CHAPTER 10

GENETIC PATENTS
AND
RESEARCH EXEMPTIONS

A patent grant gives the patent holder exclusive rights to make, use, sell, offer for sale and import the invention. Only the patent holder can exercise patent rights to the exclusion of others. If any one exercises the rights granted to the patent holder without his authorization, that person would be liable for infringement. However, if the person exercises the rights of patent holder for research or experimental purposes, he would not be liable for infringement. Use of a patented invention for experiment or research is considered to be a valid defense for patent infringement. It is called as 'Research exemption' or 'Experimental Use exception'. The objective of the exemption is to allow researchers to carry out research without any liability. It is believed that exemptions for research are as important as the rights of the patent holder in order to push the limits of science and technology. The balance between the exclusive rights of the patent holder and exemptions for research, which allows researchers to work on patented inventions without authorization, is believed to be critical for promoting the progress of science and technology. The scope and extent of research exemptions varies from country to country based on the social, economic and ideological conditions. As research exemptions allow the public to use the patented invention without infringement liability, they create a defacto public domain for purposes of research. That means that an invention is in the public domain for performing research activities and in the patent domain for other activities. So, the scope of research exemptions determines the size of public or patent domains in a country and differences in laws of different countries results in variances in sizes of public and patent domains.

Research exemptions can be broadly 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 or for experimental use.

USA

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[991]. 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[992]. 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[993]. Section 156[994] provides for the extension of the term of a patent for compensating the time lost in FDA approval, and, Section 271(e)(1)[995] 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 U.S. Congress in response to the decision of the Court of Appeal for the Federal Circuit in Roche Products, Inc. v. Bolar Pharmaceutical Co. Inc.[996], where the court held the competitor's use of a patented drug for the purpose of FDA approval of its generic version to be

[991] (1984 Act), 98 Stat 1585
[992] Patents on New Drugs and Inducing Infringement, March 13, 2003, Hollie Baker Hale and Dorr LLP | Publications http://www.haledorr.com/publications/pubsdetail.asp?ID=98153132003
[993] Id.
[994] 35 USC Section 156 (2003).
[995] 35 USC Section 271(e)(1) (2003).
[996] 733 F.2d 858 (C.A.Fed.,1984).

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)[997] 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.'

Though the objective of the section was to provide an exemption from infringement to generic companies for the development of information to obtain FDA approval, the phrase "patented invention" as it appears in Section271(e)(1) has been held by the US Supreme Court to include all inventions and not just drug related inventions[998].

In order to get exemption under the section, the Federal Circuit held that The test is whether it would have been reasonable, objectively, for a party claiming the exemption to believe that there was a decent prospect that the use of the patented invention would contribute to the generation of kinds of information

[997] 35 USC § 271(e)(1) (20(3).
[998] Eli Lilly v. Medtronics, 496 U.S. 661, 665 (1990).

that was likely to be relevant in the process by which the FDA would decide on approving a product[999]. The court in another case held that the underlying purposes or attendant consequences of the activity would not be considered as long as the use of the patented invention is reasonably related to FDA approval[1000]. It further opined that the intention behind the use or availability of alternative uses for the information is irrelevant to the inquiry[1001].

In the case of Integra, the US Supreme court expounded the scope of uses reasonably related to FDA approval under section 271(e)(1)[1002]. Integra Life sciences I, Ltd., and the Burnham Institute, (hereinafter collectively called 'Integra') owned five patents related to the tripeptide sequence Arg-Gly-Asp, known in single-letter notation as the "RGD peptide." which peptide promotes cell adhesion by attaching to <<alpha>>V<<beta>>3 integrins, receptors commonly located on the outer surface of certain endothelial cells[1003]. Merck KGaA provided funding for angiogenesis research conducted by Dr. David Cheresh at the Scripps Research Institute (Scripps) and supplied RGD peptides for the purpose[1004]. On receiving positive results from the project, Merck decided to guide one of its RGD peptides through the regulatory approval process in the United States and Europe[1005]. In furtherance, Merch shared the research on RGD peptides with the National Cancer Institute (NCI), which agreed to sponsor clinical trials[1006]. Integra filed a patent-infringement suit against Merck, Scripps, and Dr. Cheresh (hereinafter collectively called 'petitioners') and the petitioners took the defense of research exemptions under section 271(e)(1)[1007]. By granting certiorari, the US Supreme Court held petitioners to be not liable as their activities amounted to uses reasonably

[999] Abtox, Inc. v. Exitron Corp. ,122 F.3d 1019,1030 (C.A.Fed. (Mass.),1997)., 1029-30.
[1000] In Intermedics, Inc. v. Ventritex, Inc. , 775 F.Supp. 1269,1280 (N.D.Cal.,1991).
[1001] Id.
[1002] Merck KGaA v. Integra Lifesciences I, Ltd., 125 S.Ct. 2372, (U.S.,2005).
[1003] Id. at 2377.
[1004] Id. at 2377.
[1005] Id.
[1006] Id.
[1007] Id.

related to development and submission of information for obtaining FDA approval though they formed part of pre-clinical studies.

The Supreme Court started its analysis by stating that it is apparent from the statutory text that § 271(e)(1)'s exemption from infringement extends to all uses of patented inventions that are reasonably related to the development and submission of any information under the FDCA, which necessarily includes preclinical studies of patented compounds that are appropriate for submission to the FDA in the regulatory process[1008]. It further stated that there is simply no room in the statute for excluding certain information from the exemption on the basis of the phase of research in which it is developed or the particular submission in which it could be included[1009].

The court observed that the Congress did not limit Section 271(e)(1)'s safe harbor to the development of information for inclusion in a submission to the FDA; nor did it create an exemption applicable only to the research relevant to filing an ANDA for approval of a generic drug but it exempted from infringement all uses of patented compounds reasonably related to the process of developing information for submission under any federal law regulating the manufacture, use, or distribution of drugs[1010]. It stated that properly construed, section 271(e)(1) leaves adequate space for experimentation and failure on the road to regulatory approval: At least where a drug maker has a reasonable basis for believing that a patented compound may work, through a particular biological process, to produce a particular physiological effect, and uses the compound in research that, if successful, would be appropriate to include in a submission to the FDA, that use is reasonably related to the development and submission of information under federal law[1011]. It went on to state that the use of a patented compound in experiments that are not

[1008] Id. at 2380.
[1009] Id.
[1010] Id. at 2382.
[1011] Id. at 2383.

themselves included in a submission of information to the FDA does not, standing alone render the use infringing[1012].

The court observed that the relationship of the use of a patented compound in a particular experiment to the development and submission of information to the FDA does not become more attenuated (or less reasonable) simply because the data from that experiment IS left out of the submission that is ultimately passed along to the FDA[1013]. It pointed out that many of the uncertainties that exist with respect to the selection of a specific drug exist as well with respect to the decision of what research to include in an IND (Investigational New Drug Application) or NDA (New Drug Application)[1014]. Based on its analysis the court concluded that the use of patented compounds in preclinical studies is protected under section 271(e)(1) as long as there is a reasonable basis for believing that the experiments will produce the types of information that are relevant to an IND or NDA[1015].

The Integra decision cleared all doubts relating to the scope of activities covered under research exemption for federal approval under US patent law. As per the decision all experiments that might in one way of the other be remotely connected to the FDA approval process would fall within the scope of research exemptions as they are considered to be reasonably related.

[1012] Id.
[1013] Id.
[1014] Id.
[1015] Id. at 2384.

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[1016]. 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.

In Ruth[1017], 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 intent to derive profits or practical advantage there from is not 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[1018], 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

[1016] Whittemore v. Cutter, 29 F. Cas. 1120 (C.C.D.Mass.1813).
[1017] Ruth v. Stearns Roger Mfg. Co. 13 F. Supp. 697 (D. Colo 1935)
[1018] Bonsack mach. Co. v. Underwood 73 F. 206 at 210 (C.C.N.C 1896)

under which it was made, it would then be regarded as used for profit, and therefore a suit would lie for infringement.

In Embrex[1019], the plaintiff Embrex was a licensee 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 license 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[1020]. 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 involves 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

[1019] Embrex Inc. v. Service Engineering Corp. 216 F. 3d. 1343
[1020] Madey v. Duke University 307 F. 3d 1351 (Fed. Cir. 2002)

activities. After the Duke decision, it is difficult to think of any use, which would be exempted from infringement.

EUROPE

The European Patent Convention provides that a European patent will grant to the patent holder the same rights, as he would get by acquiring a national patent[1021]. It further provides that any infringement of a European patent will be dealt with by national law[1022]. So, the EPC does not contain any provisions dealing with research exemptions or experimental use, which is a defense against infringement. This part of the chapter deals with UK patent law as an example of research exemptions in Europe.

Research Exemptions in UK

In UK, the exemptions for patent infringement are provided under section 60 of the Patent Act. The section provides that an act would not be infringement, if

(a) It is done privately and for purposes which are not commercial,

(b) It is done for experimental purposes relating to the subject matter of the invention[1023] and

(c) if the act relates to conducting test or trial for getting generic drug approval.

Private and Non-commercial acts

[1021] Article 64(1), Convention On The Grant Of European Patents (European Patent Convention) of 5 October 1973 text as amended by the act revising EPC of 17 December 1991 and by decisions of the Administrative Council of the European Patent Organisation of 21 December 1978, 13 December 1994, 20 October 1995, 5 December 1996 and 10 December 1998.
[1022] See Supra, Article 64(3).
[1023] Patents Act of 1977 as amended in 2005 at http://www.jenkins-ip.com/patlaw/pa77.htm#s60 visited on Jan 24th, 2005.

This exception can be equated to the philosophical use and idle curiosity exception under the US Law. The scope of private acts that are exempt from infringement have been discussed in Smith Kline and McDonald cases[1024]. The court held in these cases that the private purposes exemption is limited to acts carried out by a person for his own use[1025]. The court proposed a two-stage test, which includes determining (1) whether an act is private or public; and (2) whether the act has or has not been carried out for commercial purposes[1026].

If an act is private and has been carried out for a non-commercial purpose, it will be exempt from infringement. As per this exception any private act, which is not commercial is exempt from infringement liability. So, if a person uses a patented invention for his personal purposes such as gaining knowledge or learning, etc, his acts would not amount to infringement.

Use for Experimental purposes

Use of a patented invention for experimental purposes is exempt from patent infringement under the UK Law. An activity would be exempt from patent infringement if the experiments were directly related to the patented invention. While discussing about the scope of experimental activities that would be exempt from infringement liability, the court in Monsanto v Stauffer, described the parameters of the experimental purposes exemption by stating that trials carried out in order to discover something unknown, or to test an hypothesis, or even in order to find out whether something which is known to work in specific conditions would work in different conditions or even perhaps to see if the experimenter could manufacture commercially in accordance with

[1024] Smith Kline and French Laboratories Ltd v Evans Medical (1989) F.S.R. 513 and McDonald v Graham (1994) R.P.C. 407.
[1025] Id.
[1026] Fiona Bor, Exemptions To Patent Infringement Applied To Biotechnology Research Tools, E.I.P.R. 2006, 28(1), 5-14. (2005) citing Smith Kline and French Laboratories Ltd v Evans Medical (1989) F.S.R. 513 and McDonald v Graham (1994) R.P.C. 407.

the patent, are fairly regarded as experiments[1027]. So, any activity, which results in probing into unknown aspects of an invention or verifying the making and working of an invention, would be considered experimental. Unlike in the US, the UK patent law does not exempt clinical trials for purposes of getting drug approval from the scope of patent infringement.

Acts for getting Drug Approval

The UK Patent Act provides for exemptions to use a patent for purposes of getting drug approval. Section 60 of the Patent Act was amended in 2005 to make way for this provision. [Section 60(5)(i), UK Patent Act, 1977 as amended in 2005.] It provides that an act done in conducting a study, test or trial which is necessary for and is conducted with a view to the application of requirements for marketing approval of generic medicines would not amount to patent infringement. [Id.] The provision allows a person to use the patented invention for conducting tests or trials in order to acquire information for getting approval for marketing generic drugs. Any activity towards that end would not be considered to be an act of infringement. The

INDIA

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 is 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.

[1027] Fiona Bor, Exemptions To Patent Infringement Applied To Biotechnology Research Tools, E.I.P.R. 2006, 28(1), 5-14. (2005) citing Monsanto v Stauffer (1985) R.P.C. 515 at 542, CA.

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[1028]. 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 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[1029]. It reads as follows: "The grant of a patent under this Act shall be subject to the condition that -... 3. 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 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,

[1028] Section 107A, India Patent Act, 1970 as amended in the year 2002.
[10291029] Section 47(3), India Patent Act, 1970.

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 "infringement". 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 interpretation of the words used in the statute.

Section 47 has been drafted in such general language that a very wide interpretation 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 meaning. The term 'experiment' has been defined by the American Heritage Dictionary as "A test under controlled conditions that is made to demonstrate a known truth, examine the validity of a hypothesis, or determine the efficacy of something previously untried" and the term 'research' has been defined as " Scholarly or scientific investigation or inquiry." As the legislature has expressly chosen words like "research" and "experiment" which have a wide scope and which encompass every scholarly or scientific activity, the court would most probably decide that it is the intention of the legislature to create a broad exception to patent liability. The phrase 'including imparting of instructions to pupils' allows universities and other educational institutions to make use of the patented invention for instruction and education without liability.

Though the phrase 'experiment or research 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 limited to experiment or research or instruction to pupils it would not make a difference because such usage would not limit the extensive scope of the terms 'research' and 'experiment'.

Public/Patent domain analysis

The aforementioned matter elucidates variations in research exemption law in USA, UK and India. The scope of research exemptions arising out of experimental activity is very broad in UK and India and it is very narrow in the United States. While UK provides exemptions from infringement for any experimental activity related to the invention and India provides for exemptions for any research or experiment or instruction to pupils, the US patent law provides exemption for only activities that amount to philosophical use or idle curiosity. So, the size of the limited public domain created by the UK and Indian patent laws is much larger than the size of the public domain created by USA. Among UK and India, the size of public domain created by India is larger than UK.

With regard to research exemptions arising out of the use of the patented invention for obtaining approval from the government patent law in all three countries is based on the same principles. Among US, UK and India, the scope of the exemption is broader in India than in USA an UK as Indian provisions are written in very broad terms as opposed to US patent law, which is limited to drug based inventions. So, the public domain created by exemptions based on government approval is larger in India than in USA and UK.

The scope of research exemptions is very important for gene based inventions because the effect of the incentives offered by the patent system would not work if there is no balance between the defacto public domain created by research exemptions and the patent domain. If the research exemptions are

too broad, a genetic invention, which was the result of long term efforts, would fall in the hands of the public to the detriment of the patent holder. On the other hand if the exemptions are too narrow, the public would not get an opportunity to work on the genetic invention for genuine research purposes as a result of which progress would be stalled.

For example, if a patent is granted over a gene sequence coding for a protein X in all three countries, a researcher in a USA will be able to use only to understand the sequence of the gene and method of isolating it and he cannot do anything in addition to that. On the other hand, a researcher in UK or India can use it in any sort of research and gain commercial benefit after developing a commercializable product based on it. As long as his product does not include the gene sequence, he is not liable to the patent holder in any way. The scope of research exemptions in USA on one hand and UK and India on the other are on two extremes. While USA does not allow any kind of research, which has even minimal commercial implications, UK and India allow all research either it includes a commercial angle or not.

As a result of the variations in the size of public domains in different countries, latitude for performing experimental and trial activity without infringement liability varies. A researcher sitting in India or UK would be able to do wider research in a particular area without any liability than a researcher sitting in USA. So, the size of de facto public domain is large in India and UK than in USA. Both have adverse consequences and a middle path has to be struck. The implications of such scopes are discussed in Chapter 11.