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EXPERIMENTAL USE AND CLINICALS TRIALS

**Recent developments in Europe
and new law in France**

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Most national Patent laws in Europe and many national Patent laws in the world have held, by way of exception to the Patent right, that acts relating to the subject matter of the invention do not constitute any infringement if and when they are performed for experimental purposes.

In practice, this exception is of particular interest to sectors such as pharmaceuticals and agrochemicals, because those industries, which are subjected to specific regulations, are compelled to conduct trials on their products in order to obtain governmental approval which necessarily precedes any marketing of a new drug or plant-related agent.

Consequently it is of considerable importance to the Patentee's competitors to precisely determine the scope of the experimental use exception, because they need to know exactly those experiments which they are allowed to conduct and they have to make sure that it will be possible to undertake, before Patent expiry, such trials (which generally take a long time) without running the risk of being sued for Patent infringement; and this in order that the patented product may be marketed immediately after the moment the Patent expires.

In pharmaceutical matters, the governmental marketing approval is delivered only following meticulously conducted trials. It is useful to know the content of the same in order to appreciate whether they are entitled to benefit from the experimental use exception.

1. PROCESS OF MARKETING A DRUG

A drug will be marketed only when it will have received governmental approval. Such approval is issued on presentation of the result of the clinical trials conducted on the drug.

Clinical trials constitute a mode of assessment pertaining to an explanatory step whose purpose is to demonstrate the effectiveness and/or the innocuousness of the products.

The firm which wishes to market a new drug has to go through four phases, according to the Food and Drug Administration, which phases are subjected to strict terms. The progress from one phase to another depends on the results obtained at each phase.

Phase I corresponds to the first administration to humans. The research, extending over one to one and a half years, is conducted on a few healthy volunteers. Such a phase makes it possible to determine the tolerance of the organism to the new product, posology and certain interactions.

Phase II, sometimes subdivided into "advanced phase II" and "late phase II", gives rise to clinical trials conducted in highly specialised services, for a period of one to two years, on selected patients. It makes it possible to define the validity of the posology and the existence of a connection between the drug and the therapeutic effects.

Phase III, where it has been decided to continue the experimentation, makes it possible to confirm the data obtained during the previous phases and to define the exact conditions of use of the new drug (under conditions as close as possible to everyday medical practice). It is accomplished on a large group of treated patients. If its results are positive, it leads to the governmental approval.

Because of these three phases, the pharmaceutical manufacturer is weighed down by many obligations. Moreover, they put him in an uncertain position for close on four years (until the beginning of phase III). Phases I and II were essentially intended to determine the aptitude of the product to attain the desired aims. On the contrary, phase III is a necessary step intended for obtaining governmental marketing approval and is conducted on many patients. Therefore, it is admissible to hesitate : does phase III benefit from the experimental use exception ? This is an important question for industrialists because they wish to be able to launch their products immediately after the Patent expiry. But they won't be allowed to do it if phase III cannot validly be conducted as long as the Patent is still in force.

The governmental approval is awarded after phase III.

Phase IV, following the marketing of the drug, will enable undesirable medicinal effects to be identified.

Only clinical trials which comply with very precise conditions will be legally conducted before the Patent expiry.

2. WHICH CLINICAL TRIALS BENEFIT FROM THE EXPERIMENTAL USE EXCEPTION ?

All the countries agree in saying that only trials which are related to the subject matter of the patented invention are covered by the exception (2.1). Equally they agree in saying that only trials which are conducted for experimental purposes - and not for administrative purposes - will benefit from the exception. However, some States outside the European Union have adopted special proceedings, especially relative to bioequivalence tests (2.2)

2.1. Subject matter of the trials : subject matter of the patented invention

Acts performed for experimental purposes which relate to the subject matter of the patented invention do not constitute an infringement of a Patent. The tests have to focus on the teaching of the Patent, i.e. the substance of the invention. The patented subject matter of the invention must not be used as a means for carrying out the trials, but must be the very object of the tests.

For example, if the patented subject matter is a research apparatus for finding valuable new pharmaceutical drugs, trials using the patented apparatus to find new pharmaceuticals and to test them for their effectiveness precisely do not relate to the subject matter of the patented invention ; they make use of the patented apparatus only as a means to obtain the new desired pharmaceuticals. Under these circumstances, such trials do not fall under the experimental use exception and, on the contrary, infringe the Patent. The situation would be different if the trials using the patented apparatus merely served the purpose of obtaining new findings about such an apparatus. In this case, such trials would be covered by the exception and also would not infringe the Patent.

To benefit from the exception, the act must, moreover, have an experimental purpose.

2.2. Purpose of the trials : experimental purpose

The concept of “*experimental purpose*” generally covers three meanings :

- the use of the patented invention for strictly academic purposes,
- the trials conducted in order to assess the technical teaching of the Patent and its validity,
- the use of the patented invention for technological development.

The first two types do not raise many difficulties. However, the experimentation performed for technological development poses the most delicate problems. It is possible to understand the idea of “*technological development*” in two ways :

- according to a restrictive interpretation, it is considered that acts for *experimental purposes* are only acts performed for *scientific purposes*,
- according to a more comprehensive interpretation, any experiment aiming to obtain data is lawful whatever the ultimate object of such a search of data, apart from a few exceptions linked to the commercial character of the act.

The leading industrial countries have adopted such comprehensive but strictly defined conception of the experimental use. Nevertheless, the exception applies only to acts aiming at testing new processes or new applications. Bioequivalence trials conducted with the aim of demonstrating that a generic pharmaceutical drug has the same properties as the patented pharmaceutical drug has, are inspired by a purely administrative purpose. Therefore, they cannot be covered by the exception because their finality is too remote from the reasons which induced the legislator to adopt an exception to the principle of infringement of a Patent.

Consequently, two cases are to be distinguished:

- trials performed for experimental purposes,
- trials performed for purely administrative purposes.

2.2.1. Trials performed for experimental purposes

In the following developments, the situation in Germany, France, the United Kingdom, Italy, the Netherlands and the United States will be respectively considered.

Germany

Article 11.2 of the German Patent Act of 1981 provides, in the same words as the Community Patent Convention, that :

"The effects of the Patent shall not extend to :

...

2. acts performed for experimental purposes relating to the subject matter of the patented invention ;"

***The ETHOFUMESAT Case - Federal Supreme Court - February 21st, 1989
(GRUR 1990, 997)***

The Federal Supreme Court stated that experimental activities were considered permissible to the extent that they served the purpose of testing the feasibility of the invention or of technically perfecting and further developing the patented subject matter. In this specific case, the trials in hand were bioequivalence tests were aiming at obtaining governmental approval of the plant treating agent (herbicide). The Court confirmed infringement and ordered that the Defendants be refrained from using the tests results for a time corresponding to that necessary to complete the field tests, after expiration of the Patent.

"Clinical trials I" Case - Federal Supreme Court - July 11th, 1995 (RPC 1997, 623 (BGH))

The "Clinical trials I" decision issued by the German Supreme Court on July 11th, 1995 is a seminal decision : it fixed very precise criteria of the legality of clinical trials performed for experimental purposes. If the only purpose of the trials is to acquire data for the governmental approval for marketing, then they are not covered by the exception. On the contrary, trials conducted with the aim of obtaining the governmental approval, but also with the aim of obtaining information about new properties or indication of a patented active ingredient, benefit from the experimental use exception.

In this specific case, the Plaintiff was the holder of a European Patent which covered immunogen interferon protein, the so-called Gamma-Interferon. The Defendants had conducted clinical studies with the active substance with a view to identifying additional therapeutical indications of Gamma-Interferon. The results of the trials aimed at obtaining governmental approval of their commercial product Polyferon containing the patented ingredient. The Defendants pointed out in their pleadings that the effects of pharmaceuticals can only be determined by trials on humans. Therefore, from the point of view of technological progress and in the public interest, human clinical trials and investigations of active substances must be covered by the experimental use exception, all the more so as these trials are aimed directly at the acquisition of fresh knowledge.

The Court ruled that the clinical trials at issue were covered by the experimental use exception and, consequently, did not infringe the Plaintiff's Patent for Gamma-Interferon. In fact, the judges held that :

"An action for experimental purposes which is related to the subject matter of the invention and therefore legitimate can exist if a patented pharmaceutical substance is used in clinical tests with the aim of finding whether and, where appropriate, in what form, the active substance is suitable for curing or alleviating certain other human diseases."

Thus, a collateral commercial purpose does not prevent true experimentation from being non-infringing experimentation. The admissibility of clinical trials tests is not barred by the circumstance that the defendants performed or supported these, respectively, with the further objective of obtaining approval under the pharmaceutical laws. The exception criterion is attached to the mere furtherance of technological progress because one of the principle reasons why industrials undertake clinical trials is the will to discover new scientific data relative to a patented pharmaceutical drug in order to be entitled subsequently to file a new Patent application for a new invention.

It is the first time in Europe that such a broad interpretation of the experimental use exception is adopted by the highest court of a country.

***"Clinical trials II" Case - Federal Supreme Court - April 17th, 1997
(RPC 1998, 424 (BGH))***

In the "Clinical trials II" case of April 17th, 1997, the clinical trials were conducted with the aim of determining whether the Defendant's generic pharmaceutical drug named "rHu EPO Merckle" was marketable and whether its activity and the way in which it was tolerated differed in a clinically relevant manner from another erythropoietin product (EPO) obtained from patented process. Such trials served in fact the purpose of obtaining the necessary data for the health authority approval as a drug for the same pharmacological indication as the plaintiff's EPO product.

The German Supreme Court declared that the clinical trials at issue did not constitute Patent infringement because they had been carried out with a pharmaceutical drug containing the patented ingredient, this resulting in obtaining information about their effectiveness and tolerability. The Court ruled that :

"the intention that is associated with an activity begun and carried out for research purposes cannot render such activity infringing merely because the results of the research will not solely serve research purposes but above all will serve commercial purposes as well."

It ruled that trials are exempted if *"oriented towards clearing up insecurities with regards to the patented invention or bringing out new discoveries about said object, provided these activities...relate to the object of the patented invention."*

Although the tests acknowledged to be lawful have consisted of a comparison between the patented drug and the generic product, it does not seem that the solution must be generalised to all the bioequivalence tests. It was a particular case in which the clinical trials did more than confirm that a generic drug was the exact copy of a patented product.

Considering the analysis of both decisions, it is possible to fix the limits of experimental use exception in Germany :

- the trials must not merely aim at clarifying economic factors,
- the scope in which the trials are carried out must not be too broad,
- the trials must not be carried out with the intention of disturbing or interfering with the Patentee's marketing of the patented products,
- the trials must not be carried out for the sole purpose of demonstrating to a third party that the product works.

France

Article L 613-5 of the Intellectual Property Code provides the experimental use exception :

"The rights of the Patent shall not extend to :

...

2. acts performed for experimental purposes relating to the subject matter of the patented invention ;"

Doctrine and jurisprudence today understand this clause in the following way :

- the clinical trials with the purpose of verifying the applications of the patented product or to discover new applications are considered as acts performed for experimental purposes,
- the clinical trials performed merely with the objective of obtaining governmental approval constitute Patent infringement.

SCIENCE UNION & CIE and SERVIER / CORBIERE and BELLON Case Paris Court of Appeals - November 27th, 1984 (PIBD 1985, 366, III-118)

The Paris Court of Appeals had to give its opinion on the notion of experimental use in a case known as "DIORIVEN". The SCIENCE UNION company was the holder of a pharmaceutical Patent relative to an active substance called diosmine which treats capillary fragility. The CORBIERE company had obtained during the lifetime of the Patent an authorisation to market a product called DIORIVEN whose the active ingredient was diosmine and which had the objective of treating the functional disorders of the venous system. The Patentee had then obtained a legal order for performing an infringement seizure in CORBIERE's premises. This infringement seizure, performed eight months after grant of the governmental approval, made it possible to seize in particular some tablets, in bulk, of DIORIVEN labelled "trials", manufactured as part of the preparation of the governmental approval file, and also copy of the documents and correspondence addressed to the Administration, relative to the obtaining of the governmental approval. CORBIERE had then requested invalidation of the infringement seizure on the grounds that the seized papers referred to the acts covered by the experimental use exception. The Court of Appeals rejected the experimental use exception on the grounds that the governmental approval granted some months before the infringement seizure established that the manufacture of DIORIVEN before such grant had a commercial purpose. The Court also ruled that the samples of DIORIVEN and the seized papers were useful for evidencing the infringement. Therefore, the non-infringing experimental use stops where the clinical trials follow a commercial aim.

PARIENTI / PEUGEOT & VIA GTI Case - Paris 1st Instance Court (Tribunal de Grande Instance), 3rd chamber, 1st section - July 2nd, 1997 (DOSSIERS BREVETS 1998;1.6)

The Court had to adjudge the infringing or non-infringing character of some trials performed in the automobile sector. The Defendant had presented a prototype to the press and to the local authorities in order to obtain suggestions and reactions of the potential users on such type of transport ("system of electric urban transport with automated recharging"). The Paris 1st Instance Court did not consider that such presentation constituted a Patent infringement, on the grounds that only one prototype had been produced, and that neither marketing nor mass production had been undertaken and that such a project with regard to its finality came under the field of research. The Court, in this specific case, applied the criterion of experimental purposes with great flexibility and ruled again that the experimentation must be performed on a limited number of specimens.

WELLCOME FOUNDATION LIMITED / PAREXEL INTERNATIONAL and FLAMEL TECHNOLOGIES Case - Paris Court of Appeals, 14th chamber, section A - January 27th, 1999

The Defendant FLAMEL was the owner of a Patent relating to a technology of encapsulation of pharmaceuticals and was trying to demonstrate that said technology was applicable to the Plaintiff's patented molecule named aciclovir. WELLCOME sued FLAMEL for infringement, on the grounds that the clinical trials undertaken by the Defendant, insofar as they had reached phase III, had lost their experimental nature so that it was entitled to obtain a preliminary injunction prohibiting FLAMEL from continuing such clinical trials because the same were not covered by the article L 613-3 of the Intellectual Property Code. The Court rejected the motion by WELLCOME for preliminary injunction. It ruled that :

- the subject matter of the clinical trials at issue was to compare different methods of administration of the patented molecule and to find out an advantageous posology in terms of daily intakes,
- the numerical importance of the patients submitted to the clinical trials was not likely to have encouraged patients to abandon the patented drug,
- the product in dispute was not commercialised,
- assuming that the clinical trials are positive, it would not be marketed before the Patent expiry (no application for a governmental approval had been filed).

Therefore, the performance of clinical trials at issue did not constitute an act of Patent infringement and, on the contrary, are covered by the exception.

This decision follows the very similar German decisions of the German Federal Supreme Court ("Clinical trials I" and "Clinical trials II"). However, this decision must not be regarded as systematically covering by the experimental use exception any clinical trials performed with the aim of obtaining governmental approval. Furthermore, the fact that such a decision ruled on a **preliminary injunction** request must be emphasised ; therefore it does not prejudge the outcome of the case on the merits.

ALLEN & HANBURYS and GLAXO WELLCOME/3M SANTE and 3M HEALTHCARE LTD - Paris Civil Court (Tribunal de Grande Instance), 3rd Chamber, September 1st, 1999
In this case, the Court tackles two problems relating to clinical trials.

First, the Court had to give an opinion on the influence of clinical trials and their publication on the novelty of the patent.

The Court turns down the defendant proposition which insisted on the large distribution of the patented product to patients involved in test, without any confidentiality obligation.

According to the Court, doctors, but also testing patients, are the "*necessary agents of the required experiments*".

Consequently, tests relating to an invention, do not constitute a disclosure, when this invention was only communicated to such persons.

Concerning the content of disclosed information, the Court considers that in any event, the drug given to test patients did not disclose the various stages of the process for obtaining the product.

Secondly, the Court had also to give an opinion on the possibility for a generic drugs manufacturer :

- to perform clinical trials,
- to request a marketing authorisation and to manufacture samples intended for doctors,
- to conduct an active information campaign among doctors before expiration of a supplementary certificate rights.

The Court considers that the samples distributed to doctors and the generic drug promotion campaign constitute an infringement.

But, in accordance with an unbroken line of precedents, the Court confirms that marketing authorisation does not constitute *per se* an infringement.

French Social Security Act of December 29, 1999

This state of the French law was about to change radically by article 31 of a French Social Security Act designed to introduce a "Bolar provision" in French law (Act n° 99-1140 of December 29, 1999).

This reform of French law aimed at allowing the generic drugs to be marketed more quickly. The last sentence of this article said that it would not be an infringement to conduct clinical studies for the purpose of obtaining a marketing authorisation for a generic drug.

It was written as follows:

"Biodisponibility studies conducted to show bioequivalency with an original drug for the purpose of obtaining a marketing authorisation for a generic drug are regarded as acts of experimental use within the meaning of article L 613-5 of French Intellectual Property Code".

However, this sentence has been held invalid by the French *Conseil Constitutionnel*.

Article 31 of December 29, 1999 Social Security Act, as in force, is drafted as follows:

"Marketing authorisation for a generic drug – in the meaning of article L601-6 of Social Security code – may be granted before expiration of intellectual property rights attached to the original drug.

However, actual marketing of the generic drug may not be started before expiration of such rights.

When it grants a marketing authorisation in such a case, the French Agency for Drug Security informs the owner of the marketing authorisation for the original drug.

This reform does not bring any change in French law and established French case law in all respects :

- as decided by the Cour de Cassation on March 24, 1998 (PROMEDICA and CHIESI v. ALLEN and HANBURYYS, the mere filing of an application for a marketing authorisation is not *per se* an act of infringement,
- Clinical trials which objective is not to search for new properties or new application of a product, but only to demonstrate to a Government Agency its properties, its innocuousness or its bioequivalency with a reference's product do not constitute experimental use but infringing acts if there are conducted before expiration of industrial property rights covering this reference's product.

United-Kingdom

The experimental use exception is provided by the section 60(5) (b) of the United Kingdom Patents Act of 1977 :

"An act which, apart from this subsection, would constitute an infringement of a Patent for an invention shall not do so if

...

(b) it is done for experimental purposes relating to the subject-matter of the invention;"

It is admitted that the clinical trials go beyond the limit of their admissibility when their purpose is no longer to obtain knowledge concerning the patented invention but merely to show to a third party that the tested product works.

MONSANTO CO / STAUFFER CHEMICAL CO & al Case. Court of Appeals - June 11th, 1985 (RPC 1985, 515)

The experimentation at issue was performed on the patented herbicide glyphosate of the MONSANTO Company. MONSANTO requested a preliminary injunction against STAUFFER alleging infringement of its Patent. The preliminary injunction was granted. On appeal, STAUFFER moved for a limitation of the preliminary injunction in order to allow various field tests. The judgement quotes a leading decision of 1971 issued in the MICRO-CHEMICAL LTD / SMITH case:

"Trials carried out in order to discover something unknown or to test a hypothesis or even in order to find out whether something which is known to work in specific conditions could fairly be regarded as experiments. But trials carried out in order to demonstrate to a third party that a product works or in order to amass information to satisfy a third party, whether a customer or a body such as the PSPS or ACAS, that the product works as its maker claims were not to be regarded as acts done "for experimental purposes."

The clinical trials directly aiming at obtaining governmental approval therefore constitute a Patent infringement.

Italy

The exception is provided in the Royal Decree of 29th June 1939 on Patents for Industrial Inventions. As a matter of principle, any scientific study in general and research in particular are indissociable from experiments. By way of example, the Milan Court of Appeals, in a case SQUIBB & SONS INC. / TESTAGUZZA, ruled that the experimental acts relative to some patented inventions were lawful even when such trials, as soon as they are started, were conducted within the framework of applying for a recordal of the tested pharmaceuticals in the Official Registry.

Netherlands

The exception has the same meaning as those quoted above. The clinical trials are lawful when the clinical trials really have a commercial purpose but provided that their performance secures the proof of the effectiveness of the product. However the judges apply such principle in a strict way. Consequently, the experimental use exception is not applied where market-oriented purposes of the clinical trials are involved or dominate.

APPLIED RESEARCH SYSTEMS / ORGANON Case - Supreme Court - February 1994

ORGANON had performed different clinical tests relative to the process of a hormone acting on the stimulation of the follicles patented by the APPLIED RESEARCH SYSTEMS Company.

Although ORGANON claimed that the clinical trials had been performed in order to assess whether the invention could be useful in practice and whether it could be improved, the Court followed the Plaintiff's argument and ruled that the necessary objective of such trials was to obtain an international registration of the process and therefore the infringement was constituted.

United States

The experimental use exception has been provided in the CHESTERFIELD / UNITED STATES case judged in 1958 (159F. Supp. 371, 116 U.S.P.Q. 445 (Ct. Cl. 1958)). It must be emphasised that clinical trials with the aim of obtaining authorisation for marketing new pharmaceutical drugs are lawful.

To sum up, all the countries mentioned above consider that experimental use includes any utilisation of the patented invention :

- as object and not as means of the experimentation
- whose purpose is to improve the invention, to make it advance or to find an alternative

2.2.2. Trials performed for purely administrative purposes

One of the major concerns which has led to the adoption of such exception to the Patent right is that the Patent must not hinder technological progress. That is why the jurisprudence of the different countries studied is attentive to the existence of a contribution to technological development for acknowledging that the trials have a non-infringing character. However the mere making of a copy of a patented pharmaceutical is not able to constitute technological enrichment. In order to sell a generic drug, some States established a new mechanism allowing the generic pharmaceutical drugs industry to perform lawful trials because the same remain invariably necessary for obtaining government approval as soon as possible.

The European Parliament adopted a resolution for a law relative to generic drugs to be passed. Nevertheless the Commission has not answered yet.

Contrary to the majority of the States of the European Union, the United States, Australia, Israel, Canada and Japan tolerated clinical trials with the aim of obtaining government approval. The result of this is to induce the generic drug makers to perform their clinical trials in countries where such acts are permitted or in countries where there is no Patent protection and, then, to proceed with the administrative formalities in the said countries.

In the United States, the WAXMAN-HATCH ACT (Act of September 24th, 1984), contains a provision settling the question of the bioequivalence tests, provision introduced at the same time as another one assuring for the Patent a maximum effective life of fourteen years thanks to an extension of up to five years beyond its normal life. This provision called "BOLAR amendment" was passed subsequently to the ROCHE PRODUCTS INC / BOLAR PHARMACEUTICAL CO case and provides that :

Shall not constitute a Patent infringement the act of manufacture which is merely and reasonably bound to the development and the filing of the Application with the federal authority in charge of regulating the manufacture, use or sale of pharmaceutical drugs.

This provision gives industrialists the possibility to file an Abbreviated New Drug Application of a generic drug before the Patent expiry. Then they will be able to launch their product on the market immediately upon Patent expiry. However the owner of the patented original drug is allowed to launch a Patent infringement suit which can delay the Abbreviated New Drug Application approval for up to thirty months or until a court issues a final judgement, whichever is earlier. Nevertheless, the BOLAR system is still advantageous for the generic pharmaceutical makers because they will save about two years on their calendar, anyway.

In Australia, the pharmaceutical Patent term can be extended up to four years from its normally expiry date. However, the acts performed by third parties more than two years after the normal Patent term expiry are not considered as infringing acts unless they relate to the distribution, offer for sale or marketing of the product concerned.

In its latest Act of February 26, 1998, Israel provided an extension of up to five years of the initial pharmaceutical Patent term and simultaneously allowed the generic drug industrialists to perform their trials before the Patent expiry.

In Canada, the generic drug maker is allowed to manufacture and stock the infringing product six months before the Patent expiry. Moreover, as there is no Patent term extension provision, the generic drug industry is allowed to enter the market as soon as the Patent expires. The situation is therefore very advantageous for such industry and has also led the European Union to prepare and introduce an action before the World Trade Organisation against Canada.

In Japan, jurisprudence had to rule on two types of cases :

- the prohibition injunction is requested while the Patent is still in force,
- the prohibition injunction is requested after the Patent has expired.

In the first type, the trials were qualified as an infringement in one case and the infringement was denied in two cases where the tested products were not aimed at being marketed before the Patent expiry.

In the second type, the owner of an expired Patent requested the generic drug makers to stop marketing for a period of time corresponding to the time which was used for performing the trials before the Patent expiry. This request was denied by the Court because the Patent infringement did not actually continue due to the expiry of the Patent and the prejudice could be compensated by payment of damages.

In the next ten years, in Europe, more than sixty major drugs in the health world will fall into the public domain. The defence by the makers of patented drugs, on the one hand, and by generic drug makers, on the other hand, of completely conflicting stakes may raise many questions.

All the clinical trials are performed with the aim of obtaining, in the more or less near future, governmental approval. Such approval which occurs after phase III may be granted before the Patent expiry. Therefore the question relative to the infringing or non-infringing character of the governmental approval itself is equally debatable.

3. GOVERNMENTAL APPROVAL

The governmental authorities grant their approval once they have made sure that the pharmaceutical drug which has been submitted to them, effectively presents the properties claimed.

The question is to know whether the application for governmental approval, or grant thereof may be considered, in itself and independently of the clinical trials which preceded it, as infringing acts when taking place during the lifetime of the Patent.

The application for, or grant of, governmental approval cannot be in itself connected with one of the infringing acts such as defined by law, because neither involves in itself a material act of making or using the product on the territory covered by the Patent. Likewise the application or grant of governmental approval does not constitute in itself any offer for sale nor any other commercial act. This is why, since there are no material acts of making, importing, detaining, using, selling or offering for sale the patented drug, the mere governmental approval application or grant thereof does not constitute an infringing act of the Patent. Such is the solution adopted by most of the industrial countries.

The following cases may be quoted by way of examples :

- THE UPJOHN COMPANY / T. KERFOOT AND CO LTD judged by the High Court of England in 1988 (FSR 1988, 1 to 7),
- ETHOFUMESAT judged by the German Federal Supreme Court on February 21, 1989 (JO OEB 3/1991 p. 196),
- PROMEDICA & CHIESI / ALLEN & HANDBURYS judged by the commercial chamber of the French Supreme Court (Cour de Cassation) on March 24, 1998 (Bull Civ. 1998. IV n°110).

In this case of preliminary injunction, the Supreme Court had to decide whether the mere filing of a regulatory approval could be considered as an infringement.

ALLEN owns a French supplementary protection certificate covering steroids having anti-inflammatory action. PROMEDICA was granted a marketing authorisation for a product falling under the scope of ALLEN's SPC.

ALLEN brought an infringement action against PROMEDICA and then petitioned for a preliminary injunction. According to French law, a preliminary injunction can be granted only if:

- the patentee starts promptly (within six months according to, prevalent case law) the action on the merits when he becomes aware of the infringement; and if
- the Court is of the opinion that the action on the merits is likely to succeed.

PROMEDICA argued that the action on the merits had not been started promptly because ALLEN had sent a formal notice more than six months beforehand: this is when PROMEDICA obtained regulatory approval.

ALLEN, however, replied that it had not been in a position to start its action for infringement earlier because the marketing of the drug by PROMEDICA was very recent. PROMEDICA then replied that the marketing approval by the French Drug Agency dated back more than six months (the usual period for a 'prompt' action).

The Court of Appeals denied the preliminary injunction in view of the long time period between the marketing authorisation and the infringement action. However, The Supreme Court quashed the Court of Appeals decision. The Supreme Court held that the mere filing of an application for a marketing authorisation did not constitute an act of infringement since it was only an administrative step and not a material act of infringement (being observed that, in France, the marketing authorisation does not require the supply of a sample).

Afterwards, this solution was confirmed by the first alinea of article 31 of December 29, 1999 French Social Security Act which says :

"Marketing authorisation for a generic drug may be granted before expiration of intellectual property rights attached to the original drugs."

However, an essential distinction must be observed between the communication of data - which is lawful - and the supply of a pharmaceutical drug - which is infringing. Indeed, the submission of samples is required in some countries when applying for governmental approval. Such is the case in the Netherlands, Belgium, Italy, Germany. The United States consider that the submission of samples during the Patent life is lawful. But generally, Patent infringement is constituted provided that such a submission happens before the Patent expires.

LABORATORIES SMITHKLINE & FRENCH / GENERICS Case - European Court of Justice- July 9th, 1997 ([1997] RPC 801)

This case was judged when Netherlands still required the submission of samples with the Marketing Authorisation. A short while ago, this formality was given up. So, this case is only interesting in its principle.

The European Court of Justice ruled on the consequences derived from this principle on the occasion of a interlocutory question raised by the Dutch Supreme Court in this case. The GENERICS Company, generic drug maker, had bought registrations of generic drugs which were entered under GENERICS' name in the Register of Pharmaceutical Preparations. Such registration operations had been carried out before the expiry of the corresponding Patent and had involved the submission of samples. According to SMITHKLINE & FRENCH (SKF), patented drug maker, GENERICS would normally have been allowed to file such registrations only after the Patent expiry and, taking into account the average time necessary for obtaining a registration in the Netherlands, it would have obtained them only fourteen months later. Therefore, SKF requested and obtained from the Dutch judge that GENERICS was prohibited from offering or delivering the product on the Dutch market before the expiry of fourteen months. This constituted a moratorium.

GENERICS argued that the national provisions which had motivated the sentence issued against it, as well as the sanctions imposed on it, constituted some measures prohibited by Article 30 of the EC Treaty which were not covered by the exception provided by Article 36 of the EC Treaty.

The European Court of Justice by its decision dated July 9th, 1997, ruled that :

"Application of a rule of national law which gives the proprietor of a Patent in respect of a manufacturing process for medicinal product the right to oppose the submission by another person of samples of medicinal products manufactured in accordance with that process to the authority competent for issuing marketing authorisations constituted a measure having equivalent effect to a quantitative restriction within the meaning of article 30 of the EEC Treaty;

...

(but) was justified under article 36 of the EC Treaty.

Therefore, the Court held that in this specific case, where the submission of samples to the governmental authority constituted the infringement of the Patent, Article 36 of the EEC Treaty allowed the judge to impose on the author of such infringement a moratorium restraining him from marketing the drug at issue for a period of fourteen months after the Patent expiry corresponding to the average effective time of such a registration procedure in the State concerned.

This decision acknowledges the possibility for a Member State to extend the lifetime of a pharmaceutical Patent up to the time necessary for conducting the registration procedure. This decision is valid only in cases where the governmental approval system involves the submission of samples. This is not the case in France.

Such a decision therefore creates discriminations because it allows the generic drug makers to market their products more rapidly in some countries than in others.

In the next ten years, in Europe, more than sixty major drugs in the health field will be in the public property.

Totally contradictory interests and generic drugs manufacturers would probably raise many questions.