Chapter 4

LIMITATIONS AND EXCEPTIONS TO PATENT:
PARIS AND POST PARIS ERA

The origin and development of patent system portrayed a golden era of limitations to patent rights molded by the sovereigns to meet their domestic exigencies. However it was a period with no international mandates. The expansion of trade in Europe necessitated countries to negotiate and reach bilateral agreements for patent protection. It was only by the end of the 19th century that countries agreed upon the need for international norms in protecting patents. The attempt in this chapter is to examine the status of limitations and exceptions in the international era of Paris Convention. The task is to find out the approach of Paris Convention towards limitations and exceptions. The study also focuses on the scope of flexibility enjoyed by countries in the post-Paris era in framing limitations and exceptions.
Chapter 4

4.1 Exceptions and Limitations in the Paris Convention

Paris Convention is the end product of a collective move for internationalization of patent rights.\(^1\) From the very first diplomatic attempt for an international consensus for patents in 1878 to the last revision of Paris Convention in Stockholm, the history of Paris Convention was a battle for conquest of patent by imperial monopolists and colonies on one hand and by social utilitarianism and natural right philosophy on the other hand.\(^2\) But unfortunately except the foreign

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1 Penrose, E. (1951) *The Economics of the International Patent System*, Johns Hopkins Press, London, p. 42. Prior to the Paris Convention, the complexity and diversity of local patent laws made it nearly impossible for inventors to obtain patent protection in multiple countries. In addition to local working requirements, many countries required fees to maintain a patent. Countries imposed limitations on what could be patented, and many refused patent grants for any invention previously disclosed to the public—including cases where the prior disclosure was a patent in another country. It was also standard to impose legal dependence among patents filed in multiple countries for the same invention, and even U.S. patent law held that the duration of patent protection was capped by the expiration date of any prior foreign patent. World’s fairs including the 1851 Crystal Palace Exhibition, the 1873 International Vienna Exposition, and the 1878 Paris Exposition served both as catalysts and occasions to address these issues and the possibility of collectively moving toward internationally harmonized patent rights.

2 At the Vienna Conference of 1873, much of the debates centered on the various justifications of the patent system – the natural right argument and social utilitarianism. The former vision was manifested at the convention in a resolution passed in recognition of patentees right and the latter vision in a resolution favoring compulsory licensing. In the Paris exhibition convention of 1878, also the controversy was raised, but the battle was won by the French principle of natural property right and the compulsory working requirement was equated with importation of articles and local working in any member country was considered as sufficient. This was followed in the final Paris Act of 1883. But again in the Brussels Conference of 1897, Belgium backed by the United States proposed a total ban on revocation for non-working of patents, as long as the patent was being worked in one member country. Following this in 1900, a major limitation on the regulatory authority of member states was by saying that no member states can revoke patent until expiration of three years from the date of patent application. In addition revocation was not to be allowed if the patentee could justify his inaction. This conflict continued in all the Revision Conferences of the Paris Convention and every time it was a success story of import monopoly countries. For a detailed study of Paris Convention and the international patent scenario, see: U Anderfelt’s, *International Patent Legislation and Developing*
vessel exemption\(^3\) and compulsory working requirement,\(^4\) there was no express or implied mention of any limitations to patent monopoly like research exception or private use which was practiced among the countries at that time. International inquisitiveness that culminated in the development of the Paris Convention itself demonstrates that, it was an attempt to protect right holders and import monopolies rather than to assist developing countries or to promote technology transfer and technological development.\(^5\) History reveals that it is through the sole

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\(^3\) Article 5 ter of the Paris Convention On industrial Property 1883: “In any country of the Union the following shall not be considered as infringements of the rights of a patentee: (i) the use on board vessels of other countries of the Union of devices forming the subject of his patent in the body of the vessel, in the machinery, tackle, gear and other accessories, when such vessels temporarily or accidentally enter the waters of the said country, provided that such devices are used there exclusively for the needs of the vessel; (ii) the use of devices forming the subject of the patent in the construction or operation of aircraft or land vehicles of other countries of the Union, or of accessories of such aircraft or land vehicles, when those aircraft or land vehicles temporarily or accidentally enter the said country”.

\(^4\) Article 5 A of the Paris Convention on Industrial Property 1883: “Importation by the patentee into the country where the patent has been granted of articles manufactured in any of the countries of the Union shall not entail forfeiture of the patent. (2) Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work. (3) Forfeiture of the patent shall not be provided for except in cases where the grant of compulsory licenses would not have been sufficient to prevent the said abuses. No proceedings for the forfeiture or revocation of a patent may be instituted before the expiration of two years from the grant of the first compulsory license. (4) A compulsory license may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last; it shall be refused if the patentee justifies his inaction by legitimate reasons. Such a compulsory license shall be non-exclusive and shall not be transferable, even in the form of the grant of a sub-license, except with that part of the enterprise or goodwill which exploits such license.

\(^5\) This is evident from the wordings of article 1 of convention which states that the object is to protect right holders and the broad definition of industrial property supports this. Article 1 of the Paris Convention on Industrial Property 1883:
weapon of local working requirement and forfeiture clauses that the patent statutes in the pre-Paris era controlled the patent abuses and ensured free flow of technology within the corresponding dominions. History has also proved the successful implementation of this tactic in achieving the stated goal of technology transfer and it should also be kept in mind that express legislative recognition of the limitations to patent rights sprang up only by the twentieth century, when the commercial significance of research and experiments was badly felt. This might be the reason why the Paris Convention was silent on patent limitations. By international ratification and enforcement of local working requirement, Paris Convention left it as matter of domestic prudence to devise their own methods of utilizing the technology available through patent disclosure. Further attempt of Paris Convention was to harmonize the existing patent practices and not to level the national legislations or to impose mandatory standards of protection.6

The Paris Convention with all its shortcomings has been widely criticized, but an analysis the origin and development of Article 5 of the Convention which is hailed as the history of the Convention itself, reveals the traces of implied provisions on limitations. This began with

Establishment of the Union; Scope of Industrial Property-1) The countries to which this Convention applies constitute a Union for the protection of industrial property. (2) The protection of industrial property has as its object patents, utility models, industrial designs, trademarks, service marks, trade names, indications of source or appellations of origin, and the repression of unfair competition. (3) Industrial property shall be understood in the broadest sense and shall apply not only to industry and commerce proper, but likewise to agricultural and extractive industries and to all manufactured or natural products, for example, wines, grain, tobacco leaf, fruit, cattle, minerals, mineral waters, beer, flowers, and flour. (4) Patents shall include the various kinds of industrial patents recognized by the laws of the countries of the Union, such as patents of importation, patents of improvement, patents and certificates of addition, etc.

the Revision Conference of 1925 at Hague. In the revised Article 5(2) it was proposed that “nevertheless the contracting parties shall have the right to take the necessary legislative measures to prevent the abuses which might result from the exclusive rights conferred by the patent, for example, failure to work.” Prior to 1925, Article 5 mentioned only the obligation to work and its sanctions. The Convention was silent on other abuses and their possible sanctions. The insertion of the concept of abuse of monopoly was a progressive provision adopted by the Union whose evolving conscience began to recognize the need to regulate the patents in public interest. Thus an implied recognition for other regulatory mechanisms crept into the system. Similarly in the Lisbon Revision Conference of 1958, the text of Article 5(A) (2) was changed to read that each country shall have the right to “take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exclusive rights conferred by patent, for example failure to work.” This textual change can also be interpreted as a provision impliedly recognizing the privilege of countries to take legislative measures other than compulsory licensing.

7 The most important revision adopted at the Hague was the substitution of the sanction of compulsory licensing for that of forfeiture. Article 5 (3) was added, which provided, “measures to prevent abuses shall not entail forfeiture unless the grant of compulsory licenses is insufficient to prevent such abuses”. See, Jayagovind, (1980) ‘The International Patent System and Developing Countries’, *Indian Journal of International Law*, 20 (1), 47-52.

8 The previous text, had provided that “nevertheless the patentee shall remain under the obligation to exploit his patent in accordance with the laws of the country into which he introduces the patented article but with the restriction that the patent may not be forfeited for non-working in one of the countries of the union until after a period of three years of the date of filing the application in the country”.


10 The previous text had read that, “states shall have the right to take the necessary legislative measures to prevent the abuses”.
Thus through an express silence on regulatory mechanisms and without any rigid standards of enforcement, Paris Convention maintained the era of maximum flexibility, where the countries enjoyed wide discretion to mold the patent policy according to the domestic needs and consequently the legislative era preceded by Paris Convention was a perceptible evidence for this.

4.2 Legislative and Judicial Developments in the Post-Paris Era

In the era of maximum flexibility espoused and encouraged by Paris Convention, the national legislations were again patterned by the absolute sovereign discretion to satisfy the domestic socio-economic and political realities. Accordingly any legislative policy across the geopolitical boundaries was a clear reflection of the vested domestic interests and exhibited extensive diversity. Limitations and exceptions to patent rights was also a genuine spectator of this. On national or regional level, a cursory analysis shows that Intellectual Property legislations frequently foresee a number of situations where patent exclusive rights may be exempted. A non-exhaustive list of them includes: private non-commercial use; use in teaching; research and experimentation; preparation of individually prescribed medicines; certain uses of foreign means of transportation temporarily in national territory; submission of information for regulatory approval; and non-commercial use of propagating material.

It is really interesting that inspite of a unanimous and universal concord on the nature, extent and scope of rights of patent holders across the countries, limitations appended to that monopoly exhibits extensive diversity. This diversity manifests from the moment of legislative drafting and continues till the actual enforcement and execution. While some countries incorporate this into the legal system as a limitation of
rights of patent owner, others slot in it as a defence in case of infringements. Thus in the case of the first set of countries, patent owners and public are placed on an equal footing when the law balances the patent monopoly at the very moment of its reward by putting the limitations. The approach of the latter set of countries portrays only a secondary concern to the user rights, when they categorize it as a defence to the right of the owners.

Again while some legislation maintains an absolute silence on this issue, some makes well drafted provisions. However even in countries which are silent on patent limitations, it should not be presumed that there is complete disregard for user rights and public interest, because the doctrine of commercial infringement is the universally accepted fundamental cannon of patent law. So every non-commercial use of patent is an accepted practice in common law depending upon the facts and circumstances of each case provided it does not conflict with the rights assured by the patent law. But what happens in these groups of countries is that the boundary between user rights and patent rights remains in a chaotic and hyperactive state of affairs while in the other group of countries it is clearly demarcated.11 This juncture leaves us confused as to which among these diverse approaches is appropriate and adequate in securing public interest – whether closed list of specific user

11 For example intellectual property consultation paper published by Australian government is concerned with the absence of an experimental use exception in their law. It has been suggested that lack of certainty about an experimental use exemption deters research in areas that are the subject of existing patents. This may not only inhibit Australian research, it may also encourage business and researchers to move their research and development offshore to jurisdictions with more favorable experimental use exemptions. This could potentially result in a loss of research investment and employment opportunities in Australia. Available at www.ipaustralia.gov.au/pdfs/news/ip_reforms_exemptions.pdf, 20, [Accessed on November 2010].
rights or rigid set of patent rights outside which everything could be user’s right? But it should be noted that commercial infringement doctrine is applicable even in those countries which have well built user rights and it is in addition to this general principle that certain specific needs, taking into account of their imperativeness have been fabricated into the law.

Even in those countries having express provisions on user rights, it should not be concluded that the above listed exceptions are uniquely followed. While some countries list all of those limitations, majority of the countries incorporates only a few. We can see that in this approach a vast majority of the countries are magnetized by the Paris Convention’s approach to limitations. Correspondingly even the identically worded limitations exhibits wide diversity in nature, scope and extent reflecting the strategic legislative policy.

Among the various limitations to patent rights it is the research or experimental use exception that enjoys an enhanced position. At the very infant stage of this doctrine itself we witnessed the divergent standards followed by two legal philosophies to achieve two different

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tasks. While Justice Story’s interpretation in the US was obstinate on the nature of experimental use for a “philosophical inquiry” or to ascertain the "verity and exactness of the patent specification"; English jurisprudence on the subject was least bothered about the nature of experiment being carried with the view to improving upon the invention or seeing whether an improvement can be made or not. The only common parameter run in between these approaches was the requirement of a bonafide non-commercial intent. Thus the very basic tenets from which the experimental use developed were based on two conflicting approaches. While one was worried about the potential abuses which might sprang up from the broad experimental use provision, other was solely concerned on the potential benefits of experimental use to technology transfer and development.

It should be noted that this diversity reached its zenith in the twentieth century. From this two distinct approaches there developed a multitude of research exemptions with wide magnitudes. While most of the legislations are unanimous on the need of a research use for an enhanced technological progression, there existed great uncertainty as to the nature of permissible experimental uses and extent of such uses. While some countries used the expression ‘experimental use or purpose’, in other legislations it appeared as use for ‘scientific research’, ‘scientific research and experimentation’, or ‘experiment or research’. Serious question arises as to whether this language syllogism is a mere legislative accident or a deliberate legislative policy.

But it is quite unfortunate that the legislative wisdom finds no explanation, illustrations or reference in any of the patent statutes expressly or impliedly except the commercial infringement doctrine which can be extended to identify the legitimate interest of the patent
holder. Black Laws Dictionary defines the term experiment as ‘a trial or special test or observation made to confirm or disprove something doubtful or the process of testing’. Webster’s dictionary also assigns a similar meaning to the term experiment by defining it as ‘an act or operation designed to discover, test or illustrate a truth, principle or effect; a test especially one intended to confirm or disprove something which is still in doubt’. So experiment in etymological sense is something static, not deviating beyond the identified facts but simply to confirm or disprove something which was already developed. Technological progression is beyond the literal and legal meaning of the term. But the terms ‘scientific research’ or simply ‘research’ conveys a positive and progressive meaning. As per Webster’s Dictionary ‘research’ means “to search again or anew- diligent, protracted investigation; studious enquiry or a systematic investigation of some phenomenon or series of phenomena by the experimental method”. The term science can be defined as “knowledge of facts, phenomenon, laws, and proximate causes, gained and verified by exact observation, organize experiment, and correct thinking and also the sum of universal knowledge.”13 It is synonymous with knowledge, art, learning and scholarship. Unlike the concept of experiment which refers to a torpid situation, research implies a budding and blossoming scenario. So when legislations uses the term ‘research or scientific research’ in addition to or apart from the term ‘experimental use’, the countries should have a definite progressive technological approach. This policy discrepancy is corroborated by the use of both terms in certain statutes. Judicial dicta from various jurisdictions also substantiate this.

For example we can see that the US judiciary adopts the literal interpretation of the term ‘experiment’ when it was carried to the legal

13 Webster’s Dictionary.
scenario by Justice Story by explaining it as something to test the
veracity of the invention or to satisfy a philosophical thirst. This narrow
approach was developed by Justice Story at a time when rapid
technological development could not even have been dreamed about.
However as per the policy of the patent system the experimental use
exception ought to apply to infringement of patented technology while
developing new uses and improvements for the patented technology
provided that the infringer does not make a monetary profit during the
infringement.\textsuperscript{14} However the US courts till the decision in \textit{Roche}\textsuperscript{15} in
1984 failed to uphold this noble task of patent system and took a very
restrictive approach towards experimental use\textsuperscript{16} and followed the ‘de

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15 \textit{Roche products, Inc.} v \textit{Bolar Pharmaceutical Co., Inc.} 221 USPQ 937 (Fed.Cir. 1984). In this case, the defendant Bolar was sued for infringement because it was using a patented drug to obtain clinical data to submit to the US Food and Drug Administration to show that the drug was safe and effective for human beings. Bolar was trying to get FDA approval prior to the expiration of the patent so that it could market the drug immediately after the patent expired. Bolar claimed that its use of the patented drug to obtain the necessary data for FDA approval was within the experimental use exception to patent infringement. After reviewing the history of the experimental use exception, the court denied the defense because it believed that Bolar was infringing the patent “solely for business reasons” and not for the purpose of philosophical enquiry or to test the verity and exactness of the invention as envisaged by Justice Story.

16 In \textit{Pairpearl Products, Inc.} v \textit{Joseph H. Meyaer Bros} 58 F.2d 802 (D. Maine 1932) defendant used plaintiff’s process of extracting pearl essence. Plaintiff’s invention was the use of a certain agent in separating the pearl essence form the skin of the fish. Defendant with that patent had invented a new agent and started sale of that new agent. Court in its anxiety to keep the experimental use within the traditional walls failed to uphold the invention and solely based on the commercial exploitation it was held to be an infringement. In \textit{Northill, Co., Inc.} v \textit{Danforth} 39 15 F. Supp 685, 30 USPQ 194 (E.D.N.Y.1936), defendant designed an anchor that was accused of infringing a patented anchor. Defendant had the anchors manufactured by various foundries and sold them commercially. In a suit for infringement, defendant claimed that he used the anchors for experimental use. The court recognized the experimental use defense, but rejected it in this case, saying defendants’ experiments “were evidently not made for philosophical or amusement purposes but were made in connection with his business as a
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minimis’ approach. In Roche, the court held that the experimental use rule could not be construed so broadly "as to allow a violation of the patent laws in the guise of 'scientific inquiry,' when that inquiry has definite, cognizable, and not for insubstantial commercial purposes". A decade back it was made clear that the defense is also limited to "tests, demonstrations, and experiments not in keeping with the legitimate business" of the alleged infringer. Thus apart from clinging to the literal interpretation of the concept, the phenomenon was again tested and distilled by the commercial versus non commercial nature of the experimentation and the profit versus non-profit status of the alleged infringer. This ruling prevented manufacturers of generic medicines manufacture and sales man of anchors”. In spray refrigeration co., v sea spray fishing, inc 2 322 F.2d 34, 138 USPQ 470 (9th Cir. 1963), defendant used plaintiff’s patented method for freezing fish on board a vessel at sea on one or two commercial fishing voyages. In a suit for infringement, defendant alleged that the use of the patented method on the trips was only for the purpose of experimentation as to the desirability of using this method. The court rejected the defense by saying that the patented method was used on the vessel while it was engaged in commercial fishing operations. It did not take into consideration of the defendant’s result of the experiment that the patented result could be produced without using the method. In cases like Ruth v Stearns- Roger Mfg Co. 13 F. Supp 697, 29 USPQ 400 (D. Colo. 1935), Chester Field v United States 47 141 Ct. Cl. 838, 159 F. Supp 371, 116 USPQ 445 (1958), Finney v United States 49 178 USPQ 235 (Ct.Cl.Trial Div. 1973), Douglas v United States, 181 USPQ 170 (Ct.Cl., Trial Div. 1974), Pitcairn v United States, 54 547 F.2d 1106, 192 USPQ 612 (Ct. Cl. 1976) were experimental use was claimed as a defence the court carefully tried to fix it within the parameters of justice story’s philosophical experiment and in many cases have failed to appreciate the genuine interests of the science.


18 Roche products, Inc.v Bolar Pharmaceutical Co., Inc. 221 USPQ 937 (Fed.Cir. 1984).

19 Pitcairn v United States, 547 F.2d 1106, 1125-26 (Fed. Cir. 1977).

placing products on the market immediately following the expiry of relevant patents as they were unable to gain prior authorisation to do so from the regulatory authorities: extending the effective protection conferred by a patent beyond its expiry date. But the US was very much alert about the negative impact of this restricted approach and it abruptly rectified the scenario by quick legislative intervention. 21

In the UK it was quite perplexing that while the common law established in 1878 took an unreserved attitude to experimental use by allowing experiments even for improvements and made an intelligible balance between actual and potential economic exploitation, 22 when it was transcribed into the statute, legislature took a much constricted approach. The term ‘experimental’ appeared in the US law was introduced as such in the UK Patent Act of 1907 23 and in the later enactment of 1977 it was further qualified by confining experiments to the subject matter of the invention. 24 This was of course turned out from the influence of the Community Patent Convention. 25 It reflects prior

21 The US enacted the “Hatch-Waxman Act” (Drug Price Competition and Patent Term Restoration Act of 1984), which, inter alia, added the regulatory review defence as section 271(1)(e) to the Patent Act. The law states that, “It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention…solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs…”

22 Frearsone v Loe (1876) 9 ChD 48.

23 Section 25 (o) of the Patent and Design Act, 1907: “Prior to the date of patent, invention was secretly worked on a commercial scale and not merely by way of reasonable trial or experiment in United Kingdom by the patentee or others, not being government departments or the agents …shall not be considered as a ground for revocation”.

24 As per section 60 (5) (b) it is not an infringement if “it is done for experimental purposes relating to the subject matter of the invention”.

25 In 1975, the then-members of the European Economic Community concluded the Community Patent Convention (CPC) as a multilateral treaty. The CPC was subsequently revised and renumbered in 1989. Article 27 of CPC 1989 (Article
experience under European national patent laws\textsuperscript{26} that avoided treating as infringement uses that did not have significant economic effects (private and non-commercial uses) as well as scientific experiments (even if done commercially).\textsuperscript{27} Apart from the UK, a majority of the European countries followed the suit.\textsuperscript{28} At a single glance, the legislative loom appeared to be quite conical towards experimental use.

This legislative conservatism was reinforced and upheld by the judiciary in the subsequent days. The UK Court of Appeal was the first senior European court to define the meaning of “experimental

\textsuperscript{31} of CPC 1975), addressed the “Limitation of the effects of the Community patent.” It provided that

\begin{quote}
“[t]he rights conferred by a Community patent shall not extend to:
(a) Acts done privately and for non-commercial purposes;
(b) Acts done for experimental purposes relating to the subject-matter of the patented invention…..”
\end{quote}

\textsuperscript{26} Countries like Sweden and Norway was having a similar provision as early as 1967 itself.

\textsuperscript{27} It thus coincides with Justice Story’s initial formulation excluding both scientific experimentation and uses that did not deprive patent holders of commercial rewards to which patent holders were legally entitled. However, the European exceptions are more generous to experimenters, given the broad construction of “use for profit” under the US Patent law, and neither early European case law nor the CPC explicitly drew from the US Patent Law when adopting these judicial exclusions.

\textsuperscript{28} Iceland Patent Act, (1991): Section 3 (3) “use of the invention for experiments which relate to the invention itself”; Patent Act 1967 Norway Section 3 (3) “exploitation by experiment relating to the subject matter of the invention”; Belgium Patent Law, 1987 - Article 28 (1) (b) “Acts done for experimental purposes relating to the subject matter of the patented invention”; Swedish Patent Act of 1967- Section 3 (3) use of the invention for experiments which relate to the invention itself. However countries like Mexico inspite of their membership in European Union was having a different perspective. Mexico intellectual property Consolidation Bill, (1991); Article 22. “The right conferred by a patent shall not have any effect against: I. a third party who, in the private or academic sphere and for non-commercial purposes, engages in scientific or technological research Activities for purely experimental, testing or teaching purposes, and to that end manufactures or uses a product or a process identical to the one patented”.

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purposes."^{29} In *Monsanto v. Stauffer*, Dillon L.J. held that that the words “experimental purposes” were to be given their ordinary meaning, and that therefore acts “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 will work in different conditions can 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 regulatory body that the product works as its maker claims are not to be regarded as acts done ‘for experimental purposes.’^{31} It follows from this that an act is an experiment if it seeks to generate genuinely new information. It is clear that the scope of the exemption is currently interpreted narrowly: experiments that are performed to further scientific knowledge and discover 'something new' can be exempted from being classed as an infringing act, in so far as the experiments performed have a 'direct' connection with the invention described in the patent. However, experiments performed purely for gaining regulatory approval, such as field trials or clinical trials, might not be considered to be exempt from being classed as an infringing act in the UK at present. Thus a century old judicial dicta was reiterated without appreciating the changed perceptions of experimental use hauled up by the biotechnology and pharmaceutical industry.


^{31} [1985] RPC 542. Given what was already known about the allegedly infringing Glyphosate herbicide, the Court of Appeal upheld an injunction prohibiting planned uses of the Glyphosate herbicide to be conducted on third-party farms.
Other national courts have followed Monsanto’s interpretive approach. Specifically, the definition of “experimental purposes” adopted in Monsanto is generally agreed upon throughout Europe. For example, in Germany the Federal Court of Justice (BGH) employed a similar definition in its “Ethofumesat” decision. In that decision, the BGH clearly stated that experiments or “trials” with a protected subject matter like a pharmaceutical would only be permitted insofar as such experiments were directed to the substance itself. For example, experiments were permitted in order to get more information regarding the substance’s inherent properties and to determine whether the substance could be manufactured at all, whether it was sufficiently pure, or whether it had the properties of the protected pharmaceutical. Clinical trials, however, were considered as being of a different nature and were not permitted. Similarly in New Zealand in Monsanto Company v Stauffer Chemical Company, which concerned field trials of an herbicide, in the light of Frearson v Loe court held that the defendant’s use of the patented compound in field trials in New Zealand “had gone well past the demarcation line of permitted experimental use.” Thus an ordinary literal meaning of the term without appreciating the changed technological scenario continued as such. The courts and legislature


33 But in this case it was the validity of clinical trials being conducted prior to the expiry of the patent. Clinical trials, however, were considered as being of a different nature and were not permitted. Accordingly, it was not possible to obtain approval for marketing a patented pharmaceutical in Germany immediately after expiration of a third party’s patent. Instead, the necessary governmental approval would have to be obtained after expiration of the patent.

34 (1984) 1 TCLR 129.

35 (1876) 9 ChD 48.
appeared to be very cautious in maintaining the balance of intellectual property pendulum. And the pendulum maintained an uneven balance flouting the desires of the emerging technologies.

The phrase “relating to the subject-matter of the patented invention” obviously intended to qualify the preceding expression “acts done for experimental purposes” made this posture more transparent. By narrowing the category of experimental purposes to those that relate to the subject-matter of the patented invention, the CPC and its associated legislations reflects the intent that experiments must be intended to develop information on the used invention itself. This would exclude experiments where the patented inventions are used solely as a research tool to investigate other things, such as use of a microscope to investigate bacteria, or are used solely to obtain a regulatory marketing approval. The legislative history of CPC, in particular the memorandum on the Convention, makes this clear, creating a distinction between experiments “on” a patented invention from experiments “with” the invention. 36 Judiciary refined the concept more transparently in Smith Kline & French Laboratories Ltd. v. Evans Medical Ltd 37 where the phrase “relating to the subject-matter of the patented invention” was interpreted as relating to the claimed subject matter of the patent in suit in the sense of having a real and direct connection with that subject matter.

36 The memorandum comments on Art. 31 (b) CPC 1975 (Art. 27 (b) CPC (1989)) that all of the exceptions of Art. 31 CPC 1975 should be applied restrictively, and:

“As is likely the case with most national patent laws, Article 31 (b) permits use of the invention protected by a community patent for experimental purposes, e.g. in order to test usability and possibilities for enhancements. The chosen wording is intended to make it clear that the experiment itself must relate to the protected invention; i.e. use of the protected invention within the scope of an experiment that relates to a different subject-matter shall not be permitted.” Memorandum is available at:

Even outside Europe, as early as in 1971, in *Microchemicals Ltd v Smith Kline and French Inter-American Ltd* 38 the Canadian supreme Court citing the English case of *Frearson v Loe* 39 held that experiments conducted for “the purpose of satisfying itself that it could satisfactorily produce the product on a commercial basis by the use of the patented process” is a valid patent infringement defence.40 This progressive attitude taken by Judiciary at such an early stage was the cumulative effect of the challenges faced from the Canadian pharmaceutical industry and consequent public health crisis existed in Canada at that point of time. This judicial insight was accepted by legislature without any hesitation.41 In Canada, neither the use of a patented product or process to obtain information to be used for a regulatory approval process, nor the use, manufacture or sale of a patented product or process solely for

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39 (1876) 9 ChD 48.
40 The small amount of product so manufactured was bottled and never entered into commerce. At first instance this Activity was held not excepted but on appeal the Supreme Court of Canada, held: “The use Micro Chemicals was making of the patented substance here was not for profit but to establish the fact that it could manufacture a quality product in accordance with the specifications disclosed in respondent’s application patent 612204. Walsh J found that Micro Chemicals experiments constituted a technical infringement as they were not carried out for the purpose of improving the process but to enable Micro to produce it commercially as soon as the license that it had applied for could be obtained. I cannot see that this sort of experimentation and preparation is an infringement”.
41 Canada Patent Act (1985), Section 55.2.- (1) It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product; (2) It is not an infringement of a patent for any person who makes, constructs, uses or sells a patented invention in accordance with subsection (1) to make, construct or use the invention, during the applicable period provided for by the regulations, for the manufacture and storage of articles intended for sale after the date on which the term of the patent expires.
the purpose of experimental or testing activity prior to finalization of a commercial product for manufacture, promotion or sale is an infringing use. The Canadian exemption appears to be too broad and solely bigoted towards research and science utterly ignoring the aspirations of patentee.42

Thus it is quite clear that when legislations use the expression ‘experiment’ or ‘experimental purposes’, they definitely have a narrow research policy. They are very cautious while opening the safety outlet of the patent system, that otherwise it will completely shake the system. This cautiousness is very evident when certain legislations like that of Kenya43 expressly bar scientific research from the scope of experimental use. And when legislations again qualify it by more narrow terms, it is matter of real concern. But in course of time this rigidness was shattered out by broadening the nature of permissible experimental uses. For example in Germany in “Clinical Trials” held that any systematic procedure aimed at obtaining new information is considered an experiment within the meaning of Article 27 (b) CPC 1989, and thus of German Patents Act.44 In New Zealand also a similar approach was taken in the decision of Smith Kline & French Laboratories v Attorney General45, where the court, referring to Frearson v Loe46, accepted the

42 This provision has raised much controversy, resulting in WTO panel dispute, which will be analyzed in the next chapter.

43 Patent Act of Kenya (1989), S.38.- (1) : “The rights under the patent shall extend only to Acts done for industrial or commercial purposes and in particular not to Acts done for scientific research”.

44 But in Clinical Trials I, published in July 1995, the BGH stated that the experimental privilege allows one, during the lifetime of a patent, to conduct trials directed toward obtaining data for approval of a pharmaceutical for a second, not-yet patented indication of a protected pharmaceutical.


46 (1876) 9 ChD 48.
existence of an experimental use defence for even improvements with ultimate commercial motive. Thus standing on the same fundamental etiquettes of law, a progressive approach developed very shortly.

But when countries use the term research and scientific use they definitely are having a broad attitude. Japan is the best example for this approach. Under Japanese Patent law, Section 69.1 provides that patent rights shall not extend into experimental research. This provision was first introduced in 1909 and has remained valid since then. It is clear why Japan employed the statutory exception relatively early compared to other countries. At that time, Japan was still a developing country. Reverse engineering was needed in all fields of technology. The experimental use exception was recognized explicitly so that people could develop new technology. The incredible technological development achieved by Japan within a short span of time was a clear evidence of efficacy of this tactic. The patent statutes of Brazil, China, Ghana, Kenya, Poland, Republic of Korea, United

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47 The court held: “Doubtless experimentation will usually have an ultimate commercial objective; where it ends and infringement begins must often be a matter of degree. If the person concerned keeps his Activities to himself even though commercial advantage may be his final goal, he does not infringe. But if he goes beyond that, and uses the invention in a way that serves to advance him in the Actual market place, then he infringes, for the marketplace is the sole preserve of the patentee”. Smith Kline & French Laboratories Ltd v Attorney-General (NZ) [1991] 2 NZLR 560, 566.


50 Patent Act of China (1992), S. 5 - “Use of the patent in question solely for the purposes of scientific research and experimentation”.

51 Patent Act of Ghana (1992), S. 30 - The rights under the patent shall— (a) extend only to acts done for industrial and commercial purposes and in particular not to Acts done for scientific research.
Republic of Tanzania,\textsuperscript{55} Thailand,\textsuperscript{56} etc are having this broad approach. Indian law also uses the expression ‘experiment or research’ connoting a wider ramification.\textsuperscript{57} The Bangui Agreement establishing the African Industrial Property Organization (OAPI) provides that “the rights deriving from the patent shall not extend to acts in relation to a patented invention that are carried out for experimental purposes in the course of scientific and technical research.”\textsuperscript{58} It appears that this attitude is more common in developing countries than developed ones. In the absence of any further qualifying language, the language contained in these legal instruments would provide a safe harbor against patent infringement for practically all scientific and technological research activities.

4.3 Conclusion

The above analysis of experimental use provisions across the countries points out the wide diversity on the nature of the permissible activities and at the same time the far-reaching uncertainty as to the

\begin{itemize}
\item\textsuperscript{52} Patent Act of Kenya (1989), S.38 - (1) The rights under the patent shall extend only to acts done for industrial or commercial purposes and in particular not to Acts done for scientific research.
\item\textsuperscript{53} Patent Act of Poland (1972), Art. 16 (8) - The use of an invention for scientific purposes shall not be considered an infringement of a patent.
\item\textsuperscript{54} Patent Act of Republic of Korea (1961), S.25 (1) - The effects of the patent right shall not extend to the following: (i) working of the patented invention for the purpose of research or experiment.
\item\textsuperscript{55} Patent Act of Tanzania (1987), S.37- (1) - The rights under the patent shall extend only to acts done for industrial or commercial purposes and in particular not to Acts done for scientific research.
\item\textsuperscript{56} Patent Act of Thailand (1979), S.36 (1) - patent right shall not relate to any act for the purpose of study, research, experimentation or analysis, provided that it does not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner.
\item\textsuperscript{57} Patent Act of India (1970), S. 47 (3).
\item\textsuperscript{58} See Bangui Agreement establishing the African Industrial Property Organization (OAPI) [online]. Available at www.wipo.int/wipolex/en/other_treaties/details.jsp? treaty_id=227, [Accessed on May 2010].
\end{itemize}
scope and extent of these permissible limitations. For example while in Monsanto’s decision the UK and New Zealand arrived at similar opinion, subsequently in conflicting decisions. While the US is very emphatic on de-minimus use and commercial and non commercial objective, the UK took a liberal view by allowing improvements on the invention and also upholds a potential economic exploitation. Positions in Germany and New Zealand are relatively absurd as a result of conflicting judicial opinions. The enactment of Hatch Waxman Act in the US, validating clinical trials in Germany, introduction of regulatory review in Canada as early as in 1971, attempt of Japan to legitimize reverse engineering etc., are also the finest instances of exercise of domestic sovereignty by nations to secure their in-house needs. As we have stated earlier it was the period of maximum flexibility with minimum of international commitments. But this position created much chaos and confusion in the arena of global village. While clinical trials and regulatory review uses are legal in some jurisdictions, others consider them as patent infringements. Thus an international consensus and compromise is lacking. It has been suggested that lack of certainty about an experimental use exemption deters research in areas that are the subject of existing patents. This may not only inhibit research in domestic countries, it may also encourage business and researchers to move their research and development offshore to jurisdictions with more favorable experimental use exemptions. This could potentially result in a loss of research investment and employment opportunities in concerned countries. So an international standard retaining the flexibility of the countries to satisfy their domestic requirements is the need of the time. For example a limited experimental use privilege may best encourage technological advancement by rewarding successful researchers with patent rights that are not easily circumvented. However, the
circumscribed nature of the experimental use privilege may in effect restrict researcher access to state-of-the-art technologies and thus discourage further technological development. It is really a matter of concern that which among this approach will best serve the patent system and contemporary scientific research community. The ideal balance between the potential effects of an experimental-use exemption on the pace of follow-on innovation and the effects on the incentives of primary inventors is also unclear.

This diversity, uncertainty and ambiguity does not prevail on ‘research use’ alone but on all limitations appended to patent monopoly. However all countries are unique on the nature of private and non-commercial use exempting it from patent infringement based on the deminimus rule. But even then, while some countries excepts all private uses, others qualifies it by commercial objective and some does not have an express private use exception but only an all embracing commercial and industrial use prohibition. On the ‘foreign vessel’ exception also the countries lack concurrence and harmony inspite of its origin from a common international document. It is really a matter of international concern that inspite of the recognition and realization of the significance of global trade and movement of goods, some countries do not have such a provision. Even in countries having a legislative provision there exist

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59 For example Article 38 of Albanian Patent law exempts Acts performed privately, not for commercial purposes from the scope of infringement. Similarly Section 60 (5) (a) of the 1977 UK Patents Act, provides that “an Act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if it is done privately and for purposes which are not commercial”. However patent laws of Canada, Angola, and Bangladesh etc simply uses the expression ‘personal use’. The commercial nature of use is irrelevant there. Nigeria has a similar provision; the rights under a patent shall extend only to Acts done for industrial or commercial purposes. Virtually identical approaches are seen in Ghana (Section 30 (a)), Kenya (Section 58 (1)) and Sri Lanka (Section 82 (1)).
wide diversity as to its nature and scope. For example while some countries like Canada, Ghana and China allows the use of the patented product for any needs of the foreign vehicle in transit, others like Belgium, India and the UK incorporates specific exceptions for the construction of the vehicle or use in any device of that vehicle. Thus even on a matter of international apprehension the countries exhibits much confusion.

It is also a notable fact that most of these pre-TRIPS patent legislations were not having well articulated provisions on parallel importing, regulatory review exception and exception for pharmaceutical preparations. A classic example is Indian patent law, which incorporated the parallel importing and Bolar provisions in the post TRIPS era. This absence of a limitation in an earlier period and the subsequent recognition of such a limitation at a later period is a typical instance of framing limitations to meet the changed exigencies of public interest. The elevated standards of protection set by TRIPS agreement together with rise of multinational pharma industries added by the worldwide public health crisis may urged the patent laws across the countries to frame limitations and exceptions to meet the changed circumstances. In India for example, when the TRIPS agreement insisted the recognition of product patent, we eagerly incorporated provisions for Bolar use and parallel importing.

However some kind of uniformity and regularity was running in between these diversities and discrepancies. All the jurisdictions were unique in safeguarding the rights of the patentee ensuring the larger public interest. But depending upon the social, economic and political priorities the countries exercised their sovereign discretion while balancing these competing interests. While economically and
technologically developed countries took a restrictive attitude towards user rights, developing ones in their eagerness to acquire technology and capital took a liberal attitude. Thus the origin of diversity owes to the domestic imperativeness and arises at the moment of this balancing mechanism. What might be a sound policy for the US may not be suitable for a developing country like India. Another common thread running in between the countries is that all legislations while allowing free user rights were cautious to protect the legitimate interests of the right holder. Here also the diversity arises on the magnitude of importance attached to the infringing factors. For example, while the US is against both actual and potential economic infringement of patent rights; the UK, Germany, New Zealand etc., does not matter the potential infringement. And lastly we can see that all the countries limits the user rights to certain special cases and not to all legitimate or non commercial activities. Thus domestic exigencies played a very important role in framing the limitations and exceptions. It may be safe to conclude that the legal and judicial panorama in the Paris and post-Paris era was thus a splendid harmony of diversities. Each unique set of limitations was a reflection of the cherished social, economic, political and philosophical ideologies of the states.