PROTECTING THE RESULTS OF FUTURE RESEARCH: REACH-THROUGH CLAIMS IN EUROPEAN AND U.S. LAWS

Pierre Véron & Olivier Moussa
Avocats à la Cour
Véron & Associés, Paris

Discovering and finalizing new drugs are processes more and more costly in time and money.

They require heavy investments which will be made only if the return is up to the efforts made.

One of the classical means to secure this return is to protect the end product, namely the discovered drug, by a patent.

However, the researchers, who beforehand identified the target of the drug, also try to make their efforts profitable by reserving for themselves a share of the profit recorded by the end product.

From a strategic point of view, the stake for the players working at the beginning of the research process is to use the intellectual property rights they were granted over the tools which made the discovery possible to obtain a share of the profit generated by this discovery.

Different mechanisms, called "*reach-through"* because the yield generated by the end products can be reached through them, can be used.

These mechanisms can be classified into three categories.

First it is conceivable to extend the claimed protection at the stage of the filing of the research tool patent.

In addition to the research method claims, a reach-through patent will hence include one or several claims relating to the compounds which will be discovered by using said method.

If the protection of the results of research through a patent has not been contemplated, it is however tempting after all to gain said protection during an action for infringement.

The holder of the patent on a research method will here attempt to have the product discovered by using the patented method held infringing said method; this is called "reach-through infringement".

Finally, the access to the profit generated by the end product can be contemplated by contract: the research method licensing agreements can provide for reach-through royalties which would be based on the sales of the drug.

The courts begin to examine these strategies; recent decisions have laid down the first principles on reach-through claims (**1.**), reach-through infringement (**2.**) as well as on the contracting of licensing agreements providing for reach-through royalties (**3.**).

1. Reach-through claims

Pharmaceutical research has known heavy changes in the last few years.

Today, technical progress enables the analysis of pathological processes at molecular level.

The trend in pharmaceutical research is now therefore to discover the targets (receptors or enzymes notably) on which to act by stimulation or inhibition, on the one hand, and the molecules (designated under the generic word of "ligand") which could act on these targets, on the other hand.

Once the target is discovered, research of candidate compounds can begin.

It starts by screening tenths of thousands of molecules to check their ability to perform the desired action (e.g. to link to the identified receptor).

Numerous steps will be afterwards necessary to develop the molecules identified during the screening process and to obtain the end drug.

It is however very tempting for the discoverer of the target to try to obtain rights over the ligands which will be discovered and will constitute the basis of the future drug.

This is the aim of a reach-through patent.

The classic structure of the claims in a reach-through patent is the following:

"1. *Receptor X useful to the treatment of disease Y*

2. *Method for identifying an agonist of the receptor X comprising the following steps:* …

3. *Agonist of the receptor X identified with the method subject-matter of claim 2*".

The reach-through claim itself is claim 3 in this example.

Reach-through claims may naturally be invalidated through classical objections, e.g. lack of novelty or lack of inventive step.

Nevertheless, they are particularly likely to be invalidated for lack of industrial application (**1.1.**) and above all for insufficient description (**1.2.**).

1.1. Industrial application

Under slightly different forms, European and U.S. laws require that an invention be susceptible of industrial application for it to be patentable.

In Europe, this patentability requirement is set forth in Articles 52 and 57 of the European Patent Convention (E.P.C.).

Article 52 of the E.P.C. sets inter alia forth:

"*European patents shall be granted for any inventions which are susceptible of industrial application, which are new …*".

Article 57 of the E.P.C. defines industrial application in these words:

"*An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture*".

In the United States, this criterion takes the form of the utility requirement.

Section 101 of the Title 35 of the U.S. Code (U.S.C.) sets forth:

"*Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title*."

The Utility Guidelines of the U.S.P.T.O. specify that an invention shall have a specific, substantial, credible and well-established utility.

The applicant should therefore take care to disclose the industrial application of a reach-through patent application.

A claim covering *"any agonist of the receptor X identified by a screening using the receptor X"*, which is a typical case of a reach-through claim, shall be dismissed for lack of industrial application or of utility, should the patent application only describe the receptor and the screening stages.

To meet the requirement of industrial application, the patent application should disclose an application of the agonist or of the receptor X, e.g. a pharmaceutical use.

Otherwise, the person skilled in the art will not know for what purpose he can implement the claimed invention.

Therefore, it is important to file such a patent application only after the function of the receptor at issue has been determined.

However, the greatest risk run by reach-through claims is that of an insufficient description.

1.2. The description

European and U.S. laws require that the inventor describe his invention.

Under European law, this requirement is set forth notably in Article 83 of the E.P.C. which reads as follows:

"*The European patent application must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art*".

U.S. law provides that (35 U.S.C. 112 §1):

"*The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention*".

Two requirements are laid down by Section 112 §1:

- the requirement of a "*written description*" according to which, on the one hand, the patent should set out the claimed invention, and on the other hand, the person skilled in the art should conclude from the reading of the patent that the inventor actually possessed the invention at the filing of the patent,

- the requirement of "*enablement*" according to which the description should enable the person skilled in the art to carry out the invention without undue experimentation.

The requirement of a written description (**1.2.1.**) should be examined before that of enablement (**1.2.2.**).

1.2.1. The written description requirement

One of the main obstacles against which reach-through patents can come is that of the requirement of a written description, notably with a claim relating to the compounds linking to a certain target ("*An agonist of the receptor X*").

If it is possible to describe the claimed target, it is a priori not possible to describe the compounds which link to this target, as long as they have not been obtained, otherwise than by their ability to link to this specific target, i.e. by their function.

A recent U.S. decision handed down in *Enzo-Biochem v. Gen-Probe* seems to offer a first legal solution to the problem of the written description requirement in reach-through patents (**1.2.1.1.**).

Recent techniques are perhaps also in a position to enable the circumvention of the obstacle the requirement of a written description represents (**1.2.2.2.**).

1.2.1.1. A legal solution

The contents of the requirement of a written description was specified in three landmark decisions handed down in 1997 and 2002 by the Court of Appeals for the Federal Circuit (C.A.F.C.), which closely regard, even if they address this subject-matter not directly, the validity of patents comprising reach-through claims.

The first of these decisions, *Regents of the University of California v. Eli Lilly & Co.*[1], was handed down regarding a patent relating to a micro-organism comprising a cDNA sequence coding human insulin.

The Court had held that when the claimed genetic material is described only by its function or by its result, the invention is not described appropriately.

According to this decision, a written description should contain "*a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention*".

The Court held in fact that "*a description of what the genetic material does, rather than of what it is, does not suffice*".

The mere contention that a molecule exists which might be an agonist of a specific receptor, without any further description – which is the case of numerous patents comprising reach-through claims – was insufficient in view of this decision.

In the decision handed down on April 2, 2002 in the *Enzo-Biochem v. Gen-Probe* case (hereinafter referred to as "*Enzo II*"[2]), the C.A.F.C. had the opportunity to confirm again the doctrine it had expressed in the *Eli Lilly* case, before it reversed it by a decision handed down on July 15, 2002 (hereinafter referred to as "*Enzo III*"[3]).

The invention in this case related to nucleotide sequences for detecting the bacteria liable for the gonorrhoea.

These sequences were only described by their ability to link selectively to the D.N.A. of the bacteria at issue: the patent comprised no information on the structure of the claimed sequences.

However, Enzo had taken care to deposit three nucleotide sequences having this ability at the American Type Culture Collection, and to mention their accession numbers in the patent.

The patent also mentioned the accession numbers of the bacterial strains to which the claimed sequences had the ability to hybridise selectively, without describing them in details.

The C.A.F.C. considered that a mere description of the function of the claimed nucleotide sequences, to link to the bacteria in that case, did not satisfy the written description requirement.

Admittedly, it pointed out that a description as to the function could be acceptable, but only when a known or disclosed correlation between function and structure exists, which it considered not to be the case here.

The Court also considered that the deposit of the nucleotide sequences alone could not be regarded as satisfying the requirement of a written description of the claimed sequences.

The C.A.F.C. however went back over its findings in its decision *Enzo III*, to:

- decide that the reference to the public deposit of the claimed material can constitute a sufficient written description,
- confirm again that a functional description can meet the requirement of a written description if the functional characteristics are coupled with a known or disclosed correlation between function and structure.

The Court found that the description of the ability to hybridise to a known or disclosed structure corresponds to the description of a function and of a correlation between said function and a structure, which is one of the means for meeting the written description requirement according to the Written Description Guidelines published by the U.S.P.T.O.[4]

This reversal is important for reach-through patents, notably those of the type: "*An agonist of receptor X"*, where the claimed agonist is only described by its function, in that case by its ability to link to the targeted receptor.

Should the validity of such claims have been very questionable under the influence of *Eli Lilly* and *Enzo II* decisions, the *Enzo III* case law seems to open new horizons for them.

When the receptor is known or disclosed (if needed by referring to a deposit at the American Type Culture Collection, which now constitutes an appropriate description), it is now possible to describe the compounds which link to this receptor by identifying them only through their function (namely their ability to link to the receptor) without risking invalidation for lack of written description.

The contribution of *Enzo III* relates however only to the description itself of the invention.

It remains necessary for the inventor to establish that he possessed the whole invention.

It is notably what Enzo will have to prove before the court to which the case is now referred: it will have to demonstrate that the deposits of three of the claimed nucleotide sequences are representative of the whole scope of the patent.

The Court reminded the precedent *Eli Lilly*, where it had found that the disclosure of the rat insulin cDNA sequence was not descriptive of the broader invention consisting of mammal and vertebrate insulin cDNA.

However, it took care to remind also that in this case the patent did not set forth any common features possessed by members of the genus, and that the specification did not describe a sufficient number of species for one to conclude that the inventor possessed the whole invention and not only one or two species.

1.2.1.2. A technical solution

A certain type of reach-through claims aims at protecting the compounds likely to be identified by a screening process which is moreover protected by the same patent, although none of these compounds has been neither identified nor described.

Such claims are drafted as follows:

"*Agonist of the receptor X identified by the screening method of claim n"*.

These claims risk the nullity if the description specifies no structural characteristic of the compounds likely to be identified by the claimed screening method.

A relatively recent technique might however enable the applicants to avoid the charge of insufficient description in such a case.

Today, it is possible, under certain conditions, to crystallise the protein which constitutes the studied target, and after several operations, to determine the three-dimensional coordinates – the space structure – by X-ray crystallography.

A three-dimensional model of the analysed target is thus obtained which can be used to identify by their spatial conformation the compounds likely to act on the target.

One has to determine the spatial structure of the tested compound, to create a graphic representation thereof on a computer and to superpose it on the representation of the structure of the target, in order to check whether the compound links to a sufficient number of active sites of the target.

According to some authors[5], the inventor of a screening method of this type could perhaps claim the compounds identified by means of this method.

One can consider that the requirement of description is met since the crystalline coordinates of the target provide enough information to allow identification of the molecules covered by said claim.

The patentee would not merely claim all the molecules able to link to the target but he would actually describe them by means of their spatial structure.

However, such a patent may be invalidated for lack of novelty, if a compound known in the prior art was included in the scope of the claim.

1.2.2. The requirement of sufficient description

European and U.S. laws require that the inventor describe his invention in a manner sufficiently clear and complete for a person skilled in the art to reproduce and implement it.

It is the requirement of "*enablement"* in U.S. law, of "*sufficiency"* in English law, and of "*sufficient description*" under French law, or the E.P.C.

It constitutes another difficulty for reach-through claims, notably for those relating to the products discovered by a screening method which is moreover protected by the patent, or those of the type "*agonist of the receptor X"*.

If the description often teaches how to identify these products, notably by the screening method which itself can be protected by another claim of the same patent, it generally indicates neither how to produce them, nor how to use the whole claimed category of compounds without undue experimentation.

Therefore, such claims risk to be invalidated for lack of "*enablement*" under American law.

It is the same in English law, where the requirement of "*sufficiency*" has been recently specified in the *American Home Products v. Novartis*[6] decision.

Although this decision was not handed down regarding a reach-through patent, the principles set forth by the Court of Appeal can completely be applied to this study.

The patent related to the use of rapamycin for producing a drug against transplant rejections in mammals.

Furthermore, it claimed the use of rapamycin derivatives – suggesting that some of these derivatives were more efficient than rapamycin itself – without identifying them however.

The Court considered that the specification did not teach how to implement the invention with the claimed derivatives.

As the patent described none of these derivatives, according to the Court it constituted only a starting point for a research program which alone would have enabled the person skilled in the art to ascertain the derivatives which could be used.

The application of these principles would probably lead the English judges to consider that, unless a significant number of compounds has been identified and characterized, the identification of the compounds involved presents too many uncertainties and requires too many efforts from the person skilled in the art for a reach-through claim relating to the compounds identified by the patented assay to be valid.

2. Reach-through infringement

One of the purposes of some reach-through claims is to circumvent the principle of territoriality which governs patents.

It is notably the case of reach-through claims which cover the products identified by means of a screening method which is moreover protected by the same patent.

Even if the method is implemented in a country not covered by the patent, if the product so obtained is imported into a country covered by the patent, the reach-through claim will be infringed.

The current doubts on the validity of reach-through claims can however lead to try to exploit other ways to reserve oneself the exclusivity of research methods.

The U.S. District Court of Delaware had to rule on the efficiency of one of these strategies in a decision handed down on October 17, 2001 in the *Bayer v. Housey*[7] case.

Housey owns U.S. patents on screening methods.

It contended that Bayer had used one of these methods outside the United States to identify an active molecule incorporated in a drug Bayer imported and sold in the United States.

Housey contended that Bayer sold a product – the drug – obtained by a patented process and violated Section 35 U.S.C. 271(g)[8].

Housey also contended that Bayer violated said Section by importing and using in the United States the information obtained by the patented method, namely the fact that the molecule acted on a certain target.

The District Court dismissed Housey's claims.

It reminded that Section 271(g) relates only to the products obtained according to a *manufacturing* process, and not according to a process for obtaining information – which a screening method is in fact: said method makes it possible to determine whether a compounds acts on a target.

The Court considered that Bayer's acts could have infringed Housey's patent only if the patented method had related to a step of the manufacture of the end product.

Thus the value of a patent relating to a research method is limited:

- by the substantial scope of the patent, which the Court brought back to its real scope by the mere application of statutory provisions,
- as well as by the territorial scope of the patent right: a U.S. patent on a screening method cannot be infringed if said method is implemented outside the United States.

Nevertheless, the Court of Appeal for the Federal Circuit has not yet had the occasion to give its opinion on this issue.

The English courts also have not yet had to apply to a research method the statutory provisions relating to the infringement of a patent directed to a "product directly obtained by means of the process".

However, they have already defined some principles for applying the relevant statutory provisions, notably through the *Pioneer v. Warner Music*[9] case.

Article 60(1)(c) of the Patent Act of 1977 sets notably forth:

"*a person infringes a patent for an invention if … where the invention is a process, he disposes of, offers to dispose of, uses or imports any product obtained directly by means of that process or keeps any such product whether for disposal or otherwise*".

Pioneer owned patents designating the United Kingdom and relating to the production of masters, which enable the production of compact discs.

Although the patent did not cover the production of the compact discs themselves, Pioneer started an action against Warner for having imported into the United Kingdom discs manufactured outside the United Kingdom by using the patented method; Pioneer alleged that the compact discs were obtained directly by means of the patented process.

Nevertheless, the Court of Appeal dismissed its claims holding that the process led only to the achievement of a master and not of discs, and that the discs, as they did not share the essential characteristics of the masters, could not be considered as obtained "*directly*" by means of the patented process.

The discs were obtained after three further stages of production; moreover, neither the master, nor the intermediate products could perform the same function as the discs.

The principles brought out by this decision, applied to research methods, would probably lead the English courts to adopt the solution found in the *Bayer v. Housey* case, however on slightly different grounds.

The issue would be to determine whether the drug imported into the United Kingdom constitutes a product obtained directly by means of the patented process (the screening method).

As the U.S. courts mentioned it, the product directly obtained by a screening method is the information whether the tested compound acts on the target.

It is less than probable that this information would be held as being a product in the meaning of Section 60(1)(c) of the British Patent Act.

Furthermore, should it be held that the compound is a product obtained directly by means of the process, it would not be necessarily the same for the drug actually marketed.

If the drug has the biological activity of the compound, the fact remains nonetheless that the compound will have passed through many stages before being incorporated into the drug, and that these stages will probably have changed its essential characteristics.

Like in the United States, a research method patent would hence cover only the implementation of this method in the countries protected by the patent.

The message sent to the owners of research method patents is clear: their patent can only cover what they have actually discovered.

The consequence is that, to increase the value of their discoveries, these inventors should implement their methods themselves in order to find out the new molecules and to obtain patents on the end products which are the real sources of income.

Besides, it is what the owners of said patents begin to do, who are now engaged in a race for the identification of active molecules which are potentially useful and patentable.

The difficulty however only moves to another issue: the patents relating to these molecules must provide enough information to support the claims relating to the use of said molecules…

3. Reach-through royalties and damages

The access to the profit generated by the products discovered by research methods can also be considered at the level of a licensing agreement directed to the discovery tools.

This way corresponds to the contracting of a licensing agreement providing for reach-through royalties (**3.1.**).

These royalties will probably be used as a basis for the assessment of the reach-through damages which could be granted in case of infringement (**3.2.**).

3.1. Reach-through royalties

In the field of method patents, the royalty is usually fixed according to the use of the method made by the licensee.

However such a criterion is inappropriate in the field of research method patents.

Their value does not lie in how much the licensee will use them but in the molecules they will enable the licensee to identify and subsequently to market.

For this reason, a more and more usual practice consists in basing the royalty under the license on the sales of the end product.

The agreements providing for reach-through royalties should thus be examined not only as to their lawfulness (**3.1.1.**) but also as to their appropriateness (**3.1.2.**).

3.1.1. Lawfulness of reach-through royalties

The system of reach-through royalties is limited notably by competition law: as the recent *Bayer v. Housey* decision has shown, the obligation to pay royalties cannot exceed some limits.

In particular, an agreement which provides for the payment of royalties during the term of patents protecting the molecules discovered by means of the patented method, such as that offered by Housey, according to Bayer, may constitute a "*patent misuse*".

Such a clause would result in obliging the licensee to pay royalties after the expiration of the patent subject-matter of the license.

This position is closely akin to that of the French doctrine and case law, which have however adopted different grounds to prohibit the licensor from requesting the payment of royalties after the expiration of the patent.

The *Pestre v. Oril*[10] case was an opportunity to examine the case of a licensing agreement directed to a patent and also to non patented know-how, which provided for the payment of royalties over 50 years.

The licensee, as he refused to continue to pay the royalties after the patent had expired, was served a writ of summons for non-performance of the licensing agreement.

The Court of first instance held that the licensee could not be obliged to pay royalties subsequent to the expiry of the patent, as the cause of the agreement laid in the monopoly attached to the granted patent.

The Court of Appeal reversed and considered that:

- the cause of the obligation to pay royalties laid in the know-how license as well as in the patent license, and the expiration of the patent did not destroy the value of the know-how,
- the parties could freely agree that the license compensation would be spread over 50 years, this spreading being a mere payment facility.

These two decisions differentiate from each other only in the designation of the main object of the agreement: patent license or know-how license.

The Court of Appeal only drew the consequence of its choice, without putting into question the solution found by the Court of first instance.

All these solutions are in accordance with the majority of the doctrine, which considers that:

- a patent licensing agreement is lapsed as soon as the patent expires and could not therefore oblige the licensee to pay royalties subsequent to this date (unless it is merely to spread the payment of the royalties resulting from the exploitation of the patent during its validity period),
- a know-how licensing agreement, which is not subject to the existence of a depriving right, can validly provide for the payment of royalties over any period agreed on by the parties,
- a combined patent and know-how licensing agreement shall accordingly be governed by the proper rules of each category of license in a distributive way, and if it is not possible, shall be governed by the rules governing its main object.

The Commission block exemption Regulation on technology transfer agreements[11] goes in the same direction, as it sets forth that:

- regarding know-how licensing agreements, the provisions providing for the payment of royalties until the end of the agreement independently of whether the know-how has entered into the public domain, are authorized,
- regarding patent licenses, there is no reason to prohibit the parties from choosing the most appropriate means of financing the technology transfer, and therefore to prohibit the payment of royalties for the exploitation of the licensed technology over a period going beyond the duration of the licensed patents[12].

For patent licenses, the Regulation however grants this free choice only to facilitate payment.

A clause obliging the licensee to pay royalties for the exploitation of an expired patent would be contrary to the rule of free competition.

Provisions setting forth reach-through royalties should therefore relate not only to the licensed patent but also to a know-how to be still valid after the expiration of this patent.

3.1.2. Appropriateness of reach-through royalties

One of the most often expressed critics against reach-through royalties is the increase in the price of the end products to which "*royalty stacking"* leads.

A drug can be subject to several licensing agreements, according to the complexity of its finalisation which may have needed:

- the contracting of a collaboration agree-ment in order to organize a research program,
- the use of a research method in order to discover the active molecule,
- and the recourse to a patented production method.

The royalty stacking resulting from this situation can however be minimized if each partner understands that his interest does not lie in an exaggerated increase in the price of the end product, which is unfavourable to the sales.

Rebates on royalties are frequently provided for in such cases.

Furthermore, sometimes there is no interest in providing for a reach-through royalty; licenses granted to universities are an example thereof: their research generally does not lead to the marketing of a product, a reach-through royalty would lack interest for the patentee.

For this reason, in such cases, the license is granted in consideration of the undertaking of the licensee to grant licenses on the discoveries he will make by means of the patented method to the patentee ("*grant back licenses"*).

3.2. Reach-through damages

Case law, either in the United States or in Europe, has not yet had the opportunity to decide on the assessment of reach-through damages.

One can only make reference to the general principles of the assessment of damages to determine the approach the courts could adopt.

U.S. law refers to the concept of "*adequate compensation"* to determine the scope of the damage suffered by a patentee following an infringement (35 U.S.C. 284).

As to French law, it refers to the classical notions of civil liability, according to which the infringer shall compensate the damage he has entailed (Article 1382 of the French Civil Code).

The English approach is quite similar to the French one: the measure of damages is supposed to be that which will put the injured party in the same position as he would have been in if he had not sustained the wrong ("*had the infringer not infringed*" or "*but for the infringement*").

In Germany, the infringed patent owner can opt for one of three possibilities for calculating damages: the equivalent of an ordinary licensing fee, the infringer's profits or a reimbursement of lost profits (actually, most plaintiffs choose the first possibility because this can be proven with relative ease).

The difficulty to assess damages in a case of infringement of a research tool patent is that the infringement does not result in the finalization of a competitive method or in the production of an item which would reduce the sales or price of the patented method.

Therefore, resorting to the loss of profit seems inappropriate in such a case.

Hence, one must turn towards the grant of a reasonable royalty.

In such a case, French courts try to determine the royalty rate which could have been negotiated by contract by referring for this purpose to the mainstream contractual practice for patents of the same field.

Likewise, U.S. courts, even if they take into account a multitude of factors, try overall to determine a royalty rate appropriate to the case.

The difficulty lies however in the number of licensing agreements entered into in this field, which is low in view of more traditional sectors where well-established practices exist.

Nevertheless, it seems that the agreements provide generally for the payment of royalties at a rate between 1 and 5% of the turnover generated by the drug issued from the research process.

Therefore, the issue of the assessment of reach-through damages depends largely on the development of the practices in matter of reach-through licenses.

Footnotes

[1.] 119 F.3d 1559 (Fed. Circ. 1997)

[2.] 285 F.3d 1013 (Fed. Circ. 2002); this decision is cited as "*Enzo II*" because another decision handed down regarding patents is often cited as "*Enzo*": Enzo-Biochem v. Calgene, 188 F.3d 1362 (Fed. Circ. 1999)

[3.] No. 01-1230 (Fed. Circ. July 15, 2002)

[4.] 66 Fed. Reg. at 1099

[5.] Rebecca S. Eisenberg, "*Reaching through the genome*", article presented during "*Science and cents: exploring the economics of biotechnology*", on April 19, 2002, at the Federal Reserve Bank of Dallas, Texas

[6.] American Home Products Corporation and Calne v. Novartis Pharmaceuticals UK Ltd and Novartis Pharma AG, [2000] EWCA Civ 231 (July 27, 2000)

[7.] 169 F. Supp. 2d 328

[8.] "Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent. In an action for infringement of a process patent, no remedy may be granted for infringement on account of the non-commercial use or retail sale of a product unless there is no adequate remedy under this title for infringement on account of the importation or other use, offer to sell, or sale of that product. A product which is made by a patented process will, for purposes of this title, not be considered to be so made after

(1) it is materially changed by subsequent processes; or

(2) it becomes a trivial and nonessential component of another product."

[9.] Pioneer Electronics Capital Inc. v. Warner Music Manufacturing Europe GmbH, [1997] R.P.C. 757

[10.] *Tribunal de Grande Instance* of Paris, March 26, 1986, then the *Cour d'Appel* of Paris, May 22, 1990, Dossiers Brevets 1990, III, 8

[11.] Regulation EC No. 240/96 of January 31, 1996, O.J.E.C. No. L 31 of February 9, 1996, p. 2 and following.

[12.] Article 2, § 1, al. 7, b, and § 21 of the explanatory memorandum