Research Exemptions in Patent Law

Kalyan Chakravarthy†
National Law School of India University, Nagarbhari, Bangalore-560 072

and

Nandan Pendsey†
1436 River Crest Road, San Marcos, CA-92078, USA

Received 4 March 2004

Providing exemptions from infringement for research on patents is equally important as granting exclusive rights to inventors. Both play a crucial role in encouraging the progress of science and technology. While exclusivity in patent rights encourages invention and innovation by providing economic incentives, exemptions for research encourage innovative improvement, testing and use of patented inventions. Research exemptions boost competitive spirit and promote further development in targeted fields of technology. In order to achieve efficient progress in science and technology, a proper balance must be struck between the patentee's rights and the exemptions granted for research. Various countries have been struggling to draw a line that defines the proper balance. The US allows a very narrow exemption for research that is limited to philosophical use and idle curiosity, but a much wider exemption is available under Indian patent law. In both USA and India, generic drug companies enjoy an exemption for research in order to develop information for drug approval, but the scope of exemption varies distinctly. This paper comparatively describes the patent law on research exemptions in India and USA with an intent to point out the differences and to suggest an ideal law that would properly balance the interests of research and exclusivity in order to achieve optimum progress in science and technology.

Keywords: Research exemptions, patent law, drug approval, patented invention, philosophical use, idle curiosity, research and experiment

The significance of the patent system has increased exponentially as a result of the globalization of trade and commerce. The most important purpose of the patent system is to promote the progress of science and technology. The patent regime grants exclusive rights to the inventor for a limited period of time allowing him to reap the benefits of his skill and labour thereby providing an incentive to invent and invest. The patent system provides exclusive rights to the inventor for the disclosure of his invention to the public that is the quid-pro-quo (give and take) incorporated in it.

†Email:kalyan@nls.ac.in and nandanpendsey@yahoo.com
A patentee enjoys exclusive rights to make, sell, use, offer for sale or import the patented invention. There are very few exceptions to these exclusive rights. Exemption for research or experimental use exemption is one of such exceptions. It protects researchers, which may include educational institutions, research institutions, non-profit organizations and other establishments, from infringement actions brought by the patentees for use of their patents.

There is a direct conflict between the right of the patentee to exclude others and the aim of the patent system to promote progress of science and technology by giving societal access to the patented invention. The patent law tries to strike a balance between these conflicting ends and this essentially determines the scope of the exemption for research. The scope of research exemption granted by the patent system differs from country to country. The difference in scope can be attributed to the difference in ideologies followed by each country based on its social conditions and needs. Nations of the world have been struggling to draw a line that defines the balance between the exclusive rights granted to the patentee and exemptions granted for research. While some countries have granted a wide exception for research, the others have made it very narrow. To avoid problems due to diversity in the scope of research exemptions in various countries, a uniform global policy on research exemptions has to be adopted by all nations of the world.

Research Exemptions in USA

Research exemptions under US law can be classified into two categories. One, exemption from infringement for the purpose of obtaining federal approval, and, two, exemption from infringement for the purpose of using a patent in order to satisfy idle curiosity and for philosophical use.

Exemption for the Purpose of Federal Approval

In 1984, the United States Congress enacted the Hatch-Waxman Act, also called the Drug Price Competition and Patent Term Restoration Act of 1984. The Hatch-Waxman Act amended the Federal Food Drug and Cosmetics Act (FDCA) and the patent laws in several important respects. The objective behind the legislation was to balance the competing interests of the patent owners of a drug patent in obtaining partial restoration for time lost on the patent term due to regulatory delays in the Federal Drug Approval on one hand and the interests of generic drug companies in conducting pre-market testing of a generic drug before the expiration of the term of the patented drug on the other hand. In order to balance the conflicting interests, the Hatch Waxman Act introduced a process for a new drug application (NDA) that extended the patent term after the grant of FDA approval and created an abbreviated new drug application (ANDA) process for generic drug developers to obtain FDA approval. Section 156 provides for the extension of the term of a patent for compensating the time lost in FDA approval and, Section 271(e)(1) allows generic companies to enter the market as soon as the patent term on the drug expires by permitting them to conduct tests for FDA approval during the patent term.
The Hatch Waxman Act was passed by the US Congress in response to the decision of the Court of Appeal for the Federal Circuit in *Roche Products Inc v Bolar Pharmaceutical Co Inc* where the court held the competitor's use of a patented drug for the purpose of FDA approval of its generic version to be infringing in spite of the fact that the generic drug was not to be marketed until the expiration of the patent term. This decision closed the door on tests conducted by generic companies during the patent term, which would have enabled entry into the market immediately upon expiration of the patent term. The decision effectively extended the term of a patent by allowing the patent holder an extra period of exclusivity during the period of federal approval of the generic companies. In order to neutralize this anomaly, the US Congress responded with the Hatch-Waxman Act and provided an exemption for the use of a patented invention if it is reasonably related to the development and submission of information under federal law. Section 271(e)(1) deals with the exemption provisions. It provides 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 federal law. Section 271(e)(1) deals with the exemption provisions. It provides 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 or veterinary biological products.’

The section provides an exemption from infringement to generic companies for the development of information to obtain FDA approval. The scope and extent of the exemption under Section 271(e)(1) have been extensively litigated in the light of the phrases used in it.

**Scope of the Term Patented Invention**

The phrase ‘patented invention’ as it appears in Section 271(e)(1) refers to an invention that requires federal approval before entry into the market. The scope and extent of this phrase was the subject of controversy before the US courts. It was contended that the phrase should be limited to the inventions covered under Section 156 as Section 271(e) was passed along with Section 156 in the Hatch-Waxman Act. Section 156 provides for extension of the patent term if the product has been subject to a regulatory review period before its commercial marketing or use. Litigants contend that Sections 156 and 271(e)(1) were passed at the same time with the same objective, and, therefore, inventions that are covered under Section 271(e)(1) should be limited only to inventions covered under Section 156. The United States Supreme Court, however, rejected this argument by holding that the patented invention of Section 271(e)(1) is defined to include all inventions and not just drug related inventions covered under Section 156.

The decisions of the Federal Circuit have interpreted Section 271(e)(1) to extend to all patented inventions whether or not covered under the scope of Section 156. In *Abtox Inc v Exitron Corp*, the Federal Circuit held that a plasma sterilizer, a class II medical device, would fall under the scope of patented invention under Section 271(e)(1) even though Section 156 does not cover it. In *Chartex Int'l*
PLE v M D Pers Prod Corp\textsuperscript{12}, the patent owner alleged that the defendant's female condom, which was either a Class I or II medical device, was not within the scope of Section 271(e)(1) because neither a Class I nor Class II device is eligible for a patent extension under Section 156. The Court rejected this argument finding that although Sections 156 and 271(e)(1) of Title 35 were passed as Sections 201 and 202 of the Drug Price Competition and Patent Term Restoration Act of 1984, the Court cannot read limitations from one section into another. Therefore, the term 'patented invention' as used under Section 271(e)(1) has been construed to mean all inventions or discoveries and is not limited merely to those inventions that are covered by Section 156.

Scope of the Phrase ‘Uses Reasonably Related to the Development and Submission of Information Under a Federal Law’

To be exempted from infringement, the use, sale, offer to sell, manufacture or importation of a patented invention under Section 271(e)(1) must be ‘solely for uses reasonably related to the development and submission of information under a Federal law’. There has been some litigation about the scope of activities that would be reasonably related to development and submission of information for FDA approval. In Abtox Inc v Exitron Corp\textsuperscript{13}, the court opined that the statute does not look to the underlying purposes or attendant consequences of the activity as long as the use of the patented invention is reasonably related to FDA approval. It further opined that the intention behind the use or availability of alternative uses for the information is irrelevant to the inquiry.

In Intermedic Inc v Ventritex Inc\textsuperscript{14}, the Court stated that the phrase ‘reasonably related’ (to development of information for the FDA) as used in Section 271(e)(1) reflects that the Congress used this phrase to communicate its intention that the courts give parties some latitude in making judgments about the nature and extent of the otherwise infringing activities they would engage in as they sought to develop information to satisfy the FDA. It further stated that the Congress did not intend that a party should lose the exemption simply because it turns out, after the fact, that some of that party's otherwise infringing ‘uses’ either failed to generate information in which the FDA was interested or generated more information than turned out to be necessary to secure FDA approval. The test is whether it would have been reasonable, objectively, for a party in defendant's situation to believe that there was a decent prospect that the ‘use’ in question would contribute to the generation of kinds of information that was likely to be relevant in the process by which the FDA would decide on approving the product\textsuperscript{15}.

Both the decisions point out that exemption under Section 271(e)(1) would be available if the activities are aimed at producing information for federal approval. Whether the use results in such information or not is not an issue at all. The intention behind the use would not be considered.

Future Infringement

It was argued in a few cases that the
use of a patented invention in the process of acquiring Federal approval would infringe the patent after the federal approval is granted. In *Telecommunications Pacing Systems Inc v Ventritex Inc*\textsuperscript{16}, the patent holder sued for a declaratory judgment alleging infringement based on the activities of a defibrillator manufacturer during clinical trials arguing that the defibrillator would infringe the patent once FDA approval was granted. The court held that the declaration of future infringement is neither warranted nor proper for activities under Section 271(e)(1). The same decision was handed down by the court in a suit for declaratory judgment in *Amgen Inc v Hoechst Marion Roussel Inc*\textsuperscript{17} involving a suit for infringement of several patents covering a recombinant form of erythropoietin.

With regard to exemption for Federal approval, Section 271(e)(1) exempts generic companies from infringement if the company uses a patented invention for the purpose of getting FDA approval. The patented invention that is used by the company could be any invention or discovery that falls under the scope of patentable subject matter under Section 101\textsuperscript{18}. The intention behind the use of the patented invention would not be considered by the courts, it is enough if the use is capable of producing information for FDA approval. The exemption, therefore, can be considered to be very wide covering a wide range of activities, which are capable of producing information for FDA.

**Exemption for the Purpose of Idle Curiosity and Philosophical Use**

The US patent statute does not have an express provision dealing with exemption from infringement liability for research. It was first formulated by Justice Story in *Whittemore v Cutter*. In that case, J Story held that it is not infringement if a patented invention is used for merely philosophical experiments, idle curiosity or for ascertaining the sufficiency of the machine to produce its desired effects. The philosophy behind such an exemption was to help potential rivals to police the inventors by ensuring that the invention does what it claims to do, thereby reducing the number of invalid patents. Following Whittemore were the *Chesterfield v United States*\textsuperscript{20} and the *Finney v United States*\textsuperscript{21} cases. The courts in these cases without analysing the issue of research exemption on its merit merely held that it was not infringement because the alleged infringing acts constituted experimental use. The Chesterfield case involved patents over cobalt-nickel alloys, which were used by the government, and the Finney case involved the patented Velcro glove used by NASA for the training mission of Appolo XIV.

In *Sawin v Guild*\textsuperscript{22}, J Story affirmed his decision in Whitmore by saying, 'This court already had occasion to consider the clause in question, and upon mature deliberation, it has held that the making of a patented machine to be an offence, must be with an intent to use for profit, and not for the mere purpose of philosophical experiment, or to ascertain the verity and exactness of the specification.'

In *Ruth*\textsuperscript{23}, the court following the proposition of law stated by J Story, held
that experimental use of patented machine without authority from patentee for the sole purpose of gratifying philosophical taste or curiosity or for instruction and amusement does not constitute infringing use. Making or using patented invention merely for experimental purposes without any intention to derive profits or practical advantage, is not an infringement. The person who supplied mining and milling machines in this case to the Colorado School of Mines for experimental use was held to be not a contributory infringer as the use of the machines was experimental and was therefore exempted from infringement action.

In Bonsack Mach Co v Underwood, the court while dealing with a suit in equity by the Bonsack Machine Company against J B Underwood for alleged infringement of certain patents for cigarette machine held that the making of an infringing machine merely as an experiment was not an actionable infringement, but if it was to be used for the purpose of selling the patent under which it was made, it would then be regarded as used for profit, and therefore a suit would lie for infringement.

In Embrex, the plaintiff Embrex was a licenecee for a patent on a method of inoculating birds against disease by injecting vaccines into a specified region of the egg before hatching. After obtaining a licence for this patent, Embrex started manufacturing machines to perform the claimed method. SEC started experimenting with these devices and the in ovo method of injecting vaccines. The court refusing the experimental use exception argument held infringement as the tests were performed for commercial purposes, regardless of whether they led to the sale of competitor’s injection machines.

The most recent case on this point is the decision of the Federal Circuit in Duke v Madey. The Federal Circuit, in consonance with the cases decided earlier, reiterated in this case that research exemption is only available for idle curiosity and philosophical use. This case involved the use of a laser patent by the University of Duke, which was owned by Madey, a research professor who worked at the University of Duke. The court held that University of Duke’s activities fell outside the scope of research exemption as it attracted federal funds for its research and as it was involved in quality research projects making the research activity conducted on the laser patent directly related to legitimate business objectives.

The above mentioned cases suggest that the law of research exemptions as it stands today in US is strictly non-commercial and is limited to idle curiosity or philosophical use, which means that the use of a patent by non-profit organizations including universities would not be exempted just on the basis of their non-profit status, if the use helps in furthering their legitimate business activities. After the Duke decision, it is difficult to think of any use, which would be exempted from infringement.

**Research Exemptions in India**

The patent system in India is governed by the Patent Act of 1970, which has been amended in 1999 and subsequently amended in 2002, in consonance with
India’s obligations under the WTO regime. The patent regime in India is still in its infancy and the courts have not got an opportunity to expound the law as there has been very little or no litigation in this area. Like United States, India also has two types of research exemptions, one is the exemption for submitting data to a drug regulatory authority and the second one relates to exemptions for research and experiment.

**Research Exemption for Submitting Data to a Drug Regulatory Authority**

The Patent (Amendment) Act 2002 expressly provides that it would not be infringement if a patent is used for generating data for submission to an Authority of India, if required under any law. This exemption has been framed to enable generic companies to get marketing approval in order to launch biologically equivalent drugs as soon as the patent term on the drug expires.

Section 107A clause (a) provides that any act of making, distributing, using or selling a patented invention would not be an infringement if such activity is solely for uses reasonably related to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use or sale of any product. Though the amendment is primarily aimed at generic companies, the exemption is not limited to activities of generic companies. It extends to all activities relating to development and submission of information under any law, not only to laws relating to drug approval process.

Interestingly, the section provides exemption to meet requirements under foreign laws also. Such an exemption is too broad and unwanted because companies and inventors would get an opportunity to exploit a patented invention under the pretext that their activities are required under some remote law in a remote country.

**Research Exemption for Research and Experiment**

The law relating to research exemptions has been codified under Section 47 of the Patent Act. It reads: The grant of a patent under this Act 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, by any person, for the purpose merely of experiment or research including the imparting of instructions to pupils. Section 107 which provides defenses in suits for infringement states under clause (2) that any suit for infringement of a patent by the making, using or importation of any machine, apparatus or other article or by the using of any process or by the importation, use or distribution of any medicine or drug shall be a ground for defense if such making, using, importation or distribution is in accordance with any one or more of the conditions specified in Section 47.

Section 47 allows the use of a patent merely for research or experiment including instruction to pupils. Any activity, which falls under the scope of Section 47,
shall not constitute an act of ‘infringe-
ment’ as per Section 47 and Section 107. 
As there is a dearth of legislative history 
and case law on this section, the scope it 
covers is not clear. Though this provision 
has not been litigated up till now, there is 
a high probability of litigation because 
liberalization of the Indian market has 
brought in multinational companies, 
which consider patents as one of their 
most important business strengths. Such a 
situation would necessitate a probe into 
the scope of the exemption through inter-
pretation of the words used in the statute. 

Section 47 has been drafted in such 
general language that a very wide inter-
pretation is possible. The section uses 
terms like experiment or research, which 
are not defined anywhere in the statute. 
As they are not defined, the terms would 
be interpreted as per their ordinary mean-
ing. The term ‘experiment’ has been de-

Hypothesised Fact Pattern 

The hypothetical fact pattern and 
the explanations that follow, clearly illus-
trate the differences in the law relating to 
research exemptions in USA and India. 

Company X is a pharmaceutical com-
pany based in USA having two branches 
in India. It specializes in drugs for genetic 
disorders of the eye. It has patents in In-
dia and USA over two compositions for 
the treatment of retinitis pigmentosa, a 
genetic eye disorder in human beings. 
Company Y, a pharmaceutical company 

Result 

In the US Court: Company Y and Uni-
versity Z would be liable for infringement 

of the patented invention for instruction 
and education without liability.

Though the phrase ‘experiment or re-
search including imparting of instructions 
to pupils’ is qualified by the term 
‘merely’ which means that an activity can 
qualify under this section only if it is lim-
ited to experiment or research or instruc-
tion to pupils it would not make a differ-
ence because such usage would not limit 
the extensive scope of the terms ‘re-
search’ and ‘experiment’.

Hypothetical Fact Pattern 

The hypothetical fact pattern and 
the explanations that follow, clearly illus-
trate the differences in the law relating to 
research exemptions in USA and India. 

Company X is a pharmaceutical com-
pany based in USA having two branches 
in India. It specializes in drugs for genetic 
disorders of the eye. It has patents in In-
dia and USA over two compositions for 
the treatment of retinitis pigmentosa, a 
genetic eye disorder in human beings. 
Company Y, a pharmaceutical company 

Result 

In the US Court: Company Y and Uni-
versity Z would be liable for infringement 

of the patented invention for instruction 
and education without liability.

Though the phrase ‘experiment or re-
search including imparting of instructions 
to pupils’ is qualified by the term 
‘merely’ which means that an activity can 
qualify under this section only if it is lim-
ited to experiment or research or instruc-
tion to pupils it would not make a differ-
ence because such usage would not limit 
the extensive scope of the terms ‘re-
search’ and ‘experiment’.
because the research activities of Y and Z would fall outside the scope of research exemptions under US patent law. US patent law provides exemptions for research only if the research activity is in furtherance of philosophical use or idle curiosity. In this fact pattern both Company Y and University Z did not use the patent only for philosophical use or idle curiosity and had a legitimate business interest, thus making their use ineligible for research exemption.

Company Y used the patent to research on developing a new therapy for genetic disorders, which was with an aim to further its business in drug therapies for genetic disorders. University Z's research on the patented genes were in furtherance of its legitimate business interests to attract good students to join the university and to get funding for research from government or private agencies. As uses of the patented genes by Company Y and University Z were in furtherance of their business interests they fall outside the scope of research exemptions under US patent law, making them liable for patent infringement in the United States Court.

In the Indian Court: Company Y and University Z might not be liable for infringement under the Indian Patent law because the scope of research exemptions is very broad in India. Under the Indian patent law, any use of the patented invention for research or experiment would not be infringement irrespective of the motive and final outcome of the research. Though Company Y and University Z used the patented genes for research in order to devise a therapy for a genetic disorder in furtherance of their legitimate business interests, such use would fall within the scope of research exemptions because the Indian patent law does not consider motive behind the use as long as such use is meant for research and experiment. Therefore, in an Indian court, Company Y and University Z might not be liable for infringement as their activities fall within the scope of research exemptions in patent law.

**Conclusion**

There is great diversity in the law relating to research exemptions in USA and India. On one extreme is USA which provides a very narrow research exemption in the form of idle curiosity and philosophical inquiry and on the other extreme is India with a very broad research exemption, exempting any kind of research and experimental activity irrespective of whether the activity is commercial or not.

The potential danger of a narrow exemption under the US law is that it impedes legitimate research activities, which would otherwise help in progress of science. On the other hand, the danger of a broad research exemption is that it dilutes patent protection and takes away the incentive to create, invent and invest. The best law on research exemption lies somewhere in between the two where enriching the public domain would not inhibit the incentive system of the patent law.

A model law on research exemption for the purposes of drug approval should clearly define the limits of such exemption to drug approval. The exemption would be ideal if it is confined to specific activities that aid in acquiring information
necessary for drug approval under a particular law. The precise drug approval law should be clearly mentioned in the provision to avoid confusion. It would be advisable to limit the exemption to the drug approval within the country as patent protection is territorial and rights under it would be undermined if exemption is allowed with regard to a foreign law.

With regard to general research exemptions the ideal law should take into account two factors: one, the commercial/non-commercial motive of the researcher and/or two, improvement of the subject area of technology. Due weight should be given to both the factors while framing or amending research exemption laws. A non-commercial research activity should be exempted as long as it does not interfere with the legitimate interests of the patentee or the normal exploitation of the patent. As the aim of any patent system is to foster development of science and technology, an exemption in favour of a research activity, which improves the subject area of technology would be reasonable. Whatever factors might be considered, an ideal research exemption law should effectively promote progress of science and technology by balancing patentee’s rights with the interest of the society in free circulation of ideas.

References
1 (1984 Act), 98 Stat 1585
3 Id
4 35 USC Section 156 (2003)
5 35 USC Section 271(e)(1) (2003)
6 733 F.2d 858 (C.A.Fed.,1984)
7 35 USC § 271(e)(1) (20(3)
9 Id
10 
11 
12 
13 
14 Id
15 Id
16 982 F.2d 1520 (C.A.Fed. (Cal.), 1992)
18 35 USC Sec. 101 (2003)
19 Whittemore v Cutter, 29 F. Cas. 1120 (C.C.D.Mass.1813)
20 Chesterfield v United States, 159 F. Supp. 371, 375-76 (Ct. Cl. 1958)
21 Finney v US , 538 F.2d 347 (Ct.Cl., 1976)
22 Sawin v Guild, 21 F.Cas. 554 (C.C.Mass. 1813)
24 Bonsack Mach Co v Underwood 73 F. 206 at 210 (C.C.N.C 1896)
25 Embrex Inc v Service Engineering Corp. 216 F. 3d. 1343
26 Madey v Duke University 307 F. 3d 1351 (Fed. Cir. 2002)
27 Section 107A, Indian Patents Act, 1970, as amended in the year 2002
28 Section 47(3), Indian Patents Act, 1970