1 ARTICLE 30

1.1 Text of Article 30

Article 30

Exceptions to Rights Conferred

> Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

1.2 General

1. In *Canada – Pharmaceutical Patents*, the Panel addressed the basic structure of Article 30, outlined the conditions for its application and then found that these conditions apply cumulatively:

> "Article 30 establishes three criteria that must be met in order to qualify for an exception: (1) the exception must be 'limited'; (2) the exception must not 'unreasonably conflict with normal exploitation of the patent'; (3) the exception must not 'unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties'. The three conditions are cumulative, each being a separate and independent requirement that must be satisfied. Failure to comply with any one of the three conditions results in the Article 30 exception being disallowed.
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> The three conditions must, of course, be interpreted in relation to each other. Each of the three must be presumed to mean something different from the other two, or else there would be redundancy. Normally, the order of listing can be read to suggest that an exception that complies with the first condition can nevertheless violate the second or third, and that one which complies with the first and second can still violate the third. The syntax of Article 30 supports the conclusion that an exception may be 'limited' and yet fail to satisfy one or both of the other two conditions. The ordering further suggests that an exception that does not 'unreasonably conflict with normal exploitation' could nonetheless 'unreasonably prejudice the legitimate interests of the patent owner'." [1]

2. The Panel then considered both the systemic importance of Article 30 within the TRIPS Agreement and the extent to which other provisions of the Agreement can impart meaning to Article 30:

> "In the Panel's view, Article 30's very existence amounts to a recognition that the definition of patent rights contained in Article 28 would need certain adjustments. On the other hand, the three limiting conditions attached to Article 30 testify strongly that the negotiators of the Agreement did not intend Article 30 to bring about what would

[1] Panel Report, *Canada – Pharmaceutical Patents*, paras. 7.20-7.21.

> be equivalent to a renegotiation of the basic balance of the Agreement. Obviously, the exact scope of Article 30's authority will depend on the specific meaning given to its limiting conditions. The words of those conditions must be examined with particular care on this point. Both the goals and the limitations stated in Articles 7 and 8.1 must obviously be borne in mind when doing so as well as those of other provisions of the TRIPS Agreement which indicate its object and purposes."[2]

1.3 "limited exceptions"

3. In *Canada – Pharmaceutical Patents*, the Panel addressed the question whether the "stockpiling" exception was exempted under Article 30, in the light of the requirement under Article 30 that exceptions to Article 28 be "limited". The Panel first agreed with the proposition that the "limited" character of an exception is to be assessed with respect to their impact on the rights of the patent owner:

> "The Panel agreed with the EC interpretation that 'limited' is to be measured by the extent to which the exclusive rights of the patent owner have been curtailed. The full text of Article 30 refers to 'limited exceptions to the exclusive rights conferred by a patent'. In the absence of other indications, the Panel concluded that it would be justified in reading the text literally, focusing on the extent to which legal rights have been curtailed, rather than the size or extent of the economic impact. In support of this conclusion, the Panel noted that the following two conditions of Article 30 ask more particularly about the economic impact of the exception, and provide two sets of standards by which such impact may be judged. The term 'limited exceptions' is the only one of the three conditions in Article 30 under which the extent of the curtailment of rights as such is dealt with."[3]

4. The Panel, however, rejected suggested approaches to measure the curtailment of the patent owner's rights by counting the number of rights impaired or by considering whether the exclusive right to sell during the patent term is affected:

> "The Panel does not agree, however, with the EC's position that the curtailment of legal rights can be measured by simply counting the number of legal rights impaired by an exception. A very small act could well violate all five rights provided by Article 28.1 and yet leave each of the patent owner's rights intact for all useful purposes. To determine whether a particular exception constitutes a limited exception, the extent to which the patent owner's rights have been curtailed must be measured.
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> The Panel could not accept Canada's argument that the curtailment of the patent owner's legal rights is 'limited' just so long as the exception preserves the exclusive right to sell to the ultimate consumer during the patent term. Implicit in the Canadian argument is a notion that the right to exclude sales to consumers during the patent term is the essential right conveyed by a patent, and that the rights to exclude 'making' and 'using' the patented product during the term of the patent are in some way secondary. The Panel does not find any support for creating such a hierarchy of patent rights within the TRIPS Agreement. If the right to exclude sales were all that really mattered, there would be no reason to add other rights to exclude 'making' and 'using'. The fact that such rights were included in the TRIPS Agreement, as they are in most national patent laws, is strong evidence that they are considered a meaningful and independent part of the patent owner's rights."[4]

5. Subsequently, the Panel stated that while economic impact was addressed by two of the conditions under Article 30, the "limited exception" condition was not related to economic concerns:

> "After analysing all three conditions stated in Article 30 of the TRIPS Agreement, the Panel was satisfied that Article 30 does in fact address the issue of economic impact, but only in the other two conditions contained in that Article. As will be seen in the

[2] Panel Report, *Canada – Pharmaceutical Patents*, para. 7.26.
[3] Panel Report, *Canada – Pharmaceutical Patents*, para. 7.31.
[4] Panel Report, *Canada – Pharmaceutical Patents*, paras. 7.32-7.33.

> analysis of these other conditions below, the other two conditions deal with the issue of economic impact, according to criteria that relate specifically to that issue. Viewing all three conditions as a whole, it is apparent that the first condition ('limited exception') is neither designed nor intended to address the issue of economic impact directly."[5]

1.4 "do not unreasonably conflict with a normal exploitation of the patent"

6. In *Canada – Pharmaceutical Patents*, the Panel addressed the meaning of the term "normal exploitation" contained in the second condition under Article 30, i.e. the phrase "do not unreasonably conflict with a normal exploitation of the patent".

> "The Panel considered that 'exploitation' refers to the commercial activity by which patent owners employ their exclusive patent rights to extract economic value from their patent. The term 'normal' defines the kind of commercial activity Article 30 seeks to protect. The ordinary meaning of the word 'normal' is found in the dictionary definition: 'regular, usual, typical, ordinary, conventional'. As so defined, the term can be understood to refer either to an empirical conclusion about what is common within a relevant community, or to a normative standard of entitlement. The Panel concluded that the word 'normal' was being used in Article 30 in a sense that combined the two meanings.
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> The normal practice of exploitation by patent owners, as with owners of any other intellectual property right, is to exclude all forms of competition that could detract significantly from the economic returns anticipated from a patent's grant of market exclusivity. The specific forms of patent exploitation are not static, of course, for to be effective exploitation must adapt to changing forms of competition due to technological development and the evolution of marketing practices. Protection of all normal exploitation practices is a key element of the policy reflected in all patent laws. Patent laws establish a carefully defined period of market exclusivity as an inducement to innovation, and the policy of those laws cannot be achieved unless patent owners are permitted to take effective advantage of that inducement once it has been defined."[6]

7. After holding that the term "normal" referred to both what is common and to a "normative standard of entitlement", the Panel deliberated regarding what could be considered "normal" in the specific circumstances of the case at issue:

> "Canada has raised the argument that market exclusivity occurring after the 20-year patent term expires should not be regarded as 'normal'. The Panel was unable to accept that as a categorical proposition. Some of the basic rights granted to all patent owners, and routinely exercised by all patent owners, will typically produce a certain period of market exclusivity after the expiration of a patent. For example, the separate right to prevent 'making' the patented product during the term of the patent often prevents competitors from building an inventory needed to enter the market immediately upon expiration of a patent. There is nothing abnormal about that more or less brief period of market exclusivity after the patent has expired.
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> The Panel considered that Canada was on firmer ground, however, in arguing that the additional period of de facto market exclusivity created by using patent rights to preclude submissions for regulatory authorization should not be considered 'normal'. The additional period of market exclusivity in this situation is not a natural or normal consequence of enforcing patent rights. It is an unintended consequence of the conjunction of the patent laws with product regulatory laws, where the combination of patent rights with the time demands of the regulatory process gives a greater than normal period of market exclusivity to the enforcement of certain patent rights. It is likewise a form of exploitation that most patent owners do not in fact employ. For the vast majority of patented products, there is no marketing regulation of the kind

[5] Panel Report, *Canada – Pharmaceutical Patents*, para. 7.49.
[6] Panel Report, *Canada – Pharmaceutical Patents*, paras. 7.54-7.55.

> covered by Section 55.2(1), and thus there is no possibility to extend patent exclusivity by delaying the marketing approval process for competitors."[7]

8. In this context, the Panel found that "normal exploitation" could not simply refer back to the general concern to protect Article 28 exclusionary rights as such:

> "The Panel could not agree with the EC's assertion that the mere existence of the patent owner's rights to exclude was a sufficient reason, by itself, for treating all gains derived from such rights as flowing from 'normal exploitation'. In the Panel's view, the EC's argument contained no evidence or analysis addressed to the various meanings of 'normal' - neither a demonstration that most patent owners extract the value of their patents in the manner barred by Section 55.2(1), nor an argument that the prohibited manner of exploitation was "normal" in the sense of being essential to the achievement of the goals of patent policy. To the contrary, the EC's focus on the exclusionary rights themselves merely restated the concern to protect Article 28 exclusionary rights as such. This is a concern already dealt with by the first condition of Article 30 ('limited exception') and the Panel found the ultimate EC arguments here impossible to distinguish from the arguments it had made under that first condition."[8]

1.5 "do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties"

9. In *Canada – Pharmaceutical Patents*, with respect to the term "legitimate interests" in the third condition "do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties" under Article 30, the Panel first acknowledged the difficulty for Canada in proving a negative proposition:

> "The third condition of Article 30 is the requirement that the proposed exception must not 'unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties'. Although Canada, as the party asserting the exception provided for in Article 30, bears the burden of proving compliance with the conditions of that exception, the order of proof is complicated by the fact that the condition involves proving a negative. One cannot demonstrate that no legitimate interest of the patent owner has been prejudiced until one knows what claims of legitimate interest can be made. Likewise, the weight of legitimate third party interests cannot be fully appraised until the legitimacy and weight of the patent owner's legitimate interests, if any, are defined. Accordingly, without disturbing the ultimate burden of proof, the Panel chose to analyse the issues presented by the third condition of Article 30 according to the logical sequence in which those issues became defined."[9]

10. The Panel then proceeded to examine whether the Canadian regulatory review's exception was compatible with the third condition under Article 30 – i.e. whether it did not 'unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties'. The exception at issue was an exception applicable specifically to producers of generic pharmaceuticals, enabling such producers to complete the burdensome and time-consuming marketing authorization procedure (up to two and a half years) prior to the expiration of the patent term of the relevant original product:

> "The ultimate issue with regard to the regulatory review exception's compliance with the third condition of Article 30 involved similar considerations to those arising under the second condition ('normal exploitation') - the fact that the exception would remove the additional period of de facto market exclusivity that patent owners could achieve if they were permitted to employ their rights to exclude 'making' and 'using' (and 'selling') the patented product during the term of the patent to prevent potential competitors from preparing and/or applying for regulatory approval during the term of the patent. The issue was whether patent owners could claim a 'legitimate interest' in the economic benefits that could be derived from such an additional period of de facto

[7] Panel Report, *Canada – Pharmaceutical Patents*, paras. 7.56-7.57.
[8] Panel Report, *Canada – Pharmaceutical Patents*, para. 7.58.
[9] Panel Report, *Canada – Pharmaceutical Patents*, para. 7.60.

market exclusivity and, if so, whether the regulatory review exception 'unreasonably prejudiced' that interest."[10]

11. The Panel addressed the claim that "legitimate interests" should be identified with legal interests:

> "The word 'legitimate' is commonly defined as follows:
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> (a) Conformable to, sanctioned or authorized by, law or principle: lawful; justifiable; proper;
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> (b) Normal, regular, conformable to a recognized standard type.
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> Although the European Communities' definition equating 'legitimate interests' with a full respect of legal interests pursuant to Article 28.1 is within at least some of these definitions, the EC definition makes it difficult to make sense of the rest of the third condition of Article 30, in at least three respects. First, since by that definition every exception under Article 30 will be causing 'prejudice' to some legal rights provided by Article 28 of the Agreement, that definition would reduce the first part of the third condition to a simple requirement that the proposed exception must not be 'unreasonable'. Such a requirement could certainly have been expressed more directly if that was what was meant. Second, a definition equating 'legitimate interests' with legal interests makes no sense at all when applied to the final phrase of Article 30 referring to the 'legitimate interests' of third parties. Third parties are by definition parties who have no legal right at all in being able to perform the tasks excluded by Article 28 patent rights. An exceptions clause permitting governments to take account of such third party legal interests would be permitting them to take account of nothing. And third, reading the third condition as a further protection of legal rights would render it essentially redundant in light of the very similar protection of legal rights in the first condition of Article 30 ('limited exception')."[11]

12. After expressing its disagreement with the suggested definition of "legitimate interests" as "legal interests", as proposed by the European Communities, the Panel put forth its own definition of "legitimate interests":

> "To make sense of the term 'legitimate interests' in this context, that term must be defined in the way that it is often used in legal discourse - as a normative claim calling for protection of interests that are 'justifiable' in the sense that they are supported by relevant public policies or other social norms. This is the sense of the word that often appears in statements such as 'X has no legitimate interest in being able to do Y'. We may take as an illustration one of the most widely adopted Article 30-type exceptions in national patent laws - the exception under which use of the patented product for scientific experimentation, during the term of the patent and without consent, is not an infringement. It is often argued that this exception is based on the notion that a key public policy purpose underlying patent laws is to facilitate the dissemination and advancement of technical knowledge and that allowing the patent owner to prevent experimental use during the term of the patent would frustrate part of the purpose of the requirement that the nature of the invention be disclosed to the public. To the contrary, the argument concludes, under the policy of the patent laws, both society and the scientist have a 'legitimate interest' in using the patent disclosure to support the advance of science and technology. While the Panel draws no conclusion about the correctness of any such national exceptions in terms of Article 30 of the TRIPS Agreement, it does adopt the general meaning of the term 'legitimate interests' contained in legal analysis of this type.
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[10] Panel Report, *Canada – Pharmaceutical Patents*, para. 7.61.
[11] Panel Report, *Canada – Pharmaceutical Patents*, para. 7.68.

> The text of the present, more general version of Article 30 of the TRIPS Agreement was obviously based on the text of Article 9(2) of the Berne Convention. Berne Article 9(2) deals with exceptions to the copyright holder's right to exclude reproduction of its copyrighted work without permission. The text of Article 9(2) is as follows:
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> > 'It shall be a matter for legislation in the countries of the Union to permit the reproduction of [literary and artistic] works in certain special cases, provided that such reproduction does not conflict with a normal exploitation of the work and does not unreasonably prejudice the legitimate interests of the author.'[12]
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> The text of Berne Article 9(2) was not adopted into Article 30 of the TRIPS Agreement without change. Whereas the final condition in Berne Article 9(2) ('legitimate interests') simply refers to the legitimate interests of the author, the TRIPS negotiators added in Article 30 the instruction that account must be taken of 'the legitimate interests of third parties'. Absent further explanation in the records of the TRIPS negotiations, however, the Panel was not able to attach a substantive meaning to this change other than what is already obvious in the text itself, namely that the reference to the 'legitimate interests of third parties' makes sense only if the term 'legitimate interests' is construed as a concept broader than legal interests."[13]

13. Another claim put forth in *Canada – Pharmaceutical Patents* called attention to the fact that patent owners whose innovative products are subject to marketing approval requirements suffer a loss of economic benefits to the extent that delays in obtaining government approval prevent them from marketing their product during a substantial part of the patent term (the same government approval which producers of generic pharmaceuticals, under the above-mentioned regulatory review exception, were able to obtain prior to the date of the expiry of the patent term). The Panel considered the relevant practice by some Members to ascertain whether the European Communities' policy concern was "a widely recognized policy norm":

> "The Panel therefore examined whether the claimed interest should be considered a 'legitimate interest' within the meaning of Article 30. The primary issue was whether the normative basis of that claim rested on a widely recognized policy norm.
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> The type of normative claim put forward by the EC has been affirmed by a number of governments that have enacted *de jure* extensions of the patent term, primarily in the case of pharmaceutical products, to compensate for the de facto diminution of the normal period of market exclusivity due to delays in obtaining marketing approval. According to the information submitted to the Panel, such extensions have been enacted by the European Communities, Switzerland, the United States, Japan, Australia and Israel. The EC and Switzerland have done so while at the same time allowing patent owners to continue to use their exclusionary rights to gain an additional, de facto extension of market exclusivity by preventing competitors from applying for regulatory approval during the term of the patent. The other countries that have enacted *de jure* patent term extensions have also, either by legislation or by judicial decision, created a regulatory review exception similar to Section 55.2(1), thereby eliminating the possibility of an additional de facto extension of market exclusivity."[14]

14. While finding some support for the European Communities' claim in the practice of a certain number of Member governments who had granted compensatory adjustment for the effective diminution of patent holder rights, the Panel held that such practice has not been universal:

> "This positive response to the claim for compensatory adjustment has not been universal, however. In addition to Canada, several countries have adopted, or are in

[12] *(footnote original)* The text of Berne Article 9(2) also served as the model for three other exceptions clauses in the TRIPS Agreement - Articles 13, 17 and 26.2, providing respectively for similar exceptions from obligations on copyright, trademarks and industrial designs. Article 13 is a nearly identical copy of Berne Article 9(2). Like Article 30, both Articles 17 and 26.2 made small changes to the text of Berne Article 9(2).

[13] Panel Report, *Canada – Pharmaceutical Patents*, paras. 7.69 and 7.71.

[14] Panel Report, *Canada – Pharmaceutical Patents*, paras. 7.77–7.78.

> the process of adopting, regulatory review exceptions similar to Section 55.2(1) of the Canadian Patent Act, thereby removing the de facto extension of market exclusivity, but these countries have not enacted, and are not planning to enact, any *de jure* extensions of the patent term for producers adversely affected by delayed marketing approval. When regulatory review exceptions are enacted in this manner, they represent a decision not to restore any of the period of market exclusivity due to lost delays in obtaining marketing approval. Taken as a whole, these government decisions may represent either disagreement with the normative claim made by the EC in this proceeding, or they may simply represent a conclusion that such claims are outweighed by other equally legitimate interests.
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> On balance, the Panel concluded that the interest claimed on behalf of patent owners whose effective period of market exclusivity had been reduced by delays in marketing approval was neither so compelling nor so widely recognized that it could be regarded as a 'legitimate interest' within the meaning of Article 30 of the TRIPS Agreement. Notwithstanding the number of governments that had responded positively to that claimed interest by granting compensatory patent term extensions, the issue itself was of relatively recent standing, and the community of governments was obviously still divided over the merits of such claims. Moreover, the Panel believed that it was significant that concerns about regulatory review exceptions in general, although well known at the time of the TRIPS negotiations, were apparently not clear enough, or compelling enough, to make their way explicitly into the recorded agenda of the TRIPS negotiations. The Panel believed that Article 30's 'legitimate interests' concept should not be used to decide, through adjudication, a normative policy issue that is still obviously a matter of unresolved political debate."[15]

1.6 Relationship with other provisions

15. With respect to the relationship of Article 30 to Article 9(2) of the Berne Convention (1971) and Articles 13, 17 and 26.2 of the TRIPS Agreement, the Panel in *Canada – Pharmaceutical Patents* stated:

> "The text of Berne Article 9(2) also served as the model for three other exceptions clauses in the TRIPS Agreement - Articles 13, 17 and 26.2, providing respectively for similar exceptions from obligations on copyright, trademarks and industrial designs. Article 13 is a nearly identical copy of Berne Article 9(2). Like Article 30, both Articles 17 and 26.2 made small changes to the text of Berne Article 9(2)."[16]

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Current as of: December 2023

[15] Panel Report, *Canada – Pharmaceutical Patents*, paras. 7.79 and 7.82.
[16] Panel Report, *Canada – Pharmaceutical Patents*, fn 420.