Patent laws and research exemption imperatives – do scientists have enough freedom to operate?†

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The genesis and evolution of patent regime could largely be attributed to the felt need of providing sustained stimulus to the human mind to pursue intellectual and creative endeavours. A researcher's freedom on carrying out research on a patented invention, however, has certain limitations according to the patent laws. Experiments which do not have any commercial intent are usually exempt from the ambit of patent infringement. However, some courts of law differ from the defendants on viewing what is purely experimental and what is not. On the contrary, experiments that have some commercial connotation would attract infringement action by the patentee. A few patent litigations involving research and development carried out on drug molecules have resulted in the birth of 'Bolar provision' and its evolution. However, there are other court cases which have dwelled upon the nature of an experimental activity, the initial objectives of the invention, the purpose of preclinical studies carried out, and the likes. This article is an attempt to examine the current provisions concerning research exemption in the patent acts in Europe, India and the US, and a few critical court decisions on the subject matter, in order to gain some insights on the freedom of a researcher to conduct research and developmental studies on patented inventions.

Keywords: Bolar provision, freedom, patent laws, research exemption.

TO provide for an enabling environment where the intellectual pursuits of the human mind are constantly stimulated has been central to the formation and evolution of the patent systems across the world. As research and development (R&D) domains progressively became more investment-intensive, a need for stimulating investments was recognized as a major enabler for inventive endeavours and hence the patent system. Thus, the patent system should provide enough impetus for scientists and researchers to pursue innovative research, the end result of which could be a new product useful to the society or a known product that is much cheaper. Such impetus also inherently implies freedom for a scientist-inventor to carry out research on anything that could result in an invention.

Public-funded research organizations in more and more countries are awakening to the impact of patents in the way research work is managed, intellectual property (IP) is generated and also the importance of obtaining intellectual property rights (IPRs). A recent review on research use of patented knowledge among Organization for Economic Co-operation and Development (OECD) countries points out concern over the escalated effect of patents on scientific enquiry because of increased pressure on public research organizations to patent inventions arising from their research[1]. However, does a scientist have sufficient space to conduct research exactly on anything in his wish list? Do the patents acts of different countries come in the way of his freedom of carrying out R&D? Are there situations where he is barred from doing a certain type of developmental activity? These questions have become pertinent now, as indicated by some recent court cases.

A scientist, out of sheer curiosity, may further carry out experiments on a patented product or use a patented device for carrying out experiments. To this extent, the research work being purely experimental to satisfy curiosity, the patent rights may not come in the way of the scientist. One can find exemption provisions to address experimental use for purely scientific purposes in the patent acts of different countries. However, patenting is predominantly a commercial activity. Hence there are a few issues to be addressed. First, what is meant to be 'purely scientific' at one point of time may not be 'purely scientific' at a later point of time. Secondly, what is

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purely scientific is subjective and a variable dependent on legal precedents. Further, there are a few instances where experiments employing a patented invention resulted in an altogether new product outside the scope and realm of the patented invention. In such cases, research goes beyond the 'purely experimental' dimension and assumes commercial connotation. In such situations, the patents acts could come in the way, limiting the 'absolute' freedom of a researcher. The issue has been a major bone of contention, specifically in the pharmaceutical sector.

There are acts other than patents laws that may necessitate changes in the patents acts. Thus, these have an indirect influence on the scientists' freedom to engage in R&D. A typical situation is development of generic version of patented drug molecules during the life of a patent, where regulatory acts concerning new drugs have played a critical role. Multilateral agreements have a major say in the area, as recently evidenced by the TRIPS-triggered changes in the patents acts world over, more so in developing countries.

'Research exemption' in this article essentially covers any research work being carried out on a patented article or a process, when the patent is in force. Broadly, research exemption could be of two types: (i) Purely scientific in nature. (ii) Developmental research aimed at generating experimental data with a commercial objective.

The latter is popularly called 'Bolar provision' in patent parlance, the term deriving its name from the famous 'Bolar vs Roche Pharmaceuticals' case in the US in 1984. This article is an attempt to bring out the issues before a researcher in the light of some of the patent litigation cases in the US and elsewhere.

TRIPS and research exemption

Historically, different specific activities, including research exemption, have been a part of the patents acts of different countries. These exemptions would have played a significant role in formulating Article 30 of TRIPS. The Article permits limited exceptions to the exclusive rights of a patent-holder provided such activity does not prejudice the patent-holder's legitimate interests or does not conflict with normal exploitation of the patent. Such exceptions could include research use of a patented technology.

The Indian situation

As mentioned earlier, The Indian Patents Act, 1970, since it became effective in 1972, has had provision for providing immunity to certain acts, including making and using the patented article or using a patented process for educational and research purposes. This provision continues to hold good as such and is covered in Section 47(3) of the amended Act, as is currently in force.

The Patents Act, 1970, as amended and currently in force, has the Section 107A (ref. 2), covering the Bolar provision. According to the Section, 'any act of making, constructing, using, selling or importing a patented invention solely for uses reasonably related to 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, sale or import of any product shall not to be considered as infringement of patent rights'.

The US scenario

In the US, this exemption is also technically called the §271(e)(1) (ref. 3) exemption or Hatch–Waxman exemption and is popularly known as 'safe harbour'. The statute exempts the acts of making, using, offering to sell or selling, and importing to the US a patented invention, from infringement, provided such an act is solely for the purpose of development and submission of regulatory data under any Federal law concerning drugs or veterinary biological products.

Situation in the UK

According to section 60(5) of UK Patent Act (ref. 4), experimental use of patented invention would not constitute an infringement if: (a) the research work is carried privately and for the purposes that are not commercial, or (b) the research work is carried out for experimental purposes relating to the subject-matter of the invention.

A famous test case for this provision was the Monsanto Co vs Stauffer Chemical Co. case of 1985. Monsanto owned a patent for herbicide and claimed infringement by the latter that had carried out some trials making use of the said herbicide, with a view to obtain safety clearances by regulatory authorities. The Court of Appeal held[5] 'that mere field trials to establish efficacy of a product for regulatory approval do not qualify for the exception to patent infringement set out in section 60(5)(b) of the Act, and that the purpose of the defense is to "encourage scientific research while protecting the legitimate interests of the patentee" '.

The patents acts of the UK and other member states of the European Union (EU) are subject to regulation by the European Patent Convention (EPC)[6]. Research for experimental purposes on patented inventions does not constitute infringement according to the EPC[6]. This obviously does not cover research with commercial intent. In 2004, in order to bring in the Bolar-type provisions, the EU introduced a new exemption in article 10(6) of Directive 2004/27/EC, amending Directive 2001/83/EC. This provision provides exemption from patent infringement

for conducting studies and trials that are required to apply for a marketing approval in a member state in respect of a generic, pseudogeneric or biosimilar product. According to this directive, the UK amended its Patent Act in October 2005 and the Bolar-type provision was incorporated in the subsection (i) of Section 60(5) (ref. 7).

According to the European Patent Convention, a European Patent once granted, takes the effect subject to the national laws of the member countries. This is as per the clause (1) of the Article 64 European Patent Convention. Article Clause (3) further clarifies that any infringement of such a European Patent is dealt under the national law. As the national laws take effect, the scope and effect of any EPC provision in a member country would be as per the corresponding provision in the respective national patent law and would be subject to court interpretation thereof.

Court cases in the recent past

In order to understand how these provisions legally affect research on patented inventions, it would be interesting to revisit some relevant and important court cases. A few select court cases that defined the scope of exceptions to the patent rights, including research exemption, are discussed below.

Roche products vs Bolar Pharmaceutical case

This perhaps is the landmark case in patent litigation history concerning research exemption on more than one count. First, it brought out clear distinction between experimental use of patented products for purely scientific nature and experimental use of the same with commercial intent. Secondly, the case also brought out an apparent conflict between the patent laws and the US Federal Food, Drug and Cosmetic Act.

The issue at stake was whether using a patented (drug) product by a third party to generate experimental data towards meeting the requirements of the regulatory approvals (such as Food and Drug Administration (FDA)) amounted to infringement of patent rights. Roche obtained a US patent covering the chemical compounds 'Flurazepam HCl' (ref. 8) in January 1967. The compound was to become the active ingredient in the Roche's successful brand, 'Dalmane', a prescription sleeping pill.

Bolar, another pharma company, intended to submit an Abbreviated New Drug Application (ANDA) to the US–FDA, for a drug containing the same active ingredient, for marketing immediately upon the expiry of Roche's patent. An ANDA requires a generic producer simply to show that it has a bioequivalent product of an earlier FDA-approved product. Thus ANDA facilitates speedy approval by the FDA. About six months before the expiry of the patent, Bolar imported a small quantity of Flurazepam HCl and used it to prepare dosage-form capsules, to obtain stability data, dissolution rates, bioequivalency studies, and blood-serum studies, for establishing the bioequivalence according to the ANDA. Roche responded by filing a suit for patent infringement at the District Court of the Eastern District of New York, USA. The question before the Court was, whether the use of a patented drug without a valid license during the life of the patent was actionable, even when the use is limited to testing and evaluation of the drug for the purposes of meeting FDA approval requirements. The District Court held that it did not, owing to the 'experimental' nature of Bolar's works.

The Court of Appeal for the Federal Circuit, however, disagreed with Bolar's argument and observed that 'experimental-use exemption' was narrowly construed by the District Court and should not apply to experiments which have a commercial objective. The Court of Appeal considered, 35 USC Sec. 154 that stated 'whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefore, infringes the patent'. Accordingly, experimental use conducted for FDA-approval purposes had a commercial objective and hence could not take place prior to the expiry of a patent. The court found the activity to be infringing[9].

The case brought out an important policy question of whether an apparent conflict between the FDA Act and the patent laws, did not favour a patentee by effectively increasing the patent term, through providing 'residual' patent rights, beyond the term of the patents. Assuming that such experiments for regulatory purposes could only be initiated after the expiry of the patent, the patentee would enjoy a *de facto* patent-term extension, thus giving monopoly rights till the time such regulatory experiments by a competing generic company were completed, the regulatory application was moved, examined by the FDA and finally drug approval was granted. As a response to the policy anomaly brought out by the Roche vs Bolar judgement, the US patents laws were amended to include a statutory experimental-use exemption. This is codified in 35 USC 271(e)(1)).

Madey vs Duke University case

In the case that concluded in 2002, the US Federal Court (ref. 10) dramatically limited the scope of the 'purely experimental use' exception, which had tremendous implication on the research works carried out by the public-funded institutions in the US. The issue at stake was whether Duke University's act of using two laser devices patented by John Madey, one covering a 'microwave electron gun'[11] used in connection with free electron lasers and the other being 'free-electron laser oscillator for simultaneous narrow spectral resolution and fast time resolution spectroscopy'[12], was infringing.

Madey held these patent rights before he moved from Stanford University to Duke University as Director of the Free Electron Laser Laboratory. Subsequently, Duke University terminated his tenure. However, as the University continued to make use of his patented equipment, he sued it for infringing his patents. The University defended on two grounds: (i) the research work being carried out was subject to government license, i.e. 'the use of a patented invention by the Federal Government is not an act of patent infringement' according to 28 USC 1498; and (ii) the act was immune to infringement under the experimental-use exception. As far as the first point was concerned, the District Court held that as the patents were being used by Duke University to fulfil government contracts, there cannot be any claim on patent infringement. The only recourse was an action seeking for compensation before the Court of Claims. On the second point, the District Court directed Madey to show that the University act did not meet the experimental exception.

In 2002, both decisions were reversed by the Federal Circuit on appeal by the plaintiff. On the government license issue, it held that there was insufficient evidence before the court to conclude whether in the present case the work carried out under a government contract was 'for the United States' as required by 28 USC 1498(a). More importantly, on the experimental-use issue, Duke University's argument that 'as a non-profit educational establishment its activities were inoculated against patent infringement as long as they were solely for research, academic or experimental purposes', was found not acceptable by the Federal Circuit. The court cited Roche vs Bolar and other cases to hold that although an experimental-use exception as crafted in the 19th century continued to exist, it was a narrow one for example 'to satisfy idle curiosity or for strictly philosophical enquiry'. The court went on to state that 'regardless of whether a particular institution or entity is engaged in an endeavour for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defence'. Moreover, the court observed that the non-profit status of the user was something not determinative.

The case emphasized two major points. First, that the 'purely scientific' enquiry was a narrow concept in the context of IPR, taking into account the possible commercial implication at a future point. Secondly, there existed a thin line between for-profit and not-for-profit entities.

Merck vs Integra Life Sciences

Patent laws-related issues concerning submission of data for new drug approval purposes to the FDA were illustrated in the Roche vs Bolar case in the US. The relevant section concerning this is 35 USC §271(e)(1). But does the section apply to use of a patented invention in preclinical research, the results of which may not be a part of the application submitted to the FDA? If the purpose of the experimental use of a patented compound was to identify a potential drug candidate *in vitro*, is such an experimental use immune to infringement according to this section? The Merck vs Integra, originally initiated by Integra 1996 that ended up in a US Supreme Court judgement of 2005 on appeal by the former, dwelled basically on these issues. In the dispute, at stake was whether Merck's conductance of preclinical studies in collaboration with Scripps Research Institute, on peptides covered in five US patents owned by Integra, qualified for exemption according to the Bolar provision.

The Integra patents covered claims directed to methods of synthetic cell attachment-promoting peptides, both *in vitro* and animal cells, altering cell-attachment activity, and claims directed to the composition of matter comprising pure peptides (called 'RDG' peptides) having affinity towards cell attachment, and hence called integrins. Four of the patent applications were filed during 1985–1987 and granted during 1988–1991. Recognizing the potential of the integrins for their use as tumour inhibitors, and in anticipation of the expiry of the patents in 2006–2007, Merck funded Scripps for angiogenesis research in 1988. In the course of his research, Cheresh, the Principal Investigator at Scripps, discovered that it was possible to inhibit angiogenesis by blocking the $\alpha\beta 3$ integrins on proliferating endothelial cells. In 1994, Cheresh succeeded in reversing tumour growth in chicken embryos, making use of the RGD peptide provided by Merck. Scripps submitted a detailed proposal for expanded collaboration with Merck in February 1995. The proposal set forth a three-year timetable in which to develop 'integrin antagonists as angiogenesis inhibitors', beginning with *in vitro* and *in vivo* testing of RGD peptides at Scripps in year-one and culminating with the submission of an Investigational New Drug (IND) application to the FDA in year-three.

As a licensing negotiation for using RDG peptides apparently fell through, in 1996, Integra filed a patent-infringement suit against Merck and Scripps in the District Court for the Southern District of California. Integra alleged that the petitioner wilfully infringed and induced others to infringe Integra's patents by supplying the RGD peptide to Scripps, and that Scripps infringed the same patents by using the RGD peptide in experiments related to angiogenesis. Integra sought damages from Merck and a declaratory judgement against the Principal Investigator at Scripps, as well as Scripps. The District Court considered whether the FDA safe-harbour provision (or the Bolar proviso) applied to the dispute. The District Court could not find sufficient evidence to link the experiments with the FDA submission and review as required by subsection (e) of 35 USC §271. The court held (ref. 13) that

Merck was liable for infringing four of the Integra patents. On appeal by Merck, the Federal Circuit Court, while affirming the District Court decision, observed that experiments in question conducted by Scripps were partly of the nature of general biomedical research to identify new compounds and hence the use was outside the safe harbour provision.

The court considered the fact[13] that Merck–Scripps did not supply any experimental data to the FDA for approval purposes. Instead it identified the best drug candidate to be subjected to future clinical testing under the FDA processes. Hence research was not 'solely for uses reasonably related to' clinical testing for the FDA. The court concluded that the exemption 'does not globally embrace all experimental activity that at some point, however attenuated, may lead to an FDA approval process'. It went on to say that 'basic scientific research on a particular compound, performed without the intent to develop a particular drug or a reasonable belief that the compound will cause the sort of physiological effect the researcher intends to induce, is surely not "reasonably related to the development and submission of information" to the FDA'.

Merck appealed before the Supreme Court, which, however, set aside the Federal Circuit Court's decision. Citing an Eli Lily case as a precedent, the court said, '§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 FDA, and that "this necessarily includes preclinical studies of patented compounds that are appropriate for submission to the FDA in the regulatory process" '[14]. The court held that §271(e)(1) was sufficiently broad to include preclinical *in vitro* and *in vivo* studies intended to obtain information on the pharmacological, toxicological, pharmacokinetic and biological qualities of the drug in animals.

CoreValve vs Edwards Life Sciences

There is a plethora of patent litigation cases so far as R&D involving patented drugs, pharmaceuticals and biotechnology inventions is concerned. This aside, what happens to research exemption provisions as applied to other technology disciplines? The experimental use defence according to Section 60(5)(b) of the UK Patents Act, 1977, was pleaded in the above case in the English High Court, and concluded in January 2009. The case pertains to a European Patent owned by Edwards claiming an artificial heart valve EP0592410 (UK 0592410) that is deliverable by a technique of catheterization. The prime claim of the patent was directed to a valve prosthesis device for implantation into the body.

CoreValve, had been supplying percutaneously delivered replacement heart valve, which was challenged by Edwards. CoreValve, while unsuccessfully trying to invalidate the Edwards patent before the court, also claimed that in any case their product was different from what was claimed in the Edwards patent. The English Court observed that as against a stent with a 'generally cylindrical shape', as covered by the claims of the patent, the CoreValve product had a stent that was 'bulbous' at one end, which was potentially advantageous, and hence there was no infringement.

More importantly, as a second line of defence, CoreValve had argued that it had been supplying the product for experimental purposes relating to the subject matter of the invention. The court examined the 'experimental use' defence issue and considered the following facts. (1) CoreValve supplied its product only to selected hospitals in Europe as part of a clinical programme referred to as the 'Registry'. (2) One of the key aims of the Registry was to 'investigate and confirm the safety and efficacy of the procedure and valve function on a long-term basis and in a large number of patients'.

The judge held that any statement of principle relating to this defence should involve the consideration whether the immediate purpose of the transaction in question was to generate revenue. The court examined the following purposes of CoreValve's activities in question: (i) to establish confidence in their product in the marketplace; (ii) to generate immediate revenue of a substantial character, and (iii) to gain information about clinical indications, and, possibly, future modifications to be made to the physical structure of the device in light of the experience.

The question before the judge was relative weightage of the purposes[15]. The judge, found that purpose (iii) was not their 'preponderant purpose'. Ultimately the court found that CoreValve's information gathering under purpose (iii) was not sufficient to constitute a defence under §60(5)(b). Thus the experimental use defence failed. This means that CoreValve would have been in trouble, had the device been found to be identical to the patented valve.

Thus, it is a clear indication that in order to be in the safe shelter of 'experimental use' exemption, the objective of a research project should remain 'purely experimental'. If there is only one of the many objectives and other objectives have some commercial aspects, the courts may assess the overriding objective in a different way than a defendant would.

Bayer Corporation vs Union of India and CIPLA Pharmaceuticals

In the ruling by the Delhi High Court[16] in August 2009, the core question addressed was whether there was any link between the laws concerning granting of a marketing authorization and the IP laws, better known as 'patent linkage'. The court ruling also re-emphasized the 'Bolar'

proviso as provided in the Patents Act, 1970, reiterating that scientists are immune to any infringement arising out of conducting experiments on a patented drug for the purposes of obtaining market approvals for its generic versions.

In the petition, Bayer Corporation, the petitioner, prayed for restraining the Drug Controller General of India (DCGI) from grant of drug license to CIPLA for license to manufacture, sell and distribute its drug 'Soranib'. Both the Union of India and CIPLA were the respondents. Bayer allegations were based on the following grounds: (i) that Soranib was a spurious drug according to Section 17B of the Drugs and Cosmetic Act, 1940; (ii) that the Controller would be exceeding his jurisdiction and deciding in contravention of Chapter IV provisions of the Drugs and Cosmetic Act, 1940, if the application for marketing license was processed, and (iii) that the grant of license shall be in derogation to the Patents Act, 1970, according to the rights enjoyed by a patentee according to Section 48 in respect of their Indian patent for 'Sorafenib tosylate' (patent linkage issue).

Bayer owned the Indian patent 215758 granted in March 2008. The patent application pertaining to this patent had 13 January 1999 as the effective date of filing and IN/PCT/2001/00799/MUM as application number[17]. The patent has life till 2019. It covered Sorafenib tosylate, a kidney cancer drug compound, branded as Nexavar by the company. Earlier, in November 2008, Bayer won the case in the Delhi High Court, which prevented the DCGI from giving CIPLA a marketing authorization for the drug, after Bayer complained this would infringe its patent. CIPLA later on went back to the court challenging the verdict, putting forward the following arguments: (i) that the grant of drug regulator approval by the DCGI could not by itself amount to patent infringement; (ii) that the existence of patent infringement could not be assumed merely because a patentee states so, but had to be clearly established before a court of law according to the infringement provisions of the Patents Act, 1970, and (iii) that the acts of making, using, offering for sale, etc. for the purposes of filing of a drug regulatory application before the DCGI did not constitute an infringement according to Section 107A of the Patents Act, 1970 (Bolar proviso).

The court examined, basically the following two issues: (i) Whether a combined reading of the Drugs and Cosmetic Act, and the Patents Act, 1970, leads to the conclusion that no marketing approval can be granted to applicants for drugs or formulations where others were patent owners. (ii) Whether the CIPLA drug was a 'spurious drug' according to the Drugs and Cosmetic Act, 1940.

On the former issue, the court found the objectives of the two acts to be distinctly separate. Linking marketing approval issues with patent rights would potentially undermine Bolar or exemption to early experimental use of patented drugs that encourages quick access to post-patent markets for generic medicines. The court also found the basis of the second issue to be flimsy. Dismissing the petition, the Court observed that the case was 'speculative foray and an attempt to "tweak" public policies through court mandated regimes. The petitioner doubtless is possessed of vast resources and can engage in such pursuits. Yet often these attempts, even unsuccessful in the ultimate analysis, achieve short term goals of keeping out competitors, through interim orders'.

Conclusion

The question whether research works being carried out on patented inventions are infringing third-party IPRs is subject to the patent laws of the country concerned. Often, laws other than the patent laws have ramifications on the issue. Further, the very nature of R&D in science and technology is such that it is often difficult to assess whether a particular R&D project had commercial intent at its conception stage. If the above court cases are any indication, the border between pure scientific research and that with commercial intent has become rather blurred.

While examining the experimental use of patented inventions, the mandate of the institution where the research is carried out – whether for-profit or not-for profit, academic or otherwise, etc. – is certainly a consideration before the court of law. However, the court may look beyond this when dealing with the crux question of whether IP rights of a patentee were hurt, the damages caused in the process and the balance of convenience aspects thereof.

In the context of the 'Bolar' provisions, an interesting question is at what point of the life of a patent, a generic competitor could initiate research activity to generate data towards generic drug approvals? This question came up briefly in the Merck vs Integra case. Could the time taken for generating required data and obtaining drug approval by a generic company be more or equal or less than the time taken by the patentee for the same activity? It may not be unreasonable to assume that the generic company should take much less a time than the patentee, as the only fact that has to be established before the drug approval authority is that the generic drug in question is equivalent to the patented drug. However, this issue has not so far been addressed by the courts.

It may be re-emphasized here that provisions akin to Bolar apply to inventions related to pharma and modern biotechnology sectors. In all other sectors, for a research work on a patented invention to be exempt from the purview of patent infringement, it needs to be established that such work is purely scientific in nature, before the court system. The issue whether a particular project had some hidden commercial objective at the beginning, is a

difficult matter to be addressed in the courts of law. Though much depends on the research exemption provisions in the patent laws of a country and the litigation precedents in that country, a clear way out seems to be entering into appropriate agreements with a patentee or the assignee, such as research agreement, before commencing any research on a patented invention. Research institutions could leverage such agreements for generating new IPs and could use such IPs for negotiating back with the patentee or its assignee, for mutual advantage. This way, the hardship of a researcher in the context of freedom to carry out research is minimized.

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