

## 26: Process Patents: Burden of Proof

### Article 34 Process Patents: Burden of Proof

1. For the purpose of civil proceedings in respect of the infringement of the rights of the owner referred to in paragraph 1(b) of Article 28, if the subject matter of a patent is a process for obtaining a product, the judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process. Therefore, Members shall provide, in at least one of the following circumstances, that any identical product when produced without the consent of the patent owner shall, in the absence of proof to the contrary, be deemed to have been obtained by the patented process:

- (a) if the product obtained by the patented process is new;
- (b) if there is a substantial likelihood that the identical product was made by the process and the owner of the patent has been unable through reasonable efforts to determine the process actually used. Any Member shall be free to provide that the burden of proof indicated in paragraph 1 shall be on the alleged infringer only if the conditions referred to in subparagraph (a) is fulfilled or only if the condition referred to in subparagraph (b) is fulfilled.

2. In adduction of proof to the contrary, the legitimate interests of the defendants in protecting their manufacturing and business secret shall be taken into account.

### 1. Introduction: terminology, definition and scope

Article 34 is concerned with patents the subject matter of which is a claim or claims to a process for the manufacture of a product, which may itself be the subject of a patent though it does not necessarily have to be.

Article 34 reverses the procedural principle under which the person asserting a fact must prove it. Its purpose is to meet the so called "*probatio diabolica*": it is always difficult for a plaintiff owning a process patent to prove whether or not the process used by the alleged infringer to manufacture an identical product to the one resulting from the patented process infringes his exclusive

## 2. History of the provision

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right, unless the plaintiff gains access to the manufacturing process of the alleged infringer.<sup>967</sup>

The conditions on which the onus of proof should be reversed are as follows:<sup>968</sup>

1. The alleged infringer's product must be identical for material purposes to the product produced by the patented process.
2. If this is the case, Members should implement a presumption that such product has been obtained by the patented process if –
  - (a) the product obtained by the patented process is new; or
  - (b) if there is a substantial likelihood that the identical product (new or existing) was made by such process and the owner of the patent was unable through reasonable efforts to determine the process actually used, and the patent owner produces evidence that he/she has used reasonable efforts to try to determine the process used and was unable to do so.

## 2. History of the provision

### 2.1 Situation pre-TRIPS

The rule on the reversal of the burden of proof was introduced by the 1891 German patent law (Article 139). It was also incorporated in the patent laws of Italy, Belgium and Spain. It was also included in the Community Patent Convention (Article 35), as well as in the proposed WIPO treaty for harmonization of patent law (Article 24)<sup>969</sup> on terms substantially similar to the text adopted later on under TRIPS.

### 2.2 Negotiating history

Negotiations on this provision were based on the proposals submitted in 1990 by the European Communities, the USA and Switzerland. Equivalents of this provision existed in both the Brussels Draft of TRIPS and in the Anell Draft of July 23, 1990. The two conditions for the reversal of the *onus probandi* were similar in both drafts, but in its final version Article 34.2 makes it clear that Members may provide that the onus shall be on the alleged infringer if *either* of the conditions is fulfilled. During the negotiations the European Commission favoured the first condition and the United States the second.<sup>970</sup>

#### 2.2.1 The Anell Draft

##### “2.3 Reversal of Burden of Proof

2.3A.1 If the subject matter of a patent is a process for obtaining a product, the same product when produced by any other party shall, in the absence of proof to

<sup>967</sup> See, e.g., Miguel Vidal-Quadras Trias des Bes, *Process patents on new products and reversal of the burden of proof: factors contributing to the interpretation of its scope*, European Intellectual Property Review 2002, vol. 24, No. 5, p. 237–243 (237) [hereinafter Vidal-Quadras Trias des Bes].

<sup>968</sup> See Gervais, p. 171.

<sup>969</sup> See WIPO, 1991, p. 32.

<sup>970</sup> See Gervais, p. 172.

the contrary, be deemed to have been obtained by the patented process in [at least one of] the following situation[s]:

(a) if the product is new, [or,

(b) where the product is not new, if there is a substantial likelihood that the product was made by the process [and the owner of the patent has been unable through reasonable efforts to determine the process actually used].

2.3A.2 In the adduction of proof to the contrary, the legitimate interests of the defendant in protecting his manufacturing and business secrets shall be taken into account.

2.3B Where the subject matter of a patent is a process for obtaining a product, whether new or old, the burden of establishing that an alleged infringing product was made by the patented process shall always be on the person alleging such infringement.”

Alternative 2.3B, introduced by developing countries, was clearly intended to counter the proposals for reversal of the burden of proof. But this strategy was not successful, as is obvious from the text finally adopted.

## 2.2 The Brussels Draft

“Reversal of Burden of Proof

1. For the purpose of civil proceedings in respect of the infringement of the rights of the owner referred to in Article [28](1)(b), if the subject matter of a patent is a process for obtaining a product, PARTIES [shall] [may] provide in at least one of the following circumstances that any identical product when produced by any party not having the consent of the patent owner shall, in the absence of proof to the contrary, be deemed to have been obtained by the patented process:

(a) if the product obtained by the patented process is new;

(b) if there is a substantial likelihood that the identical product was made by the process and the owner of the patent has been unable through reasonable efforts to determine the process actually used.

2. In the adduction of proof to the contrary, the legitimate interests of the defendant in protecting his manufacturing and business secrets shall be taken into account.”

## 3. Possible interpretations

1. For the purpose of civil proceedings in respect of the infringement of the rights of the owner referred to in paragraph 1(b) of Article 28, if the subject matter of a patent is a process for obtaining a product, . . .

The reversal of burden of proof logically applies to civil procedures only, since the presumption of innocence generally governs in criminal cases. The subject of the patent for the reversal to proceed should be a “patent for obtaining a process”. It is left to Members, however, to determine whether such a process should be the

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*sole* object of the patent, or whether “hybrid” patents (including claims over both a process and a product) should also be subject to Article 34.

This Article only applies, further, in cases where an infringement of the acts described in Article 28.1(b) of TRIPS is alleged, that is, whenever the identical product has been directly obtained with the patented process. It is not enough, hence, to argue that the product is *obtainable* with such a process.

... the judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process.

Article 34.1 requires Members to empower their judicial authorities to order the reversal of the burden of proof. It is not an operative, self-executing provision, but requires positive action both by the Members and, in a particular case, the competent judge. The defendant can be obliged to prove that the process is different from the patented process, but cannot be obliged to prove that the process has not been infringed. If the defendant proves that the process used by himself on the one hand and the patented process on the other hand are different, the proof of infringement, which would normally require the application of the “doctrine of equivalents”,<sup>971</sup> remains a plaintiff’s burden, according to general principles of procedural law.<sup>972</sup>

Therefore, Members shall provide, in at least one of the following circumstances, that any identical product when produced without the consent of the patent owner shall, in the absence of proof to the contrary, be deemed to have been obtained by the patented process:

Whether a product is “identical” to the product obtained by a patented process is to be determined on the basis of its structural composition. Similarity, therefore, is not sufficient to trigger the reversal of proof.<sup>973</sup>

<sup>971</sup> This doctrine provides a conceptual framework to determine if a violation of a patent exists when there is no literal infringement of patent claims. See, e.g., Correa, 2000a, p. 85.

<sup>972</sup> See the decision of the Barcelona Provincial Appellate Court of September 18, 2000, in *Enaaprile II*, according to which the defendant’s burden of proving the contrary “is confined to disclosing the process actually used by the defendant (which would convert the proceedings into a mere comparison of both processes) and to show that the two processes are not identical, but not that the presumption also involves proof that the processes are not equivalent”. See also the judgment of the German Federal Court of June 25, 1976, in *Alkylendiamine II*, which held that a similar rule under German law did not shift the responsibility for determining the scope of the plaintiff’s right on the defendant; but merely required the defendant to provide sufficient proof of the process actually used in manufacturing the product. G.R.U.R 1997, p.103 (cases quoted in Vidal-Quadras Trias des Bes, p. 240).

<sup>973</sup> The German Federal Supreme Court in the *Alkylendiamine II* case clarified that the notion of “same substance” under the old Patents Act Section 47(3) applied also when established differences exist between two substances within the limits that technical experience shows to be attributable to a variation of the patented process, but not the application of a different process. See Straus, p. 820.

In addition to requiring that judges be empowered to order the reversal, Article 34 provides for the establishment of a *juris tantum* presumption that the patented process has been effectively used. This presumption admits proof to the contrary.

As mentioned, the conditions stipulated in Article 34.1 for the reversal to proceed constitute options for Members. They may opt for establishing one or the other,<sup>974</sup> at their discretion.

### 3.1 Article 34.1(a)

(a) if the product obtained by the patented process is new;

This condition, probably inspired by European law, requires the “newness” of the product obtained through the protected process. In many cases, the product may be new but not inventive and, hence, not patentable. In the case of countries that did not grant product patent protection for pharmaceuticals or other products, there exist many instances in which the inventor was able to patent the process, but not the product. The rationale for this option is that when a product is new, it is unlikely that competitors had the time to develop alternative processes to obtain the same product. The older the product, the higher the possibility that such alternatives have been developed.<sup>975</sup>

For countries that opt for alternative (a), there is no obligation to order the reversal of the burden for products which are not new.

TRIPS does not determine when a product should be considered new for the purposes of this provision. Members enjoy considerable room for manoeuvre in this respect. They may, for instance, establish that newness be judged:

(1) according to the novelty requirement under the patent law on the date of the application (or the priority date). This solution is significantly advantageous to the patent owner: though a long period may have passed between that date and the date of infringement, the product would still be considered new for the purposes of the burden of proof. Under this approach the attribute of new is fixed once and forever ignoring that, as time passes, it may be reasonably presumed that other processes to obtain the product may have been developed.<sup>976</sup>

<sup>974</sup> A “TRIPS-plus” solution may obviously be to order reversal of the burden of proof when *any* of the conditions are met, as originally sought by the USA during TRIPS negotiations.

<sup>975</sup> Thus, it has been noted that “it seems to be reasonable to assume that, where subsequent processes have been described for obtaining the product resulting from the claimed patented processes to the extent that such processes may vary to a greater or lesser extent, bring different advantages or simply be practicable, when the patent invoked is close to expiry and alternative processes have been described, these circumstances must be taken into account in order to undermine the grounds for presuming that the patented process has been used” (Vidal-Quadras Trias des Bes, p. 242).

<sup>976</sup> The District Court of Munich considered (as long ago as 1963) that the “new product” characteristic required by the article of the Patent Law relating to the reversal of the burden of proof did not necessarily have to be interpreted as having the same meaning as novelty for the purpose of patentability. More recent German authors have taken the same view since such an interpretation

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Or:

(2) at the time the product is introduced into the market. If other products obtained by non-infringing processes were available at that time, it would be *prima facie* proven that other processes existed for obtaining the product and, therefore, there would be no logical basis for the legal presumption to operate. This solution was proposed in one of the texts considered in the preparatory work of the WIPO Diplomatic Conference for the adoption of a Patent Law Treaty,<sup>977</sup> and has also been suggested by some authorities in Europe.<sup>978</sup>

#### 3.2 Article 34.1(b)

(b) if there is a substantial likelihood that the identical product was made by the process and the owner of the patent has been unable through reasonable efforts to determine the process actually used. Any Member shall be free to provide that the burden of proof indicated in paragraph 1 shall be on the alleged infringer only if the condition referred to in subparagraph (a) is fulfilled or only if the condition referred to in subparagraph (b) is fulfilled.

A “substantial likelihood” is more than the mere “possibility”. The plaintiff must be able to prove that, in the circumstances of the particular case, the identical product is likely to have been obtained with his patented process. Under this option, the plaintiff would also have to prove that he has made reasonable and unsuccessful efforts to determine what process was used, for instance, by undertaking the chemical analysis of the product, requesting information from the product manufacturer (if known and different from the alleged infringer), or other measures that the owner could undertake at a reasonable cost and within a reasonable time.

#### 3.3 Article 34.2

2. In adduction of proof to the contrary, the legitimate interests of the defendants in protecting their manufacturing and business secret shall be taken into account.

As noted, Article 34.2 makes it clear that the obligation to reverse the burden of proof may apply in *either* the circumstances specified in Article 34.1(a) or (b) set out above. If the product has in fact been produced by a different process, the alleged infringer will not want to disclose his process to competitors. Article 34.2

would be contrary to the purpose of the procedural rule contained in German law (Vidal-Quadras Trias des Bes, p. 242).

<sup>977</sup> Article 301(1)(b) of the 1987 Draft Patent Law Treaty disregarded the presumption of infringement “if, at the time of the alleged violation, an identical product emanating from a source other than the owner of the patent and the defendant was already known in commerce in the country in which the patent applies”. See, e.g., Harold Wegner, *Patent Harmonization*, Sweet & Maxwell, London 1993, p. 334.

<sup>978</sup> See, e.g., authors quoted by Straus, p. 821.

provides that in the presentation of evidence to the contrary, the legitimate interests of the defendants in protecting their manufacturing and business secret shall be taken into account. Obviously, those legitimate interests include not disclosing the defendant's trade secrets to the other side, including technical and commercial information (e.g., the source of a given intermediate used in the process).

However, the defendant will be bound to disclose the process that has actually been used in order to rebut the *juris tantum* presumption. Otherwise, he will be deemed as infringing the patent. A possible strategy to protect the defendant's trade secrets is for the rules of court procedure of a Member to require the trade secrets to be disclosed only to an independent expert, who is under an obligation of secrecy, and who will advise the court under conditions of confidentiality. Another strategy which is perhaps more appropriate to adversarial (as opposed to inquisitorial) court procedures is to require the information to be disclosed to one member of the plaintiff's team who is similarly bound by an obligation of secrecy. That person will communicate the information to the plaintiff's independent lawyers (who are similarly under an obligation of confidentiality), who will then advise whether the proceedings are to continue or to be discontinued.

"Legitimate interests", as defined by the panel in *Canada-Patent protection of pharmaceutical products*, must be "construed as a concept broader than legal interests",<sup>979</sup> encompassing any business interest that the defendant may legitimately wish to protect.

#### 4. WTO jurisprudence

There is no WTO jurisprudence on this provision. In a case settled between USA and Argentina after consultations, the Argentine government agreed to amend its patent law in order to comply with Article 34.1. The proposed amendment opts for the alternative provided for under Article 34.1 (a).<sup>980</sup>

#### 5. Relationship with other international instruments

This provision has no counterpart in either the Paris Convention or the European Patent Convention, both of which leave the question of onus of proof to national law. However, Article 35 of the Community Patent Convention provides that

"1. If the subject-matter of a Community patent is a process for obtaining a new product, the identical product when produced by any other party shall, in the

<sup>979</sup> WT/DS114/R, 17 March 2000, at para 7.71.

<sup>980</sup> With regard to the definition of "new", the proposed amendment reads as follows: "[I]t shall be presumed that, in the absence of proof to the contrary, the product obtained by the patented process is not new if the defendant or if an expert appointed by the court at the request of the defendant is able to show that, at the time of the alleged infringement, there exists in the market a non-infringing product identical to the one produced by the patented process that originated from a source different from the right owner or the defendant". See WT/DS171/3, WT/DS196/4, IP/D/18/Add.1, IP/D/22/Add.1 of 20 June 2002.

## 7. Comments, including economic and social implications

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absence of proof to the contrary, be deemed to have been obtained by the patented process.

2. In the adduction of proof to the contrary, the legitimate interests of the defendant in protecting his manufacturing and business secrets shall be taken into account”.

## 6. New developments

In implementing the rule on reversal of burden of proof mandated by TRIPS, some countries opted for alternative (a),<sup>981</sup> others for alternative (b),<sup>982</sup> while many incorporated both conditions set out in Article 34.1.<sup>983</sup>

## 7. Comments, including economic and social implications

Process patents are a weak form of protection, because of the difficulties involved in proving infringement. As noted above, formerly some countries while barring the patenting of pharmaceutical products would allow the patenting of processes. The effect was that for practical purposes pharmaceutical products were not fully protected, because the key feature of a pharmaceutical product is usually its molecule, and in practice the composition of this is fairly easy to analyse, though the same molecule must be manufactured by an alternative method in order not to infringe the process patent. Article 34 attempts to ameliorate this weakness by reversing the onus of proof, so that if the defendant has produced an identical product to that produced by the process patent, the onus shifts to the defendant to show that the product was produced without use of the process covered by the patent. It is, of course, no defence in patent law that the defendant independently developed the identical process. Independent creation is a defence in copyright and trade secrets law, but a patent confers an exclusive right on the patentee.

The reversal of the burden of proof, hence, may be of particular importance in developing countries and economies in transition that did not recognize product patents for pharmaceuticals or in other fields of technology prior to the implementation of TRIPS. With the universal introduction of product patent protection for pharmaceuticals and chemical products under Article 27.1, the practical importance of such principle will diminish, since infringement of product patents would be easier to prove. However, Article 34 will provide a valuable procedural tool to patent holders that have only been able to obtain process and not product protection.

Those countries that opted, in implementing Article 34.1, for alternative (a) generally aimed at excluding the application of such a rule for products already in the market. The extent to which this will be achieved, however, would depend

<sup>981</sup> See, e.g., Argentine patent law 24.481 (Article 88).

<sup>982</sup> This alternative is often found, for instance, in bilateral agreements concluded between the USA and former centrally managed economies (Straus, p. 810).

<sup>983</sup> See, e.g., Indonesian patent law No. 14 of year 2000 (Article 119); Industrial Property Common Regime of the Andean Community, Decision 486 (Article 240).



on the way in which the concept of “new” is defined by law and jurisprudence. If “new” is assimilated to the “novelty” standard for patentability, and a product was new at the time of the patent application, it would remain “new” for the purposes of the reversal of the burden of proof until the patent expires, possibly many years after its introduction into commerce.