovation and unduly affect competition, it will also constitute a violation of international law.

In this connection, the person skilled in the art for whom disclosure must be sufficiently clear and complete is not necessarily the same person for whom the invention must be new and nonobvious. Whereas the latter may be defined as a recognized expert – or a team of experts – with extensive practical know-how, the former may be defined as an average engineer with average skills and experience.

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The non-discrimination principle in Article 27(1) of the TRIPS Agreement does not prevent states from adapting the subject matter and requirements of patentability to the characteristics inherent in the technology at issue. They may, for example, apply

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- a different demarcation line between inventions and discoveries in different fields of technology;
- different standards of novelty, non-obviousness and disclosure depending on the technology's maturity and dissemination.

These options would constitute instances of legitimate *bona fide* differentiation rather than discrimination within the meaning of Article 27(1) of the TRIPS Agreement (see *supra* paras 6 *et seq.*).

A rigorous policy towards patentability does not mean that knowledge goods that do not meet the eligibility criteria under patent law must remain without protection. Provided that a lack of protection would lead to market failure (see *supra* para. 1), states remain free to adopt alternative approaches to incentivizing innovation. For example, instead of conferring upon the inventor a right to exclude, they may grant him or her a right of remuneration (after a certain period of market exclusivity).

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Scope of Protection

In most jurisdictions, the scope of protection is determined by the patent claims, read in conjunction with the description and drawings. Accordingly, the exclusive rights conferred by the patent relate to all forms of use that are covered by the claims. In most cases, this approach creates no further problems, because technical inventions usually serve a rather specific and clearly defined purpose. In some cases, however, it may lead to overprotection. Where an invention can have multiple uses or functions not all of which may be known or expected at the time the patent is granted, there is a potential lack of causality between the rationale of patent pro-

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tection and the extent of that protection. Affording ‘absolute product protection’ (*i.e.* for all possible uses, purposes or functions of the invention, whether known or unknown at that time) may unduly restrict competition beyond what is necessary to prevent market failure (see *supra* para. 1).

Articles 27 and 28 of the TRIPS Agreement do not prevent States from limiting the scope of protection to those uses, purposes or functions that have been disclosed and expressly claimed in the patent (‘purpose-bound protection’). Such a limitation may only be applied in certain fields of technology or for certain categories of inventions whose range of application is particularly wide and unpredictable (typically chemical compounds, gene sequences and other ‘information products’). Again, this would constitute a legitimate differentiation rather than discrimination within the meaning of Article 27(1) of the TRIPS Agreement (see *supra* paras 6 *et seq.*).

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Exhaustion

Article 6 of the TRIPS Agreement specifies that, ‘for the purposes of dispute settlement ... nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights’. In other words, it has been agreed to disagree. Some states apply international exhaustion (*i.e.* the patent rights are exhausted once the product has been placed on the market by the patent holder or another authorised party, such as a voluntary or compulsory licensee, in any part of the world), others have opted for national or regional exhaustion. Article 28 of the Agreement should not be misconstrued to undermine this agreement to disagree by interpreting the exclusive right to import as an obstacle to the principle of international exhaustion.

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Article 27 of the TRIPS Agreement does not prevent states from differentiating and even discriminating between industries or fields of technology with regard to the scope of exhaustion. This approach can be of particular relevance with regard to the issue of international exhaustion. Some industries may be more prone to parallel imports than others; and some may depend more on price differentiation than others. States remain free to apply the concept of exhaustion that they expect to be most favourable for the development of the industry in the field of technology concerned.

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Exceptions to Exclusivity

By applying appropriate thresholds of patentability (see *supra* paras 9 *et seq.*) and properly relating the scope of protection to the merit of the invention (see *supra* paras 16 *et seq.*), states may reduce the risk of unnecessarily restricting access to technical knowledge. In addition, they may exempt certain purposes and forms of use from the coverage of the exclusive rights conferred by the patent, *e.g.*

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- for experimental purposes;
- for private and/or non-commercial purposes;
- for educational purposes;
- to obtain marketing approval (regulatory review or ‘Bolar’ exception);
- to prepare or facilitate the sale of competing products immediately after the patent has expired (see also *infra* para. 26).

Occasionally, an exception for certain purposes and forms of use can be a credible policy alternative to restricting patentability. Methods of medical treatment may, for example, be excluded from patentability from the outset or, alternatively, may be exempted in relation to medical practitioners. Similarly, where the rights conferred by a patent are restricted to commercial use from the outset, there will be no need for a private, non-commercial use exception; and where novelty is also destroyed by non-public use, there is no need for prior user rights.

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Article 30 of the TRIPS Agreement establishes three criteria that must be met in order for an exception to be consistent with the Agreement ('three-step test'):

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- the exception must be limited,
- it must not unreasonably conflict with a normal exploitation of the patent and
- it must not unreasonably prejudice the legitimate interests of the patent holder, taking account of the legitimate interests of third parties.

Contrary to what a panel of the WTO's Dispute Settlement Body seemed to assume (cf. WT/DS114/R of 17 March 2000), the three conditions are not cumulative. The three-step test may be understood to require a comprehensive overall assessment rather than a separate and independent assessment of each criterion. Failure to comply with one of the three conditions need not result in the exception being disallowed.²

In order to be 'limited', an exception must not necessarily be narrow in effect. It is limited within the meaning of Article 30 of the TRIPS Agreement if the scope of the exception is reasonably proportionate to its objective and purpose. It must fulfil a legitimate purpose, be adequate to achieve that purpose, and not exceed what is necessary and sufficient to achieve it.

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An exception 'unreasonably conflicts with the normal exploitation of the patent' if it undermines its functional efficiency as a price-setting mechanism. This is the case when it unduly curtails the innovation rewards provided by the market.

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An exception does not 'unreasonably prejudice legitimate interests' if it is both proportionate and reasonable. In this context, it must consider all interests involved, including those of

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- the patent holder and his or her actual and potential licensees;
- follow-on inventors;
- competitors and other market actors who need to operate on the market under conditions of effective competition;
- scientific and academic researchers who require access to the findings of basic research;
- consumers enjoying the benefits of technological advancement;
- the public at large in improved social, cultural and economic well-being.

² See also the Declaration on a Balanced Interpretation of the 'Three-Step Test' in Copyright Law (2006), available at <http://www.ip.mpg.de/en/pub/news/declaration-threestepstest.cfm>.

Against this background, and in contrast to what the WTO Dispute Settlement Body has decided in the past (cf. WT/DS114/R of 17 March 2000), even *prima facie* ‘unlimited’ exceptions such as the stockpiling of generic medicines prior to expiry of the relevant patents, can be considered compatible with Article 30 of the TRIPS Agreement, as long as the principle of proportionality is respected and all affected interests are taken into consideration.

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Compulsory Licence

Not all conflicts of interest between those who benefit from patent protection and those who may be adversely affected by it, including competitors, consumers and ultimately the general public, can be solved by an *ex ante* determination of the scope of exclusive rights and exceptions thereto. In order to accommodate important public interests and confine exclusivity within reasonable limits during the entire lifetime of a patent, states must be able to adjust the scope of exclusive rights even after the patent has been granted.

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The discretion of states to make use of compulsory licences as regulatory instruments is ensured by the fact that neither Article 31 of the TRIPS Agreement nor Article 5A of the Paris Convention contains any restriction with regard to the grounds on which a compulsory licence may be issued.

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In general, two kinds of compulsory licences may be distinguished: those that serve to maintain the functional efficiency of the system of protection (see *supra* para. 1 *et seq.*), and those that serve to accommodate other public interests (see *supra* para. 3).

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Compulsory licences ensure an efficient operation of innovation markets by avoiding the risk that patents themselves become barriers to invention and innovation. This includes the issuance of compulsory licences for improvement patents (*i.e.* when a later patent cannot be exploited without infringing an earlier patent), for enabling the use of biotechnological inventions as research tools or as a remedy against abuse or other inappropriate conduct by the patent holder.

As policy tools, compulsory licences help to ensure that patent protection remains properly balanced with other socio-economic interests. Compulsory licences in the public interest may, for example, be granted when the demand for the patented invention is not being met to an adequate extent or on reasonable terms or when, by reason of a refusal of the patent holder to grant a voluntary licence, the establishment or development of domestic industries is prejudiced.

A compulsory licence may also be granted if the patent holder fails to work the patent within the territory of protection. Since the non-discrimination principle of Article 27 of the TRIPS Agreement – namely the prohibition to discriminate as to whether products are imported or locally produced – does not apply to Article 31 of the Agreement (see *supra* para. 8), states remain free to implement ‘local working requirements’. However, since such requirements are in some tension with the economic rationale of patent protection on globalising markets and need to be reconciled with the WTO’s overarching principle of free trade, states may wish to make the grant of a compulsory licence subject to additional requirements (*e.g.* that the patent holder has been given sufficient time to make preparations for local produc-

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tion and that a compulsory licence is a proportionate measure to accommodate the interests at stake). A compulsory licence may however not be granted if the patent holder can justify his or her inaction (cf. Article 5A of the Paris Convention).

Despite the strong regulatory autonomy of states with regard to determining the grounds on which compulsory licences may be issued, their actual use may be limited in practice. Due to an overly restrictive implementation of the procedural modalities set out in Article 31(a) to (l) of the TRIPS Agreement, the disciplinary effect on the patent holder is often negligible. This may induce him or her to exploit his or her bargaining position in voluntary licence negotiations in ways that may harm the public interest. The procedural requirements must thus be calibrated so as to avoid an excessive burden for the licence petitioner.

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In order to level the playing field, states may reverse the burden of proof concerning the existence of an obligation to licence, and they may give immediate effect to a compulsory licence pending administrative or judicial review (cf. Article 31(i) and (j) of the TRIPS Agreement).

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In determining the scope and duration of a compulsory licence (cf. Article 31(c) of the TRIPS Agreement) states should take into account the commercial interests of licensees. A compulsory licensee should not be deprived of the possibility of obtaining reasonable compensation and an adequate return on investments. Otherwise, he or she will have no incentive to apply for a compulsory licence in the first place. This may require extending the scope and duration of a compulsory licence beyond what would actually be necessary and sufficient in the light of the circumstances which led to it. By the same token, Article 31(g) of the Agreement does not mandate the termination of a compulsory licence on the sole ground that the circumstances on the basis of which it was granted have ceased to exist.

In the case of a compulsory licence granted as a remedy against abuse or other inappropriate conduct, it is not required that the proposed licensee engage in prior negotiations with the patent holder (cf. Article 31(b) of the TRIPS Agreement) or that the licence be authorised predominantly for the supply of the domestic market (cf. Article 31(f) of the Agreement). Given the nature of patents as means of competition (see *supra* para. 1 *et seq.*), any illegitimate exploitation of the exclusive rights conferred by the patent, whether specifically addressed by competition law (such as *e.g.* tying and bundling, discrimination, restrictions of output, excessive pricing or market leveraging) or condemned by some other law (such as patent law itself, civil law, tort law, administrative or procedural law), may be considered ‘anti-competitive’ within the meaning of Article 31(k) of the Agreement. In fact, states frequently address concerns of competition by laws other than those of antitrust.

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Government Use

The rationale behind government or Crown use lies in the responsibility of the state towards its citizenry and its obligation to step in where the market alone becomes incapable of providing essential public goods. It is the state that grants patent protection in the first place, so it is up to the state to eventually limit that protection if it turns out to conflict with the attainment of other public policy goals.

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Undisclosed Information

Despite the strict disclosure requirements in Article 29 of the TRIPS Agreement, the information actually contained in a patent alone is often insufficient to enable others to practice the invention. Third parties thus depend on additional know-how that only the patent holder possesses. This is of particular importance when the third party has no contractual relationship with the patent holder that entitles it to a transfer of know-how, as in the case of a compulsory licence. In such cases, authorities may impose an obligation on the patent holder to provide the licensee – where appropriate in exchange for an adequate compensation – with know-how that is needed to exploit the protected invention. Access to such know-how may only be denied if the balance of hardships tips towards the patent holder as a result of overriding confidentiality reasons within the purview of Article 39 of the TRIPS Agreement.

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Article 39 of the TRIPS Agreement may prohibit the disclosure of clinical test data to third parties, including the generic company, but it does not prevent these parties from relying on that data in order to demonstrate the safety and efficacy of a bioequivalent generic. Consequently, authorities may process market approval applications for generic drugs even before the expiry of the originator's patents.

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Enforcement

The decision whether or not to grant injunctive relief, permanent or preliminary, is an act of equitable discretion by the competent authority. In exercising this discretion, account should be taken of all the interests at stake (*i.e.* not only those of the patent holder and the alleged infringer, but also those of licensees, business partners, competitors, customers, consumers and ultimately the general public) and the circumstances of the individual case, such as

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- the economic consequences of the envisaged remedy for the parties at issue;
- the intentional or unintentional character of the infringement;
- the contribution of the infringing technology to the market value of the end product in which it is incorporated;
- whether the interests of the plaintiff are of exclusionary or pecuniary nature.

The conditions for the grant of provisional measures need to be carefully scrutinised to avoid their abuse and unwarranted limitations to legitimate trade. Establishing the validity and coverage of patent claims and the possible existence of an infringement requires technical knowledge that judges are not generally in possession of. The cautious judicial approach towards provisional measures applied in many countries provides useful guidance on this matter.

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The alleged infringer should normally be allowed to articulate his or her defence. Granting relief *inaudita altera parte*, *i.e.* without prior hearing of the other side, should remain the exception. In principle, a provisional measure should not be granted unless the harm caused to the patent holder is higher than the harm that could be caused to the alleged infringer if the measure were wrongly granted. Furthermore, the public interest should not be negatively affected. Article 50 of the TRIPS Agreement provides ample room for countries to determine the conditions under which their judicial authorities may grant provisional measures.

The procedural modalities of Article 31(a) to (l) of the TRIPS Agreement do not apply to denials of injunctive relief, even if the effect is essentially the same as that of a compulsory licence (*i.e.* when injunctive relief is tied to the payment of ongoing royalties by the infringer).

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Transit

Patent rights should not create barriers to legitimate trade (cf. Recital 1 of the Preamble and Article 41 of the TRIPS Agreement). Goods in transit cannot be deemed to infringe any of the exclusive rights that a patent normally confers if those goods are not destined for the market of the country where transit occurs. The territoriality principle applicable under patent law has not been overridden by the TRIPS Agreement (see, for example, Paragraph 6(i) in fine of the 30 August 2003 WTO decision on the ‘Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health’, concerning the export of pharmaceutical products produced or imported under a compulsory licence). Customs authorities and courts of the country of transit usually lack competence to determine whether goods in transit are infringing in the countries of origin or destination and cannot decide to grant preliminary or permanent injunctions in their respect.

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The detention of goods by customs authorities based on claims of infringement can also violate the principle of freedom of transit enshrined in Article V of the GATT.

Criminal Measures

The scope of a patent depends on the interpretation of its claims, which is conducted under various theories and approaches by courts in different countries. Uncertainty often exists about the scope of exclusive rights conferred and the validity of the patent itself. Applying criminal law in these circumstances can discourage legitimate activities and block legitimate trade. The TRIPS Agreement does not require the criminalization of patent infringement. Infringers should only be subject to civil remedies as regulated under the applicable legal system.

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DECLARATION

The Signatories,

observing that states have often not taken full advantage of the regulatory discretion available under international law, notably the TRIPS Agreement;

perceiving an increasing limitation of national regulatory sovereignty in the field of patent law as a result of obligations arising from multilateral, regional and bilateral agreements;

recalling that the TRIPS Agreement and the Paris Convention are both part of, and should be interpreted in the light of, a wider set of international rules and principles, including regimes dealing with human rights and biological diversity;

recalling that the patent system should ultimately serve the public good by fostering economic growth and technological progress for the benefit of society as a whole;

stressing, in the light of the foregoing, the need for legal certainty regarding the obligations that international law imposes on states, and the policy space that it leaves to them, in formulating and administering their domestic patent systems;

declare as follows:

General Principles

The TRIPS Agreement preserves the right of states to determine the goals of their own patent systems, and to adopt measures ensuring that

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- competition is not restricted beyond what is necessary and sufficient to prevent market failure, and
- the pursuit of other equally or more important public policies is not unduly encumbered.

In particular, states are not prevented from taking measures to

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- maintain a proper balance between patent protection and principles of competition, including measures against abuses of patent rights or other inappropriate conduct by patent holders and applicants;
- provide their population with essential public goods, such as environmental protection, biological diversity, health care, nutrition, food security, technological and scientific progress, education and security.

Such measures are consistent with the TRIPS Agreement – within the meaning of Article 8(1) and (2) of that Agreement – to the extent that they are necessary and reasonable in the light of the objectives pursued and the interests involved.

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Differentiation	Article 27 of the TRIPS Agreement does not prevent states from reasonably differentiating between fields of technology according to <ul style="list-style-type: none"> - the characteristics inherent in the technology at issue and - the state's public policies pertaining to the sector at issue. 	2
Patentability, Disclosure	States have latitude to define what constitutes patentable inventions. Article 27 of the TRIPS Agreement does not require states to provide patent protection for subject matter that they <ul style="list-style-type: none"> - classify as discoveries rather than as inventions or - do not consider to be technical in nature. <p>States have latitude to determine how the patentability requirements are interpreted and applied. In particular, Article 27 of the TRIPS Agreement does not prevent states from denying patent protection for <ul style="list-style-type: none"> - new uses of known products or substances; - derivatives of known products or substances; - selection inventions otherwise lacking novelty and/or an inventive step.</p> <p>States are not required to provide patent protection for inventions that have not been sufficiently disclosed and expressly claimed in the patent application.</p> <p>States are not prevented from making the grant of a patent subject to revealing the origin of claimed biological material and associated traditional knowledge.</p>	3.1 3.2 3.3 3.4
Scope of Protection	Articles 27 and 28 of the TRIPS Agreement do not prevent states from limiting the protection conferred by a patent to products or processes in relation only to the specific function(s) of the invention expressly claimed in the patent.	4
Exhaustion	Article 6 of the TRIPS Agreement does not prevent states from determining whether patent rights are to be exhausted nationally, regionally or internationally.	5.1
	Article 27 of the TRIPS Agreement does not prevent states from discriminating among fields of technology with regard to the geographical scope of exhaustion.	5.2

Exceptions to the Scope of Protection	The non-discrimination principle set out in Article 27 of the TRIPS Agreement does not apply to exceptions otherwise permissible under Article 30.	6.1
	Article 30 of the TRIPS Agreement constitutes an indivisible entirety. The ‘three steps’ are to be considered together and as a whole in a comprehensive overall assessment. ³	6.2
	Article 30 of the TRIPS Agreement does not	6.3
	<ul style="list-style-type: none"> - limit the grounds for introducing exceptions to the exclusive rights conferred by a patent; - prevent legislatures from introducing open-ended general exceptions, as long as the scope of such exceptions is reasonably foreseeable; - prevent courts from applying existing statutory exceptions to similar factual circumstances <i>mutatis mutandis</i>; - require exceptions to be interpreted narrowly; they are to be interpreted according to their objectives and purposes. 	
	Exceptions do not unreasonably conflict with a normal exploitation of the patent if they	6.4
<ul style="list-style-type: none"> - are based on important competing public policy considerations or - have the effect of countering unreasonable impediments to the operation of markets (notably secondary markets). 		
	Article 30 of the TRIPS Agreement does not require states to take account of patent holders’ interests that exceed the purpose of preventing market failure.	6.5
	Legitimate interests of third parties include those of	
	<ul style="list-style-type: none"> - follow-on innovation; - competitors and other market actors; - scientific research; - consumers; - the public at large. 	
Compulsory Licence	Article 31 of the TRIPS Agreement does not limit the grounds on which a compulsory licence can be granted.	7.1
	The non-discrimination principle in Article 27 of the TRIPS Agreement does not apply to compulsory licences otherwise permissible under Article 31.	7.2

³ See also the Declaration on a Balanced Interpretation of the ‘Three-Step Test’ in Copyright Law (2006), available at <http://www.ip.mpg.de/en/pub/news/declaration-threestepstest.cfm>.

In particular, Article 27 of the TRIPS Agreement does not prevent states from granting a compulsory licence if the patented product is not manufactured or the process is not used within the territory of protection, subject to the requirements of Article 5A of the Paris Convention. 7.3

Article 31 of the TRIPS Agreement does not prevent states from 7.4

- requiring, in appropriate cases, the patent holder to prove that the conditions for a compulsory licence are not met;
- giving immediate effect to a compulsory licence pending administrative or judicial review, provided that adequate protection of the legitimate interests of the patent holder is assured.

Article 31 of the TRIPS Agreement does not require the limitation of a compulsory licence to a degree that would unduly impede reasonable and good-faith investments of the licensee. In appropriate cases, states are not prevented from 7.5

- determining the scope of a compulsory licence beyond what is specifically required to eliminate the circumstances which led to it; or
- ordering the continuance of a compulsory licence even though the circumstances which led to it have ceased to exist and are unlikely to recur.

Article 31 of the TRIPS Agreement does not prevent states from granting a compulsory licence as a remedy against the abuse of patent rights or for practices that unreasonably restrain trade or adversely affect the international transfer of technology, even when 7.6

- the proposed licensee has not made prior efforts to obtain authorization from the patent holder, and
- the use is authorised predominantly for the supply of foreign markets.

The system set out in the WTO decision of 30 August 2003 and in the proposed Article 31^{bis} of the TRIPS Agreement does not affect the independent right of a state to allow exports under Article 31(k) or within the confines of Article 31(f) of that Agreement. 7.7

Government Use

Article 31 of the TRIPS Agreement does not limit the grounds on which government use of patents can be authorised. 8.1

In implementing the government use of a patent, Article 31 of the TRIPS Agreement does not require any third party, such as a subcontractor, acting under the authority of the government, to operate on a non-profit basis. 8.2

Undisclosed Information	Articles 31 and 39 of the TRIPS Agreement do not prevent the authority granting a compulsory licence from requiring the patent holder, in appropriate cases, to provide the compulsory licensee with knowledge that is necessary, in the light of the purpose for which the licence was granted, to effectively work the patent, provided that legitimate confidentiality interests of the patent holder are sufficiently taken into consideration.	9.1
	Article 39 of the TRIPS Agreement does not prevent states from authorising a third party, including a compulsory licensee, to rely on or use clinical data submitted by originator companies necessary to obtain marketing approval of a product, when needed.	9.2
	Articles 28 and 39 of the TRIPS Agreement do not prevent states from relying on clinical data submitted by originator companies in order to process market approval applications for generic products prior to the expiry of the relevant patent.	
Enforcement	Articles 44 and 50 of the TRIPS Agreement do not require the authority finding an infringement to grant injunctive relief. An injunction may be inappropriate when <ul style="list-style-type: none"> - the legitimate interests of parties may be adversely affected; - it is contrary to the public interest; - the legitimate interests of the patent holder can be protected by other means, such as damages or security; - in the case of preliminary relief, the patent holder is unlikely to prevail in establishing validity or infringement. 	10.1
	Article 50 of the TRIPS Agreement does not require the grant of provisional measures without prior hearing of the other party. If granted, an opportunity for review of the decision shall be given pursuant to Article 50(4) of the Agreement.	10.2
	States are not prevented from denying injunctive relief to prevent or control abuse or other inappropriate conduct by the patent holder.	10.3
Transit	Goods in transit are <ul style="list-style-type: none"> - not subject to border measures under the TRIPS Agreement; - outside the scope of the patent holder's rights as defined in Article 28 of that Agreement, subject to the principle of freedom of transit under Article V of the GATT.	11

**Criminal
Measures**

Article 61 of the TRIPS Agreement does not require states to apply criminal procedures and penalties to cases other than those of wilful trademark counterfeiting and copyright piracy on a commercial scale.

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