Experimental Use Exception: An International and Comparative Overview with a Possible Answer to The Forthcoming Indian Patent Legislation

Aditya Nagarsheth
EQUIP, Queen Mary Intellectual Property Research Institute, John Vane Science Centre
Charterhouse Square, London EC1M 6BQ, United Kingdom

Received 13 August 2004

Experimental use exception allows researchers to use patented inventions for carrying out experiments and research without taking the licence from the patent holder. Experimental use exception is a recognized exception to patent laws across the globe. However, differences arise on the nature and scope of the exception. These differences are largely dependent on the nation’s economic circumstances, capability and level of existing science and technology standards and its prospects of exploitation. Hence, United States, being an economic superpower and global leader in most of the technologies provides for an extremely limited experimental use exception to patent rights. However, for countries like India, where science and innovation is still at a nascent stage, it would be prudent to learn from history of Japan and allow an extremely broad experimental use exception to bolster research and innovation. This paper deals with the international position of exceptions to patent laws. An experimental use exception and its importance is also explained. Comparison of the present legal position in England, United States, Germany, Japan and India on experimental use exception to patent laws is also given in detail. In the end, it draws out the rationale for a broad experimental use exception for India and concludes with some emerging issues where further research is required.

Keywords: Experimental use exception, Indian patent legislation

The TRIPS Agreement, to which India is a signatory and which is to be fully enforced in India from 1 January 2005, allows the member states to have exceptions to patent rights. Article 30 states that member states have the discretion to provide for limited exceptions and such exceptions should not unreasonably conflict with normal exploitation of the patent and must not unreasonably prejudice the legitimate interests of the patent owner taking into account the legitimate interests of third parties. However, this provision is vague and very general in nature. Questions such as what are the legitimate interests of the patent owner and what are the legitimate interests of third parties remain unanswered. This is so because Article 30 was one of the most contested provisions during the negotiations of TRIPS Agreement. Consequently, member states have not harmonized the exceptions to patent laws. This has led to differences in scope and nature
of exceptions, particularly, with regard to
the experimental use exception. For in-
stance, in European Union v Canada,2
though the WTO Panel has held that test-
ing, conducting clinical trials, develop-
ment of samples during the patent term
for gathering data for drug regulatory
purposes is compatible with the TRIPS
Agreement, some states continue to con-
sider them to be patent infringement.

What is an Experimental Use Excep-
tion?
A patent grants the inventor the right to
exclude others from making, using and
selling the patented process or product.
The use right of a patent is not absolute. It
has its own limitations and exceptions.
External limitations such as competition
law, public health and internal restrictions
like private use exception and experimen-
tal use exception are some of the limita-
tions to use right available across the
globe. Experimental use exception allows
researchers to use patented inventions for
carrying out experiments without taking
the licence from the patent holder. This
includes both usage of patented invention
as a research tool and experimenting on
the patented invention to better it or oth-
erwise. Furthermore, depending upon the
scope of the experimental use exception,
researchers may be allowed to manufac-
ture the patented invention for the pur-
poses of experimentation. Most of the
laws around the world provide for some
sort of experimental use exception. Some
countries like Germany and Japan have
broad experimental use exceptions which
allow all experiments for commercial
purposes, while the United States of
America has an extremely narrow ex-
perimental use exception which terms any
experiments for commercial purposes as
patent infringement, except those for drug
regulatory purposes. England is ambigu-
ously muddled somewhere in between the
two.

Importance of the Experimental Use
Exception

While engaging in a research and de-
velopment activity, a researcher often
uses different patented and unpatented
sciences and technologies for experimen-
tal purposes. In the absence of an experi-
mental use exception, the researcher do-
ing research on how to better an existing
technology would be forced to take li-
cences for all the patented products and
processes that he/she is going to use in
her research. In case of refusal of licence,
he/she might have to apply for a compul-
sory licence, which would consume time
and cost. This would deter the researcher
from undertaking research. Furthermore,
it would encourage big innovators to cre-
ate patent thickets. Since the main objec-
tive of patent law is promotion of science
and innovation, experimental use except-
ion is imperative for the research com-

munity. Additionally, experiments of pat-
ented technologies are performed to
gather data for regulatory purposes in
pharmaceutical, chemical and agriculture
industries. Since all the countries have an
experimental use exception, this is not a
problem. The problem is the scope of the
experimental use exception. Would an
experimental use exception include re-
searches undertaken for commercial
purposes? In today’s world, most of the
organizations undertake researches for
commercial purposes. Hence, the scope of an experimental use exception is extremely important to patent laws. The future of research-based industries such as engineering, biotechnology, pharmaceuticals and computers is dependent on the scope of interpretation of the experimental use exception in patent laws.

Experimental Use Exception in England

Since Indian courts regard English judgements to have persuasive value, a brief overview of the English law on the experimental use exception to patents is necessary. However, in view of the formation of European Union and European Court of Justice, an opinion to cease this tradition has emerged.

The current source of English patent law is the Patents Act, 1977, as amended. The Act was designed to take account of the European Patent Convention (EPC), 1973 which established the European Patent Office. Article 64(3) of the EPC provides that any infringement of a European patent shall be dealt with by national law. Thus, the EPC does not have any specific provision regarding experimental use exception. Rather, the experimental use exception finds its roots in Article 31(b) of the Community Patent Convention, 1975 (CPC). The same provision is found in Section 60 (5) (b) of the Patents Act, 1977. It states that an act done for experimental purposes relating to the subject matter of the invention would not infringe a patent.

According to the Judge, Mr Michael Fysh of the Patents County Court, Section 60 (5) (b) contains two elements: (i) the acts must be done for experimental purposes, and (ii) those purposes must relate to the subject matter of the invention. According to him, this demands inquiry of the nature of invention and more significantly, the nature of the relationship.

English Jurisprudence

In Freason v Loe (1878) 9 Ch. D 48, the Court held that if a patented product was made only for bonafide experiment, without intention to sell or use it, but with the view to improving upon the invention or seeing whether an improvement can be made or not, would not infringe. Hence, an experiment undertaken for commercial purposes would not infringe. However, judicial attitudes have changed since then. In Smith Kline & French Laboratories Ltd v Evans Medical Ltd (1989) FSR 513, the Court observed that what is not an experiment must depend upon the facts of each case, but can include experiments designed with a commercial end in view. In Monsanto v Stauffer (1999) RPC 397 CA, the Court of Appeal limited the interpretation of word ‘experimental’ in accordance to its size, scale, recipient and methodology. The Court held that experiments done at one’s own premises were held to be not infringing, however, those done outside in different conditions or to amass information to satisfy a third party, were held to be infringing. In Inhale Therapeutic Systems Inc v Quadrant Healthcare Plc (2002) RPC 21, the Patents Court held that since the defendant had carried out experiments to exploit and sell its technology to third parties, experimental use exception would not apply.
Conclusion of English Law

English jurisprudence demonstrates that experiments carried out to gather data for regulatory purposes are likely to infringe in England. When experiments or research is carried out for innovation, the present English law is ambiguous about the application of experimental use exception if such experiments are performed for commercial purposes. It is certain that not all commercial experiments would avail the benefit of the experimental use exception; however, demarcating experiments as infringing and not infringing is difficult. This ambiguity has created immense concerns amongst the various stakeholders in England, particularly, the research community and the debate is far from over.

US Law

US experimental use exception to patent rights can be divided into two sections:

Statutory Exception Relating to Drugs And Medical Devices

Section 271(e) of 35 USC Patent Act provides for an experimental use exception reasonably related to testing drugs and medical devices for regulatory data gathering. Initially, the Courts had given a broad interpretation of the wording ‘reasonably related’ to include food additives, colour additives, new drugs, antibiotic drugs and human biological products [Eli Lilly v Medtronic, 496 US 661 (1990), Intermedics v Ventritex, 775 F. Suppl. 1269 (N.D Cal 1991)]. However, recently in Integra v Merck, 2003 US App LEXIS 11335 (Fed Cir 2003), the Federal Circuit Court has limited the scope of this exemption to experiments carried out for the purposes of facilitating expedited marketing approvals for generic drugs only. The Court further held that extending the exception to new drug development is contrary to the purpose of Hatch-Waxman Act.

Common Law Exception

This exception was first laid down in US patent law by Justice Story in a couple of 19th century judgements. In Whitemore v Cutter, 29 Fed. Cas. 1120 (1813), the Court stated that when a patented product is made or used as an experiment, whether for gratification of scientific tastes, curiosity, or to ascertain the verity and exactness of the specification or for amusement, without intent to use for profit, would not infringe. Justice Story further commented that it could never have been the intention of the legislature to punish a man, who constructed (another’s patented invention) merely for philosophical experiments, or for the purpose of ascertaining the sufficiency (of the patented invention) to produce its described effects. The term ‘philosophical experiments’ corresponds to ‘scientific experiments’ in modern age. The US Courts have refused to apply experimental use exception where the defendant’s use was for commercial purpose. In Roche v Bolar, 733 F.2d 858 (Fed Cir 1984), the Court held that this exception was ‘truly narrow’ and any slightest intent of commercial use would infringe. In Duke v Madey, 307 F.3d 1351 (Fed Cir 2002), the Court held that Duke University could not rely on the experimental use exception as it used Madey’s patents...
to further its business, one of providing education. The Court accepted the arguments of *Duke v Madey* without much hesitation in *Applera Corp v M J Research Inc*, 311 F.Supp. 2d 293 (D.Conn., 2004), while rejecting the experimental use exception. The Court held that experimental use defence applies only where use of patented invention was for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry; the defendant’s use of patented device does not come within ‘experimental use’ exception, even if its use is non-commercial or not-for-profit, if it is in keeping with defendant’s legitimate business objectives, including educating project participants, and increasing defendant’s status or ability to lure research grants, students, or researchers. However, it seems that the rationale of holding universities liable for patent infringement in *Duke v Madey* and *Applera v M J Research* is the enactment of the Bayh-Dole Act in 1980 whose explicit objective is to promote collaboration between the industry and universities. The Act envisages the universities to innovate with the assistance of federal government funds, which would thereafter be licensed to the industry. Another possible rationale is that US universities are very zealous in protecting their intellectual property rights. For instance, University of California recently sued Microsoft for patent infringement where the federal jury awarded damages worth US$520 million. It appears that the basis of narrowness of the experimental use exception in US law is based on factors that are extraneous to the patent paradigm. One must be extremely cautious whilst applying US patent jurisprudence before Indian courts. Though, the debate in the United States is ongoing on the scope of experimental use exception, at present, the experimental use exception in the US is truly narrow and any research with slightest commercial intent would require a licence from the patent holder.

**German Law**

Like the English law, Article 11.2 of the German Patent Act of 1981 is drafted exactly like the provision contained in the CPC. Two decisions relating to pharmaceutical industry are noteworthy. In ‘Clinical Trials I’, German Federal Supreme Court, 1995, held that experiments including clinical trials for obtaining second usage of a patented product are well within Article 11.2 and hence does not infringe patents. In ‘Clinical Trials II’, German Federal Supreme Court, 1997, went further to hold that clinical trials undertaken to obtain regulatory approval were also within Article 11.2. This generated considerable criticism from the ‘Big Pharma’, but was affirmed by the German Constitutional Court in 2000. Hence, Germany has a broad experimental use exception, at least with regard to the pharmaceutical industry.

**Japanese Law**

Article 69(1) of the Japanese Patent Law, 1959 provides ‘the effects of the patent rights shall not extend to the working of the patent right for the purposes of experiment or research.’ This provision was enacted by Japan in 1909 when Japan was importing most of the intellectual property and was a developing country. It
was introduced to increase economic growth through reverse engineering. The rationale of this provision was to promote the development of new technologies. Any experiments or research undertaken to develop new technologies does not infringe patents in Japan. Furthermore, with regard to tests for regulatory approvals, the Supreme Court calmed the prevailing uncertainty when it held that tests carried out during the term of the patent to obtain regulatory approval does not infringe in Ono Pharmaceuticals Co Ltd v Kyoto Pharmaceutical Industries Ltd (1999). The Court stated that one of the basic principles of patent law is to allow anyone to exploit freely a new technology after the expiry of the patent term, thereby generating benefit to society. Hence, Japanese law allows an extremely broad experimental use exception regardless of any fields of science or technology and its purpose.

Indian Law

Sections 107 and 47 of the Indian Patents Act, 1970, are relevant to the experimental use exception.

Section 107(2) states that in any case of patent infringement by making, using or importation of any machine, apparatus, or other article or by using any process or by importation, use or distribution of any medicine or drug, it shall be a ground of defence that such making, using, importation or distribution is in accordance with Section 47.

Section 47 states that grant of patent shall be subject to the condition that any machine, apparatus or other article in respect of which the patent is granted or any article made by the use of the process in respect of which the patent is granted, may be made or used, and any process in respect of which the patent is granted may be used by any person, for the purpose merely of experiment or research including imparting education to pupils.

It seems that experiments carried out to gather information for regulatory purposes is likely to benefit from the experimental use exception. However, both Sections 107(2) and Section 47 have been drafted in an extremely complicated manner. First, words such as research and experiment are not defined in the Patent Act. Second, Section 47 does not make any distinction between experiments done for commercial purposes and non-commercial purposes. Third, the language of the provision is not clear; the inclusion of the word merely in Section 47 raises doubts and questions. Fourth, Section 47, being an inclusive provision, includes an example of imparting education to pupils. This is obviously an academic use of patents and not a commercial use of patents.

In view of this preliminary analysis, the language seems to suggest that the legislative intent was to provide for an extremely narrow experimental use exception to patents. However, a detailed examination of Parliamentary debates is required to ascertain the exact legislative intent and scope of Section 47. Furthermore, since the Indian courts regard English cases to have high persuasive value, it would be interesting to see how the Indian courts would interpret these provi-
Rationale for a Broad Experimental Use Exception in Indian Law

In view of the recent controversies occurring around the world in relation to the experimental use exception, it is likely that India too would witness such litigation in the foreseeable future. Since the Indian Government is having a re-look at the patent legislation, the Government must utilize this opportunity to clearly lay down the scope of the experimental use exception to ensure legal certainty to the Indian and foreign stakeholders.

Patenting is a new ball game for the Indian stakeholders. The discussion paper of the Confederation of Indian Industry states that nearly 85% of the patent applications in India are filed by foreigners. Additionally, WIPO statistics demonstrate that out of the 114,048 PCT applications received in 2002, only 480 PCT applications were from India. In view of these statistics, it is prudent that a broad experimental use exception is drafted to take into the account the interests of the Indian industry. This is so particularly in the small and medium sized enterprises where heavy transaction costs like negotiation of licences, etc. would be detrimental to foster innovation. Besides, an express broad exception is likely to give a tremendous boost to foreign investment into commercial research and development projects, particularly, from the United States, where the experimental use exception virtually does not exist. Furthermore, since there is no international consensus on the issue of the scope of experimental use exception, India has an ideal opportunity to draft a liberal and broad experimental use exception like Japan. This would give an impetus to the local and foreign manufacturing and services industry to understand the existing technologies, which would lead to ‘incremental’ innovation. Hence, it would be prudent for India to amend Sections 107 and 47 and make them simpler in lines of the Japanese law.

Conclusion

Notwithstanding that a broad experimental use exception is drafted in the forthcoming patent legislation, some issues still remain for the Indian and foreign industry. For instance, on the basis of the broad experimental use exception, an Indian company undertakes research and performs experiments using patented technologies of a United States company in India. Then the Indian company files a patent application in the United States before the USPTO. In case of opposition or infringement proceedings by the US patent holder, would the USPTO and/or the US Court grant/revoke the patent? Perhaps, answers lie in the review of USPTO and US courts decisions in respect of Japanese and German patents, which innovated using US patents without taking a licence from the US patent holder. It would be prudent for the Indian stakeholders to factor this issue while commencing research based on foreign, particularly, US patents.

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