Chapter 5
ENFORCEMENT AND COMPULSORY LICENSING OF BIOTECHNOLOGY PATENTS

Universally biotechnology patents are offered protection for a term of twenty years. Protection is offered to the inventor as a reward to his efforts in inventing something, which is useful to the society. Patent monopoly gives an exclusive right to the inventor to use, make and exploit the invention. During the term of the patent it is only the patent owner who only can use or exploit the invention. Without his authorization no one can use or exploit the invention. If any body uses or exploits the invention without the authorization of the patent owners he does infringe the patent for which patent law offers remedies. The patent owner may institute an infringement suit to enforce his patent. The question of enforcement arises at the instance of infringement of the rights of the patent owner. However as far as enforcement of biotechnology inventions is concerned the international conventions like Paris convention or the TRIPS agreement does not say anything specifically. International convention leaves the enforcement of inventions to the respective states. Therefore it the respective forum state which must enforce a patented invention as per the municipal law.

Enforcement of biotechnology inventions in the United States

The patent law of US provides for certain mechanism for the purpose of the enforcement of patented inventions. The patent law states that till the expiry of the period of a patent except the owner no other person can use or exploit the invention. If any person without the authorization of the owner happens to use the invention he does infringes the patent. The patent law provides for certain remedies to the patent owner against infringement. Remedies may be made available in the form of injunction, damages or compensation. In case of infringement a suit may be filed in a District Court, from the decision of the District Court appeal may lie to the Courts of Appeals for the Federal Circuit. From the decision of the Court of Federal Circuit again an appeal may lie

849 See: TRIPS: article: 27.
to the Supreme Court of America. Therefore it is pertinent here to know what exactly constitute infringement of a patented invention.

**What does constitute infringement?**

Any unauthorized use or exploitation of a biotechnology invention does constitute infringement of the patent on such invention. The infringer is liable to the patent owner. The following acts do constitute infringement.  

1) Making, using, exploiting in any manner a patented biotechnology invention.
2) Selling, offering to sell patented biotechnology invention.
3) Importing a patented biotechnology invention.

**Exceptions to infringement:**

There are certain exceptions to infringement. Certain acts though involve unauthorized use or exploitation a patented biotechnology invention does not constitute infringement. The following acts even if involves unauthorized use of the patented invention do not constitute infringement.

1) Government use or exploitation of any biotechnology invention
2) Using the invention for research or education purpose.
3) Making, using, offering to sell or selling within the United States or import into the United States a patented biotechnology invention solely for uses reasonably related to the development and submission of information under a Federal Law.

**Defenses in case of infringement:**

The alleged infringer has got certain defenses, which he can contend for in infringement suits. There may be counter claim alleging the invalidity of the patent by the alleged infringer. In general the following are the defenses that could be contended by the alleged infringer of a patented biotechnology invention.

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852 But the Government can use or exploit any biotech invention without the authorization from the patent owner subject to the payment of compensation. In such cases no infringement suit can lie against the government. Government use of any biotech invention is subject to the payment of compensation to the inventor.
853 See: U.S.C 271: Infringement of patent, sub clause (e). However making, using, offering to sell or selling within the United States or import into the United States a patented biotechnology invention like a new animal drug or veterinary biological product which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology or other biotechnology methods or processes involving site specific genetic manipulation does constitute infringement of a patented invention.
1. The patent owner is not entitled to the patent as he is not the original inventor or he has got no right to apply for patent or he got the patent through misrepresentation or fraud or patents owners rights have exhausted.\textsuperscript{854}

2. The patented biotechnology invention does not meet the requirement under the United States patent code.

3. The patented invention is not novel as it was in existing in the public domain prior to the grant of the patent\textsuperscript{855} hence the patent is invalid.\textsuperscript{856}

4. The patented invention does not amount an inventive step and is obvious in the light of the prior art.

5. Specification of the invention provided in the patent application does not define the invention properly and it does not enable a person skilled in the art to reduce the invention to practice.\textsuperscript{857}

6. The method disclosed by the inventor to practice the invention does not set out the best mode of practicing the invention.\textsuperscript{858}

7. The alleged infringer or the defendant acting in good faith actually reduced the subject matter to practice and commercially used at least one year before the effective filing date of the patent involved in the issue.\textsuperscript{859}

8. The patent owner did not exploit the invention or he is not exploiting the in a way to satisfy the needs of the public and the products of the patented invention are not available to the public at affordable prices.

9. Use of the invention is for research or education purposes

10. Use of the invention is for public purpose and authorized by the government.

11. The rights of the patent owner have exhausted and the rights are no more protected.

In the recent past law courts have decided infringement cases of patents involving biotechnology inventions. Where the courts happened to discuss and evaluate the actions

\textsuperscript{854} See: U.S.C See: 273 Defense to infringement based on earlier inventor.

\textsuperscript{855} U.S.C 282: Presumption of validity defenses.

\textsuperscript{856} See: U.S.C: 273: Defense to infringement based on earlier inventor.


\textsuperscript{858} Ibid.

\textsuperscript{859} See: U.S.C See: 273 Defense to infringement based on earlier inventor.
of alleged infringement of biotechnology patents and possible defenses there under. In most of the biotechnology infringement cases defendants’ counter claim the invalidity of the patents. The *Regents of University of California V. Oncor*\(^660\) sets out the best example where invalidity of the patent is successfully taken as defense in an infringement suit. The invention was a method for improving the specificity of in situ hybridization process frequently used to bind and identify the specific location of a targeted DNA\(^661\) sequences on chromosomes. Once hybridization takes place, location of the target DNA can be determined.

The invention was significant in the light of the fact that earlier the in situ hybridization process was not yielding exact result. The probes that had been used to identify targeted DNA sequences were binding non-targeted sequences; hence there was no specificity. The inventors improved the specificity of the hybridization process by using non-labeled probes to bind non-targeted DNA sequences along with labeled probes, which will bind targeted sequences. The use of non labeled probes were blocking the labeled probes from binding to non-targeted DNA sequences there by bringing specificity to the hybridization process in yielding exact results. The patentees instituted an infringement suit against the Oncor a Maryland Corporation that began selling and marketing the blocking DNA invention patented by the patentee.\(^662\)

Oncor counterclaimed the invalidity of patent on the ground of failure to describe the best mode of practicing the invention. They contended that the inventors did not disclose that single stranded probes could be used in hybridization. Infact the inventors stated and informed the U.S. Department of Energy that use of single stranded probes would improve the efficiency and specificity of the process. The defendants further contended that inventors did not disclose the use of Rnase (an enzyme used to degrade or cut RNA) treatment as the preferred method of practicing though have used Rnase as standard

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\(^{660}\) See: U.S. patent No. 5,4,77,841 (841 patent)


\(^{662}\) See generally Jennifer James Tressa Jennifer James, Implications of the best mode requirement on patents involving biotechnology, Houston Business and tax Law Journal, University of Houston Law Center, 2001-2002
protocol in the experiment they described in the application. The Court disregarded Oncor’s arguments regarding single standard probes by holding that inventors statement that simple standard probes are the way to go is only a supported argument, which does not state the mind of the inventor at the time of application.

The Court viewed that inventors’ state of mind was not signaling the use of single standard probe, hence best mode description of their invention does not require the use of single standard probe. Further the inventors contended that Rnase was not needed all the time and could be removed from the in-situ hybridization. Hence using of Rnase is not compulsory therefore it is not the best mode for the patented process. But the Court did not accept the University’s contention and held that even if Rnase is not needed in all cases it is necessary to describe the exceptions in order to understand the invention properly and also to fulfill the best mode requirement. This case illustrates how invalidity could be claimed as a defense in case of infringement suit and at the same time it demonstrates how the inventor could rebut invalidity. Further the case details how court considers the infringement and invalidity claims in case of biotechnology inventions. The validity of patents is presumed under the patent law. The person claiming the invalidity of the patent shall prove the invalidity.

Again In Evans medical V. American Cyramid Plaintiffs brought infringement suit against defendants for infringing their patent. The invention patented was a procedure for the development of a cellular antigen, which could be used in vaccines for Bordetella pertussis (B-pertussis) otherwise known as whooping cough. Defendants counterclaimed the invalidity of the patent on the ground of not satisfying the best mode requirement. Defendants contended that BBOS was the best antibody for the purification process described in the application and the plaintiffs have concealed the best mode of practicing the invention by not describing it.

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863 See: U.S.C 282 Presumption of validity: defenses
865 An antibody is a protein produced by an animal in response to a foreign element, such as B. Pertussis antigen
Initially in the patent application the inventor described the antibody that they used as “a monoclonal immunoglobulin specific for Adenglate cyclase associated protein (ACAP). In fact the antibody actually used was “BBOS”, a specific antibody belonging to the ACAP class. Later after five years from the date of filing patent application the inventors made a biomaterial deposit. Further after two years from the date of making the deposit they amended the patent application in order to comply with the requirements. The inventors argued that biomaterial deposit that they made afterwards and amendments made to patent application before the grant of the patent has satisfied best mode requirement therefore the patent is valid.

Defendants argued that inventors know that BBOS was the best antibody suitable for the process they described in the invention. Hence they intentionally concealed the best mode of practicing the invention. Court rejected defendant’s argument that the inventors’ concealed use of BBOS an antibody used in the invented process. The Court held that deposit of the biomaterial used for the invention after the filing of the patent application but before the grant of patent, is sufficient to satisfy the best mode requirement. The defendants did not have any intention to conceal the information since they have deposited the material. The Court concluded that the deposit of the invention and the amendments made to the patent application before the grant of the patent fulfilled the requirement of best mode, hence the patent is valid. The court further held that defendants by exploiting the invention without the permission of the inventor have infringed a valid patent. Eventually the infringer was made liable to the patent owner for violating monopoly of the patent owner over the patented invention. If the patent invalid or if the patent suffers from certain lacunas such as lack of novelty, inventive step, utility, insufficient description, failure to disclose best mode of practicing the invention or failure to deposit the invention no action can be instituted for infringement. Besides the patent is obtained unlawfully or if the patent owner has got no right to apply for patent no action can be instituted against infringement.
Further in *Mycogen V. Monsanto* a biotechnology patent infringement case had come to the forefronts of the courts. The invention was a method to modify the structure of a gene in order to express a protein responsible for insect death. The inventors i.e., Mycogen Company intended to insert this gene into plant cells so that the intended plant produces a protein which if eat by any insect causes its death. Inventors brought an infringement claim against defendants Monsanto who claimed to have invented the invention. The defendants counterclaimed invalidity and failure to satisfy the best mode by the inventors. The defendants argued that the Inventors have removed few sequences from the gene so as to make it function properly in producing targeted protein, when it is inserted in an intended plant. In particular a sequence of ATTTA (adenine, tenine, tenine, tenine, adenine) in the intended gene was removed by the inventor, which was preventing it from performing the intended function. But the inventor did not disclose the removal of ATTTA in the patent application. Hence the inventors have concealed the best mode of practicing the invention therefore the patent is invalid.

Plaintiffs contended that removal of ATTTA sequence is a natural consequence of the removal of AT sequence the best mode described in the application. The Court accepted the inventor’s testimony that removal of AT (adenine, tenine) sequence was the best mode and removal of ATTTA was a natural consequence of this approach. The Court ruled that defendants had not provided sufficient evidence to conclude that the inventors considered the removal of ATTTA sequence as the best mode of their invention. Court concluded that the inventors have not violated best mode requirement in not describing

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866 U.S patent No. 5,567,600 (600) patent, October 1996. See generally, Tressa Jennifer James, Implications of the best mode requirement on patents involving biotechnology, Houston Business and tax Law Journal, University of Houston Law Center, 2001-2002

867 The intention was to invent a plant capable or resisting the insects. Inventors intended to develop inbuilt mechanism in plants in order to avoid using of chemicals to control insects.

868 There are four nucleotides in the formation of every DNA, by name adenine, tenine, guanine and cytocine. As DNA structure is in the form of double helix each helix consist of two nucleotides. Adenine always pairs with tenine and guanine always pairs with cytocine. One helix will have base pair of adenine and tyenine (A&T); other one will have base pair of guanine and cytocine. A gene consists of such different sequences. In the instant case gene was having a sequence of ATTA, i.e., adenine, tenine tenine, tenine, adenine. See generally, David Kelly, THE FEDERAL CIRCUIT TRANSFORMS THE WRITTENDESCRIPTION REQUIREMENT INTO A BIOTECH-SPECIFIC HURDLE TO OBTAINING PATENT PROTECTION FOR BIOTECHNOLOGY PATENTS 2002, Albany Law Journal of Science and Technology 2002. See also, Leslie G. Restaino, Steven E. Halpern and Dr. Eric L. Tang, PATENTING DNA-RELATED INVENTIONS IN THE EUROPEAN UNION, UNITED STATES AND HAPAN: A
the removal of ATTTA sequences, as they have not had the state of mind to conceal it. Moreover the inventors did not consider it to be the best mode. The patent was held as valid and the suit against infringement was upheld in holding the action of the defendants as a violation of the patent.

Therefore the state of mind of the inventor at the time of filing the patent application is significant. If his state of mind signals a method as the best mode of practicing the invention which is described in the application, renders the patent valid irrespective of the fact whether the defendant considers the same as the best mode or not. On the other hand if the state of mind of the inventors considers a method, which is not disclosed in the application as the best mode, it does not fulfil the requirement and renders the patent invalid. The above discussed case laws illustrates how invalidity of the patent and the violation of written description, best mode could be counter claimed and taken as defense in case of infringement suits. However there is an assumption regarding the validity of the patent. Whoever claims the invalidity of the patent should prove the invalidity. The burden lies on the one who claims the invalidity to prove. If invalidity is proved in infringement suit the action of the defendants would not be considered as infringement of the patent.

**Infringement of biotechnology patents and Doctrine of equivalents**

The doctrine of equivalence plays an important role in deciding infringement cases. The doctrine says, where there is no substantial difference between the accused invention and the previously patented invention, the accused invention is equivalent to the patented invention and falls within the purview of the doctrine of equivalents and therefore infringes the patented invention. United States federal courts in many cases adopted this doctrine in deciding some important patent infringement cases. Courts while adopting this doctrine often apply function way result test, which examines whether the accused invention performs substantially the same function as the patented

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invention in substantially same way to obtain substantially the same result. Further courts use to examine the interchangeability between each element of the accused invention and its corresponding element in the patented invention. According to the doctrine if the accused invention is substantially similar to the patented invention and performs the same functions in the same way that the patented invention performs than the accused invention infringes the patented inventions.

For the first time In Genetech Vs Welcome Foundation Ltd the Court of Federal Circuit applied the doctrine of equivalence to decide the infringement of a biotechnology patent. The invention was a recombinant protein produced through recombinant DNA technology, which activates the protein tissue plasminogen and converts it to plasmin. The protein tissue plasminogen activator (t-PA) plays an important role in the dissolution of fibrin clots in the human body. The defendants were producing a modified protein through recombinant DNA technology with same activating function. The patentees filed infringement suit against the Welcome Foundation Ltd allegedly infringing the patented invention.

The Court of Federal Circuit found that the affinity to fibrin, the mode of binding to fibrin in the alleged invention, were not equivalent to the affinity to fibrin and the mode of binding to fibrin in the patent. While testing the defendants method with doctrine of equivalents the court observed that “though the defendants practiced recombinant DNA technology to produce the recombinant protein the same end product as produced by the patent holders, the methods to bind to the fibrin in order to produce the recombinant protein is different” and not equivalent to the method involved in the patent. Eventually it was decided that the practice of the invention of the defendants does not amount to infringement of the patent in the dispute. Therefore it can be inferred that as per the doctrine of equivalence when there is no substantial difference between the patented method and the accused method the practice of the accused method does not infringe.

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872 29 F.3d 1555 (Fed.Cir.1994)
infringes the patented method. However if there exists difference between the patented method and the accused method even though the end product is same and the technology is same the practice of the accused method does not amount to infringement of the patented method.

The presumption is that if a product is allegedly made out of a patented process it is deemed to be so when there is a substantial likelihood existing that the product was made by the patented process, and when the plaintiff in the suit for infringement was unable to determine the actual process involved in producing alleged products. In such circumstances the burden lies on the alleged infringer to prove that the patented process does not make the alleged product. In *Regents of University of California V. Eli Lilly* the University of California sued Eli Lilly for infringing its patent involving the use of recombinant DNA technology to produce human insulin. The defendants counterclaimed the invalidity of the patent on the ground of insufficient description of the invention, which did not enable a skilled person in the art to reduce the invention to practice.

The patent disclosed a method of the isolation, the synthesis and characterization of the rat insulin cDNA (Complementary DNA, a copy of the DNA). The patent also describes the method of obtaining the human insulin cDNA by using the same method used to obtain the rat insulin cDNA. But the inventors did not obtain the human insulin cDNA until nearly two years after the original application for the patent was filed. The inventors claimed the method to produce human insulin through recombinant technology and patent was granted for the same. The defendants contended that University of California did not adequately describe the human insulin cDNA in the patent application and they have neither isolated nor in the position of the cDNA coding for human insulin. The University of California argued that the disclosure of insulin cDNA in a single species insulin cDNA of rat in the instant case implies the possession of the insulin cDNA in all species within the genus of the disclosed species. Moreover the method to isolate the human insulin cDNA and rat insulin cDNA is same and further rat and human by and large possess same genetic structure. Therefore disclosure of the method to obtain

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875 119 F.3d 1559 (Fed. Cir. 1997)
rat insulin and the disclosure of the rat insulin cDNA is adequate enough to practice the invention on human beings to produce human insulin cDNA, hence the patent is valid.\footnote{David Kelly, \textit{THE FEDERAL CIRCUIT TRANSFORMS THE WRITTEN DESCRIPTION REQUIREMENT INTO A BIOTECH-SPECIFIC HURDLE TO OBTAINING PATENT PROTECTION FOR BIOTECHNOLOGY PATENTS}, \textit{Albany Law Journal of Science and Technology}, 2002}

However the Court of Federal Circuit held that description of human insulin cDNA involves the description of relevant structural and physical characteristics. Describing the method to obtain human insulin cDNA or describing the protein that cDNA codes would not necessarily describe the insulin cDNA itself. The isolation and characterization of rat insulin cDNA does not necessarily describe the characterization of human insulin cDNA though the method to obtain human insulin cDNA is same. Therefore it was held that the patent is invalid for inadequate description, which does not enable a person skilled in the art to practice the invention. Eventually the infringement suit was dismissed on the ground of invalidity of patent for failure to describe the invention sufficiently to enable a person skilled in the art to practice. The case illustrates how invalidity or insufficiency of description could be successfully taken as a defense in biotechnology patent infringement cases. A patent, which suffers from insufficient disclosure, cannot be maintained and no suit can be instituted against infringement of the same.

Further in \textit{Amgen Inc. V. Hoechst Marion Roussel, Inc.},\footnote{314 F.3d 1313 (Fed. Cir.2003) See 22 BLR 122 April 2003} The invention concerned recombinant technology related to the production of non-naturally occurring Erythropoietin (EPO) and to vertebrate cells and mammalian cells used in the production of EPO. The patent disclosed methods of producing EPO using hamster and monkey cells adequately described. Amgen claimed patent on the production of EPO using any vertebrate or mammalian cells including hamster and monkey.\footnote{John Behringer, Melody Wu, Haiyan Chen, \textit{AMGEN v. HOECHST MARION ROUSSEL; THE WRITTEN DESCRIPTION STANDARD IN BIOTECHNOLOGY PATENTS}, October, 2003} Amgen the owner of patents on the production of erythropoietin (EPO) filed an infringement suit against Hoechst.

The defendants counter claimed the invalidity of patents on the ground of inadequate written description of the invention. Defendants relaying on the decision of
the Eli Lilly\textsuperscript{879} contended that description of method of producing EPO in one or two species does not necessarily implied the description of method to produce EPO in all the mammals as claimed by the inventors. The inventors argued that practice of the invention in hamster and monkey, necessarily enables a person skilled in the art to practice the same on any mammal including human being. They contended that a method of producing EPO in monkey a genetically close relative of human being would definitely enable a person skilled in the art to practice the invention on human being.

The inventors cited two successful practices of the invention on two mammals (hamster and monkey) in claiming the patent on the production of EPO in any mammal. The District court in contrast to the Eli Lilly decision took the view that description of producing EPO in one or two species would imply the description of method of producing EPO in any mammals. The description of the invention in the patent application would enable a person skilled in the art to practice the invention on any mammal.\textsuperscript{880} The final inference was that the patent is valid and enforceable and the action of the defendant in using the invention without the permission of the patent owner has infringed the invention. This case sets out an illustration how the inventor could rebut the claims to the invalidity of the patent.

The decisions of the courts are causing confusion in Eli Lilly case the court declared the patent as invalid on the basis of inadequate description when by describing the method of producing insulin in rat the method of producing human insulin was claimed. But diverging from the Eli Lilly stand in Amgen the patent was held valid when by describing the method of producing EPO in hamster and monkey, the method of producing EPO in any mammal was claimed. In both the instances infringement of the patent was alleged, the defendants took invalidity of the patent on the ground of inadequate description. In the Eli Lilly case the patent was declared invalid and infringement suit was dismissed and in Amgen the validity of the patent was upheld implying the unsettled law on the biotechnology inventions. The law relating to biotechnology is not yet settled, until it is settled the stumbling voyage of biotechnology

\textsuperscript{879} See: 119 F.3d 1559 (Fed. Cir. 1997)

\textsuperscript{880} The Federal Circuit affirmed the decision of the District Court in part and dissented in part and remanded the case for further proceedings.
patent law continues. However it can be inferred from the present law on biotechnology that anybody without the consent of the patent owner if uses or exploits the invention in any manner does infringe the patented invention.

**Remedies for infringement of a biotechnology patent**

A patent owner is provided with remedies against infringement. The remedy is available in the form of a civil action in any District Court where the cause of action has arisen or where the parties do reside or have their palace of business. If one party is from different country suit could be filed in the District Court of Colombia. The respective courts where infringement suits have been instituted should give notice of the suit to the Director of USPTO informing the names and addresses of the parties involved in the suit and the patent involved in the dispute along with the patent number. Further soon after the disposal of the suit the decision of the court will be informed to the Director of the USPTO through notice.

The party instituting a suit against infringement of his patent can seek injunction against the infringer to stop him from further infringing the invention or damages in order to compensate the loss already suffered due to the alleged infringement. In case of compensation the compensation must not be less than a reasonable royalty that the inventor would have got if he happened to license or assign his invention. In *Pioneer Hi-Bred International V. Holden Foundation Seeds Inc* sets out the best example where remedy in the form of damages was awarded against infringement of a patented invention. Plaintiffs instituted a suit against infringement of their patent claiming damages as a compensation for the loss suffered due to the infringement. The plaintiffs were able to show that the seeds used by the defendants were likely to have been derived from its proprietary hybrid seed. The plaintiffs showed genetic similarities between the seeds used by the defendants and the patented seeds. The court was convinced that the action of the defendants in using the seeds derived from the patented seeds amounted to the infringement of the patented invention. The court

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881 See: 35 U.S.C 281 Remedy for infringement of patent.
882 See: U.S.C 290 Notice of patents suits.
883 See: U.S.C 283 Injunction
884 See: U.S.C 284 Damages
awarded huge damages to the inventors for the loss that they suffered due to the infringement of their patent.886

Infringement suits must be instituted within six years from the date of infringement otherwise no compensation or damages could be obtained. In actions involving the infringement of a patent the defendant asserting the invalidity of the patent shall give thirty days notice887 in writing to the patent owner. Further parties may even agree to settle the dispute through arbitration.888 In case of infringement of patent by the state or state instrumentalities a suit against infringement could be instituted in the same manner as instituting a suit against a private individual or company. State or state instrumentalities are not immune from liability arising under infringement.889

Biotech patents are enforced against infringement in order to guarantee the patent owner exclusive over the invention. Infringement violates the exclusive rights of the patent owner. In order to protect biotechnology inventions for a period of twenty years patent law provides for the enforcement of biotechnology patents. In case of infringement the infringer is made liable to the inventor for the damage caused to him. The patent owner can seek remedies against infringement in the form of injunction or damages. However using the patented invention for experimental or research purpose does not constitute infringement. Further use or exploitation of the invention by the government does also not constitute infringement and no remedies can be claimed.

**COMPULSORY LICENSING OF BIOTECHNOLOGY PATENTS IN U.S.A**

Compulsory license is defined to mean an authorization permitting a third party to make, use or sell a patented invention without the patent owners consent. If the patent owner does not exploit the invention or if he is unable to work on it in order to satisfy the needs of the society usually compulsory licensing of inventions may be sought by any interested party to exploit the invention. Unexploited or improperly exploited invention

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885 See: 35 F. 3d 1226, 31 USPQ 1385 (8th Cir. 1994)
887 See: 35 U.S.C 281 Remedy for infringement of patent
888 See: U.S.C 294 Voluntary arbitration.
could be exploited through the instrument called compulsory licensing. Compulsory licenses are generally authorized in the public interest, in the event of undesirable such as anti-competitive, non-working, high prices or blocking behavior by the patentee.\textsuperscript{890} Infact compulsory licensing ensures transfer of technology from the laboratory to the commercial market. Compulsory licensing lifts the invention from the patent owners monopoly by the government to the licensee. Any interested party can file an application to the government of India seeking compulsory license on any invention. The Government grants compulsory licenses to widen the distribution of and increased access to the patented technologies. Compulsory license may be granted against the payment of reasonable royalty to the patent owner as determined by the government.

The government prescribes the term of the compulsory license. In the United States of America from long time compulsory licensing has been controversial. The United States of America advocates for strong patent protection and in the way it strongly opposes compulsory licensing of patents. The view of the U.S is that compulsory licensing of the inventions harms the incentive for research and innovation. However with the coming into being of the TRIPS agreement now compulsory licensing of inventions remained unexploited is mandatory in the public interest. The agreement postulates for a comprehensive framework for the compulsory licensing of inventions. It states that member states may grant compulsory licenses in case of public emergencies in public interest.\textsuperscript{891} Meanwhile compulsory licensing of biotechnology inventions is on demand in the recent past. The present medical and pharmaceutical industry is vastly depending on the biotechnology in producing new and improved drugs. Biotechnology has brought forth new techniques to develop drugs. Many antibiotics, vitamin drugs are resulted due to research in biotechnology. Research in biotechnology resulted in the innovations of new medicines and drugs produced through utilizing natural antibiotics, pain killing hormones, enzymes and proteins having medicinal values produced in the body of living beings. Especially biotechnology inventions in the medical field are sought

\textsuperscript{889}See: U.S.C 296 Liability of states, instrumentalities of states, and state officials for infringement of patents.

\textsuperscript{890} Colleen Chien, Cheap drugs at what price to innovation: Does the Compulsory licensing of pharmaceuticals hurt innovation? Barkley technology law journal, summer 2003

\textsuperscript{891} See: Article 30 of the TRIPS agreement
for licensing and compulsory licensing by different commercial undertakings. In order to plug down the prices of drugs government use to interfere in the drug market by granting compulsory licenses for the production of drugs. As the biotechnology industry is promising to develop life saving drugs the attention of the society is much focused on biotechnology. As the government could interfere and grant compulsory license on any invention there is always scope for the grant of compulsory licenses in the field of biotechnology, which is promising to produce life saving drugs. Researches are going on to find some vaccine for cancer and AIDS. In African countries compulsory licenses were made available over AIDS vaccines. Biotechnology is helping the medical industry to develop new drugs by making available natural antibiotics and proteins having medicinal values. Therefore the innovations in the biotechnology field having diverse applications in different fields are in demand for licensing.

However compulsory licensing comes into picture only when the inventor is not exploiting the invention in order to make it available to the public or not offering the products of the invention at affordable prizes. Further before applying for compulsory license the applicant must exhaust all other ways to get the authorization from the patent owner to work on the invention. Biotechnology patents are granted in a way almost no different from the way of granting other patents. The basic difference is that the grant of patent on a biotechnology invention requires the deposit of the invention. Due to the complexities involved in biotechnology invention and the characteristics of such invention special attention is given while granting patents. The regular requirements under the patent law are liberally interpreted or even relaxed some times while granting patents on biotechnology inventions. Granting of biotech patents involves a through scientific investigation into the field of biotechnology. Therefore assistance from experts is being sought in processing examining and evaluating biotechnology inventions before the grant of patent.
ENFORCEMENT OF BIOTECHNOLOGY PATENTS IN THE EUROPEAN UNION

In the European Union EPC governs the law relating to biotechnology patents. However enforcement of biotechnology patents is left to the respective member states of the Union. The EPC states that national law shall deal with any infringement of a European patent.\textsuperscript{892} Neither the EPC nor the Directive on biotechnology inventions does provide for the enforcement of biotech patents. Both the above documents do not define infringement or specify what does amount to infringement. Even the TRIPS agreement does not deal with the enforcement of patents comprehensively. The TRIPS agreement lay down general guidelines for the enforcement intellectual property rights.\textsuperscript{893} Hence it is left to the respective states to enforce biotechnology patents as per the respective local law.\textsuperscript{894} In order to study the infringement and enforcement of biotechnology patents in the European Union here the national law of England one of the member states of the European Union and signatory to the EPC and the Directive is considered. The patent Act of England ensures fair and equitable judicial proceedings to adjudicate biotechnology

\textsuperscript{892} See: EPC Article: 64 Rights conferred by a European patent, see sub clause (3)
\textsuperscript{893} See: TRIPS Part III (Article: 41) Enforcement of intellectual property rights.
\textsuperscript{894} See generally, David Bainbridge, Intellectual property, Pearson education (Singapore) Ltd, Delhi, First Reprint, 2003, Pf. No. 392
patent infringement cases. The enforcement mechanism under patent law recognizes and follows principles of natural justice in adjudicating infringement suits.

**What does constitute infringement in Europe?**

The patent Act of England states that unauthorized use or exploitation, importing and disposing of a patented product or process amounts to infringement. However a patented biotechnology invention could be used for non-commercial and research purposes. State may also use or exploit the invention without the authorization or consent of the patent owner, in the public interest. The Act further states that a product substantially similar to the patented process infringes the patented product. A product substantially similar to the patented product is considered equivalent to the patented product and producing of such equivalent product without the authorization of the owner does constitute infringement.

**Who can sue against infringement?**

A suit may lie against the action of infringement with an intention to make the infringer liable to the patent owner. The patent owner or his assignee or licensee or legal representatives can sue against infringement of the patent. In case of infringement the burden lies on the patent owner to prove that; the action of the defendant does amount to infringement of his patent. If the patent owner happens to prove the infringement then the burden shifts to the defendant to disprove the alleged infringement of the patent. In case if the defendant claims the invalidity of the patent than the burden lies on him to prove that the patent is invalid. The validity of the patent is presumed in infringement cases therefore the defendant should prove the invalidity of the patent.

**Defenses in case of alleged infringement**

The alleged infringer can take certain defenses in infringement suits. In most of the infringement suits defendants counter claim the invalidity of the patent as a defense

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896 See: TRIPS Article: 31 others use without authorization of the right holder.
897 See: Qing Lin “A proposed test for applying the doctrine of equivalents to biotech inventions: The non-obviousness test” 74 Washington Law Review. 885
898 See: David Brain Bridge, Intellectual property, Pearson Education (Singapore) Ltd, Delhi, Firth edition, First Indian reprint, 2003, Pg. No. 403
899 See: Ibid Pg. No. 401
for the infringement. The possible defenses available for the defendant can be illustrated as follows.\(^{900}\) The following defenses are illustrative but not exhaustive, there could be other defenses apart from the below illustrated defenses, which the defendant may take up.

1) The patent owner is not entitled to the European patent as he is not the original inventor or he has got no right to apply for patent or he obtained the patent through misrepresentation or fraud or the rights of the patent owners have exhausted.\(^{901}\)

2) The invention does not meet the requirements under the EPC and the Directive as due to the reason that:
   a. The patented invention is not novel as it was in existing in the public domain prior to the grant of the patent\(^{902}\) hence the patent is invalid.\(^{903}\)
   b. The patented invention does not amount an inventive step and is obvious in the light of the prior art.
   c. The specification of the invention provided in the patent application does not define the invention properly and it does not best mode of practicing the invention to enable a person skilled in the art to reduce the invention to practice.\(^{904}\)

3) The alleged infringer or the defendant acting in good faith actually reduced the subject matter to practice and commercially used at least one year before the effective filing date of the patent involved in the issue.\(^{905}\)

4) The patent owner did not exploit the invention or he is not exploiting the in a way to satisfy the needs of the public and the products of the patented invention are not available to the public at affordable prices.

5) Use of the invention is for research or education purposes or use of the invention is for public purpose and authorized by the government.

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\(^{900}\) See generally, Ibid Pg. No. 403-409
\(^{901}\) See: U.S.C See: 273 Defense to infringement based on earlier inventor.
\(^{902}\) U.S.C 282: Presumption of validity defenses.
\(^{903}\) See: U.S.C: 273: Defense to infringement based on earlier inventor.
\(^{905}\) See: U.S.C See: 273 Defense to infringement based on earlier inventor.
6) The claims in the patent application are too broad.

Though in the European Union granting of patents on biotechnology invention has started in the recent past we have few case laws where infringement of biotechnology patents has come to the forefronts. In England the law courts in England happened to adjudicate issues involving the infringement of biotechnology patents. A classic biotechnology patent infringement case is that of Chiron Corporation V. Murex Diagnostics Limited. The plaintiffs have patent on the kits/method of detecting the presence of Hepatitis-C virus. The invention involves the determination of the genetic sequence of the Hepatitis-C virus. The defendants started manufacturing and selling their own kits for the detecting the presence of Hepatitis-C virus. The petitioners filed a suit alleging infringing their patent by the defendants and they wanted to prevent the defendants from selling their own immunoassay kits.

The defendants counter claimed the invalidity of the patent. They contended that the invention does not involve an inventive step, as it was available in the public domain. The determination of the genetic sequence of the Hepatitis-C virus is does not involve an inventive step as the presence of the Hepatitis-C virus could be established by conventional methods of tissue culture growth, microscopic growth or genomic characterization. Meanwhile the Court viewed that; the invention involves the identification and sequencing of a specific stretch of genetic material responsible for causing Hepatitis-C virus. It was observed that the genetic material is not available to be isolated and moreover it is not available in the purified form. The identification and purification of the genetic material does involve immense creative work. The invention was not general in nature, it was specific and having substantial utility in identifying virus causing Hepatitis-C. Besides the prior art was not consisting of such a genetic material. There was no evidence in the prior art suggesting the subject matter of invention prior to the date of the patent application.

It was held that the conception of the invention involves an inventive. The Court by striking down the contention of the defendants upheld the validity of invention. Further it was held that the defendants who produced kit for the detection of the detection of

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906 (1997) R.P.C 535, CA
Hepatitis-C have infringed a valid patent on the production of kit for the detection of Hepatitis-C virus. Accordingly, the patentee was granted suitable remedies in the form of; an injunction restraining the defendants from producing the kit and damages to compensate the loss suffered by the patentee due to the selling of kits by the defendants. In contrast to the above decision in Biogen V Medeva the Court invalidated a patent in an infringement suit. The claims were for genetically engineered DNA molecules coding Hepatitis B virus. The claims were broad enough to cover any recombinant DNA molecule, which expresses Hepatitis-B virus in any host bacterium. The claims included expression of a protein crucial in producing vaccine for Hepatitis-B. The plaintiffs brought infringement suit against the defendants who were producing vaccine for Hepatitis-B virus.

Defendants raised different issues in defense in the infringement suit. They counter claimed the invalidity of the patent on the ground of broad patent, lack of inventive step, insufficient disclosure of the invention. Defendants argued that the invention does not involve inventive step as it was in the public domain at the time when the patent application was filed. Further the application does not disclose the invention sufficiently to enable a skilled person to practice the invention. They further argued that the inventor described a method to produce recombinant DNA molecules coding for Hepatitis-B. However they claimed patent on any recombinant DNA molecule coding for Hepatitis-B virus in any host cell. Therefore they contended that the claims in the patent are broad, hence the patent is invalid.

House of Lords observed the prior art consisting of large fragments of Hepatitis virus. It was viewed that the inventor produced DNA molecules by using the available large fragments of Hepatitis-B virus. It was viewed that the description of the method to produce recombinant DNA molecules coding for a protein useful in the production of vaccine against Hepatitis-B does not enable a person skilled in the art to practice the invention on any recombinant DNA molecule to express the genes of any Hepatitis B

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907 (1997) RPC 1
908 The claims included expression of a protein crucial in producing vaccine for Hepatitis-B.
virus in any host cell. In the light of the above observations House of Lords held the patent as invalid on the ground of lack of inventive step. Further it was held that the inventor could not describe the invention sufficiently, which forms another ground to declare the patent invalid. It was also held that the patent involves broad claims, which the applicant did not conceive and describe. Eventually the infringement suit instituted by Biogen was dismissed. The case illustrates how the defendant can take defenses such as invalidity, lack of inventive step, insufficient disclosure and broad claims in infringement suits. In case of invalidity of the claims the patentee cannot claim against infringement, because invalid patents are not enforced against infringement. No remedy is available for the infringement of a patent, which is invalid.

The burden lies on the patent owner to prove the infringement with relevant evidence. The patent owner must prove beyond doubt that the defendant has used his patented product or process without his authorization. He must also prove that the alleged product or process is substantially similar or equivalent to the patented invention. However in the biotechnology field infringement cases draw special attention due to the fact that many a times in this field alteration, modification or shuffling of an existing product or process, give rise to a new invention. New inventions some times involve using of existing products to produce a new product or same product with different function. Hence the nature, characteristics, and functions of the invention should be considered and complexities involved in the invention should be given attention to in adjudicating biotechnology patent infringement issues.

**Remedies for infringement**

Patent law in England offers certain remedies for infringement of biotechnology patents. Remedies are available in the form of injunction, damages to the owner of the patent\(^9\) on the establishment of infringement. The patent owner can seek injunction\(^10\) to refrain from continuing with the infringement in future. Even interlocutory injection could be claimed to stop the alleged infringer from continuing his activity pending the case. However the plaintiff has to prove that there would be irreparable damage to him if

\(^10\) See: TRIPS Article: 44 to 46
injunction is not issued during the pendancy of the infringement suit. In such cases if the plaintiff fails to prove the infringement he should pay compensation to the defendant for refraining him from doing his activity. Further on the establishment of the infringement damages\textsuperscript{913} may be granted to the patent owner to compensate the loss that he suffered due to the infringement. Besides infringing articles could be disposed or seized and handed over to the patent owner.\textsuperscript{914}

Enforcement of biotechnology inventions is a stake against the infringement of biotechnology inventions. Till the expiry of the tenure of the patent it is the owner or a person authorized by him who can use the invention. Without the authorization of the patent owner no body can use or exploit the invention. Infringement of a patent is an unauthorized use or exploitation of the patented invention. Enforcement of the rights under the patent grant checks the infringement of a patented invention. Enforcement guarantees the patent owner certain remedies against the infringement of his inventions and assures the inventor exclusive rights over his invention for a certain period of time. The EPC or the Directive does not say anything about the enforcement of biotechnology patents. The EPC specifically states that the enforcement of biotechnology patents is left to the respective member states. Therefore enforcement of biotechnology patents is done as per the local laws of the EPC member’s states.

**COMPULSORY LICENSING OF BIOTECHNOLOGY PATENTS IN THE EUROPEAN UNION**

The patent owner cannot sleep on the invention without exploiting it. He should exploit the invention in order to satisfy the public demands on his invention. The purpose behind the grant of monopoly is to see that the invention is exploited and public needs are satisfied. If the inventor does not exploit the invention any interested party can seek compulsory license to exploit the invention. Further if the inventor improperly exploits the invention failing to serve the needs of the public or if the invention is not available to

\textsuperscript{912} See: Ibid: Article: 44
\textsuperscript{913} See: Ibid: Article: 45
\textsuperscript{914} See: TRIPS Article: 46 and 59
the public at affordable price, any interested party can seek compulsory license to work on the invention.

Biotechnology inventions have got different utilities and public expectations are high on the results of the inventions. Biotechnology inventions are vastly used in the agriculture sector and medical sector; there is vehement demand from these two sectors for the proper exploitation of the inventions in order to meet the public demand for agriculture and medical products. In the agriculture sector there is increased demand for the genetically engineered herbicide resistant, pest resistant, insect resistant and high yielding plants. An inventor of such engineered plant should satisfy the needs of the agriculture sector by exploiting and keeping available engineered plants having different characteristics.

Likewise biotech products such as engineered cells, DNA, genes, gene fragments coding for specific proteins crucial in the production of medicine have very good demand in the market. The inventor should satisfy the demands in the market by exploiting the invention. The situations where the inventors are not exploiting the invention or insufficiently or improperly exploiting the invention or if the prices of the products are not affordable may give rise to the granting of compulsory licensing to work on the invention. In such circumstances any interested party can apply for compulsory license. Compulsory licenses are also granted to prevent the abuses, which might result from the exercise of the exclusive rights conferred by the patent.

**Grant of compulsory license**

In Europe the patent laws does not consider compulsory licensing of patents. The European patent convention does not provide any express provision on the compulsory licensing of patented inventions. It was only the Community plant variety rights regulation provides compulsory exploitation of rights in general. The regulation states that in the public interest compulsory exploitation rights can be granted. With the coming

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915 See: TRIPS: Article: 31 other use without authorization of the right holder.
916 See: The Paris convention on the protection of industrial property, Article: 5(2)
917 In Europe compulsory licensing of patents was not considered in the patent laws. It was only the Community plant variety rights regulation provides compulsory exploitation of rights in general.
918 See: Community plant variety rights regulation, Article: 29
into being of the Directive on the legal protection of biotechnology inventions the system of compulsory licensing of biotechnology patents is instated in the European Union.\footnote{See: The European Union Directive on the legal protection of biotechnology inventions 1998}

The Directive states that where the holder of a patent concerning biotechnology invention cannot exploit it without infringing a prior plant variety right he may apply for a compulsory license. In such circumstances compulsory license can be granted for nonexclusive use of the plant variety subject to the payment of an appropriate royalty. At the same time the owner of the plant variety is entitled to a cross license to use the biotechnology invention on reasonable terms. On the same lines if the exploitation of a plant variety is not possible without infringing a biotechnology patent the owner of plant variety can seek compulsory license. In such circumstances compulsory license can be granted for the non-exclusive use of the biotechnology invention subject to the payment of appropriate royalty.\footnote{See: Article: 12 Compulsory and cross licensing} At the same time the owner of the biotechnology invention is entitled to a cross license on the protected plant variety on reasonable terms.

The Directive does not state anything about the compulsory licensing of patents on the failure of the patent owner to exploit the invention. It just provides for the compulsory and cross licensing of biotechnology patents and plant varieties on mutual terms. But the Paris convention and the agreement of TRIPS postulate for compulsory licensing of inventions in the public interest. All the member states of the TRIPS agreement may provide for compulsory licensing of inventions. But the European patent convention or the Directive on the biotechnology invention does not provide for the compulsory licensing of patents. Hence it is left to the member states of the Union to provide for the compulsory licensing of patents. However before seeking compulsory license the applicant must have exhausted other means to obtain the authorization of the patent owner to work on the invention. Compulsory license is granted only after the unsuccessful attempts of the applicant in obtaining the authorization from the owner. The applicant must demonstrate the significance of the patented invention or the plant variety, which constitutes significant technical progress of considerable economic interest. The
patent office must be convinced that; it is necessary to work on the invention for the further advancement or to satisfy the needs of the general public.

In particular the owner of the younger patent, which is depending on, an older patent may request for a compulsory license of the old patent, if the younger patent compared with the older one brings about an important technical progress of significant economical importance. This situation will particularly exist, just as an example in case of improvements of already patented pharmaceutical substances or, even more often, as pharmaceutical is concerned, in case that a new indication of a protected pharmaceutical substance is found. In the later case the owner of the younger patent can seek a compulsory license of the older patent under reasonable condition. Compulsory license may not grant absolute rights over the patented invention. It may be subject to certain terms and conditions. The patent owner is entitled to get a reasonable remuneration or royalty against the grant of compulsory license. The owner of the patent may claim the patent by asking for the revocation of the compulsory license if the circumstances, which warranted the grant, have reversed.

ENFORCEMENT OF BIOTECHNOLOGY PATENTS IN INDIA

In India biotechnology patents are enforced against infringement under the patent Act. The Act states that it is the owner who can exclusively use and exploit the patented invention. If any person without the authorization from the owner uses, makes, exploits, sells offers to sell or imports the patented invention, he does infringe the patented invention. However any act of making constructing using or selling a patented biotechnology invention 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 any country that regulates the manufacture, construction, use or sale of any product does not constitute an infringement.

On the same lines importation of patented products by any person from a person who is duly authorized by the patentee to sell or distribute the product also does not

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921 Dr. Heinz Goddar, European Patent and Trademark Attorney, “Patents/Public –Limits of Patent Protection”, A paper presented at the Faculty of Law, University of Delhi, on November 14, 2005
922 Patent Act was amended in the month of March 2005; it got the assent of the president in April 2005 in the same month the Act was published in the official gazette of India.
constitute infringement. The patent owner cannot claim against few acts though such acts amount to infringement of the patented invention. If the government uses the patented invention without the authorization of the patent owner, there cannot be instituted infringement suits as the government can use any patented invention without any authorization from the owner. On the same lines if the invention is used for governmental purpose or public purpose or for research and education purpose the patent owner cannot institute infringement suit against such use.

**Instituting infringement proceedings**

In case of infringement of the patent the patent owner or the legal representatives of the patent owner can sue against infringement. The assignee or licensee of the patent with the authorization from the owner can also sue against infringement. Besides the authorized exclusive licensee shall have same powers and rights as of the registered owner in case of the infringement of the patent. On the same lines any person to whom a license has been granted shall be entitled to call upon the patent owner to initiate proceedings to prevent any infringement of the patent. If the patent owner neglects or refuses to institute infringement proceedings a licensee may in his own name or in the name of the patent owner can institute infringement proceedings.

Infringement proceedings shall be instituted in any Court inferior to a District court. A suit against infringement instituted must be transferred to the High court when a counter claim for revocation of the patent is made. The burden of proof lies on the plaintiff to prove that the alleged product is identical or similar to the patented product or the alleged product is obtained from the patented process since the product is identical or similar to the product obtained from the patented process. If the applicant proves that the alleged product is a result of using a patented process or is identical or similar to the patented product the burden shifts to the defendant to prove that his product is not obtained from the patented process or his product is not identical or similar to the

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923 See: The Act, Section: 107A: Certain acts not to be considered infringement. This section was inserted by the amendment made to the Act in 2002.
924 See: The Act, Section: 109 Rights of exclusive licensee to take proceedings against infringement. The exclusive licensee is entitled to such remedies for infringement in the form of injunction or damages or accounts of profits.
925 See: Ibid, Section: 110 Right of licensee to take proceedings against infringement.
BIOTECHNOLOGY AND LAW: PATENTING OF LIFE

Further prior to the institution of infringement proceedings any person can institute a suit for a declaration that the use by him of any process or the making, use or sale of any article does nor or would not constitute an infringement of patented invention. Such suit for declaration could be instituted only if the plaintiff in such suit had approached the patent owner to acknowledge to the above effect and the patent holder refused or neglected to give such an acknowledgement.

**Defenses in case of alleged infringement**

The patent Act of India illustrates certain defenses, which can be claimed in case of alleged infringement. An alleged infringer can defend his act on the same grounds the basis of which a patented can be opposed or revoked. The alleged infringer can counterclaim the invalidity of the patent on the grounds like: lack of novelty, inventive step, insufficient specification, invention not patentable, wrong mention or not mentioning of biological sources used for the invention, broad claims etc.,

While adjudicating infringement suit Court may take help from scientific advisors. In order to determine whether an act does constitute infringement of an existing patent or not an investigation into the scientific and technical merits of the invention and the alleged act should be done. Since judges may not be having scientific and technical expertise in the field of biotechnology it is advisable to take assistance from the experts in the field in determining the novelty, inventive step and broadness of claims in the patent in dispute. The opinion of the experts may help the Court in reaching a decision in adjudicating the biotechnology patent in dispute, given the inherent complexities of biotechnology inventions.

**Remedies available to the patent owner**

The patent Act states that the owner of biotechnology patent shall get certain remedies on proving infringement his patent. According to the Act the patent owner may

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926 See: Ibid, Section: 104 Jurisdiction
927 See: The Act, Section: 104A: Burden of proof in case of suits concerning infringement. This section was inserted by the patented amendment Act, 2002.
928 See: The Act, Section: 105 Power of court to make declaration as to non-infringement.
930 See: Ibid: Section: 25 for grounds of opposition
931 See: Ibid: Section: 64 for grounds for revocation
932 See: The Act, Section: 115 Scientific advisors
seek relief\textsuperscript{933} in the form of injunction to refrain from further infringement of the patent or in the form of damages or accounts of profits to compensate the loss suffered. Interlocutory Injunction can be sought even pending the infringement proceedings as an immediate relief from the infringement to stop the infringer from continuing the infringement. However in such cases if infringement is not proved the applicant will have to compensate the defendant for refraining the defendant from doing his act. If the infringement is proved as a final determination an injunction can be granted to prohibit the infringer from infringing the patent anymore. Besides the court may award damages to compensate the loss suffered by the patent owner due to the infringement. Further accounts of profits can be awarded which compels the wrongdoer to submit all the money he made or the profit he earned through infringing the patent in question along with accounts.

Further Court may order the seizure of infringing articles, which are similar or identical to the patented biotechnology product or articles derived by using the patented biotechnology process. If in the infringement proceedings it is found that any claim of the specification is invalid but other claim is valid relief may be granted only in respect of the valid claim.\textsuperscript{934} However Court shall not grant any damages or accounts of profit in infringement proceedings if the defendant proves that at the time of the alleged infringement he was not aware and had no reasonable grounds for believing that the patent on such biotechnology product or process is in existence.\textsuperscript{935}

The objective behind enforcing patents against infringement is to guarantee exclusive rights on the invention to the patent owner. Such rights are granted for a particular period of time. During such period if anybody uses the invention without the authorization from the patent owner he does infringe the patent there by violating the rights of the patent owner. In order to prevent such infringement patent law enforces patents. The question of enforcement of patent does arise only in case of infringement. If there is no infringement the question of enforcing the patent does not arise. In case of infringement certain remedies or guaranteed to the patent owner for having suffered loss

\textsuperscript{933} See: Ibid: Section: 108 Relief in suit for infringement

\textsuperscript{934} See: The Act, Section: 114 Relief for infringement of partially valid specification.
due to the infringement of his patent. Using of the patented invention after the period of twenty years does not constitute infringement. A patent is protected only for a certain period and during that period patents are enforced against infringement. After the expiry of the period of patent when it falls into the public domain, anybody can use the invention without any authorization.

**COMPULSORY LICENSING OF BIOTECHNOLOGY PATENTS IN INDIA:**

The patent Act says that the patent owner must exploit the invention after obtaining the patent. The patent owner is not supposed to keep the invention without exploiting it. He should work on it to fulfill the reasonable requirements of the public. The patent Act states that if the patent owner does not exploit the invention any interested person can seek compulsory license to work on the invention. However compulsory license can be sought after the expiry of three years from the date of granting and sealing of the patent. The objective behind granting compulsory license is to exploit the invention in order to satisfy the needs of the public. As per the provisions of the Patent Act compulsory licenses maybe sought on the following grounds. ⁹³⁶

1) The reasonable requirements of the public with reference to the patented invention have not been satisfied.

2) The patented invention is not available to the public at a reasonably affordable price

3) The patented invention is not been exploited or worked in India.

Further in case of international patents if the invention is not exploited in India through the invention is protected in India compulsory license can be obtained to work on it in India. Compulsory license could also be sought even the patent owner is working on it, if the needs of the public or not satisfied or if the price of the products of the invention are not affordable to the public. Compulsory licenses are granted to commercially exploit the inventions to serve the needs of the public.

**Mode of granting compulsory license**

⁹³⁵ See: Ibid: Section: 111 Restrictions on power of court to grant damages or accounts of profit against infringement.
⁹³⁶ See: The Act, Section: 84 Compulsory license
The application for compulsory license shall be accompanied by a statement setting out the nature of the applicant’s interest together with such particulars as may be prescribed and the facts upon which the application is based.\textsuperscript{937} Before applying for compulsory license the applicant must have exhausted all the other possibilities to work on the invention. He must have approached the patent owner for the license or assignment of the patent to work on it. The copies of the application for compulsory license shall be served on the patent owner and other interested persons to invite their objections. Statements by the patent owner and other interested in opposition to the grant of compulsory license shall be served on the applicant. Both the parties will be heard by the patent office before deciding to grant or not to grant compulsory license.\textsuperscript{938}

Besides a person having a general license to work on the invention may also apply for compulsory license. In such case by amending or abandoning existing license compulsory license can be granted.\textsuperscript{939} Further if the patent owner owes more than one patents that are related to each other and if it is not possible to work on one patent without infringing other patents the patent controller may grant compulsory license with reference to other patents also to enable the licensee to work on the patents efficiently.\textsuperscript{940} Generally compulsory licenses are granted subject to following conditions or patent office may impose following conditions while granting compulsory licenses.\textsuperscript{941}

1. Royalty shall be paid to the patent owner or persons entitled to the benefit of the patent.
2. The invention shall be exploited to the fullest extent.
3. The products of patented invention must be made available to the public at reasonably affordable prices.
4. The licensee shall not assign or license the patent further.
5. The license is only for the remaining period of the patent
6. The licensee shall not import the licensed biotechnology product or the products of licensed biotechnology process from abroad.

\textsuperscript{937} See: Ibid Section: 84(3)
\textsuperscript{938} See: Ibid Section: 87 Procedure for dealing with applications for compulsory license.
\textsuperscript{939} See: Ibid Section: 84 Power of controller in granting compulsory license.
\textsuperscript{940} See: Supra Note No. 358
\textsuperscript{941} See: Ibid: Section: 90 Terms and conditions of compulsory license
7) The license should not be abused or misused.

The patent Act states that the central government may at its satisfaction in circumstances such as national emergency or extreme urgency may make a declaration in the official gazette authorizing the controller of patents to grant compulsory license on any patent subject to such terms and conditions. In order to serve the public interest government authorizes granting of compulsory licenses. Such licenses are granted to exploit the inventions for non-commercial purposes in order to secure the availability of a patented biotechnology product or articles or substances made out of a patented biotechnology process at the lowest prices to the public.\textsuperscript{942}

Especially in case of patents on food products and medical products compulsory licenses are granted on the declaration made by the central government to meet the emergencies. In case of shortage of food or in the light of prevailing drought conditions or floods or earthquakes in order to serve food to the needy government may authorize the granting of compulsory license on such patents on food articles. Further in case of spread of diseases to supply drugs and medicines at lowest prices or at free of cost compulsory licenses may be authorized on the patents on medical inventions.

\textbf{Government acquisition of patents on biotechnology inventions}

The government can acquire any patented biotechnology invention by a notification in the official gazette against payment of compensation to the patent holder.\textsuperscript{943} On such acquisition all rights with respect to the invention stands transferred to the central government. Further government may authorize in writing any person to use the patented invention for the purpose government in the public interest against the payment of adequate remuneration\textsuperscript{944} to the patent owner or to the person entitled.\textsuperscript{945} In fact the TRIPS agreement postulates for the use of a patented invention in the public interest without

\textsuperscript{942} See: Ibid: Section: 92 Special provision for compulsory license on notification by the central government.
\textsuperscript{943} See: The Act Section: 102 Acquisition of inventions and patents by the central government
\textsuperscript{944} See: Ibid Section: 100 Power of central government to use inventions for purposes of government.
\textsuperscript{945} If the patent owner has licensed or assigned the patent to any person such person is entitled for remuneration in case of compulsory licensing or authorization to any person to work on or use the invention by the central government.
authorization from the owner.\textsuperscript{946} Such authorization may be given even before the grant of the patent. Any dispute with regard to the use of inventions for the purposes of government and authorization to any person to work on the invention in the public interest shall be referred to the High court.\textsuperscript{947}

Once granted the compulsory license holder shall work on the invention in the light of the terms and conditions imposed on him. If he fails to meet any of the terms and conditions compulsory license may be revoked on the application of the patent owner or any interested person.\textsuperscript{948} Further compulsory license may also be revoked if the licensee is abusing it or not exploiting it properly to satisfy the needs of the public or the patent owner establishes that the situations that warranted the granting of compulsory license have changed. Compulsory license is an instrument to exploit the invention, which is remained unexploited. It is a weapon in the hands of the government to keep vigilance on the patent owners who shall meet the requirements of the public in exploiting the inventions. The patent Act intends to serve the public purpose in granting compulsory licenses in order to make the products of a patented invention available to public at affordable prices.

Meanwhile inventors need not patent their invention if they do not wish to enforce their invention. Infact without patenting also an inventor can work on his invention. However patenting gives a legal recognition to the invention. The patenting of invention does not give any positive right to the inventor to use his invention. But it gives a negative right to exclude all others from using his invention. Patent gives an exclusive right to the inventor to use the invention. He can exclude all others from using the invention as a matter of right. This right to exclude is conferred on him by virtue of patent. If the invention is patented than only right to exclude others can be enjoyed.

Further patent gives the inventor a right to enforce his invention. During the term of the patent without the authorization of the inventor nobody can use the invention. If any body uses the invention it does constitute infringement. The patent owner can institute infringement suit against the infringer seeking remedies. The question of enforcement of

\textsuperscript{946} See also TRIPS agreement Article: 31 others use without authorization of the right holder.
\textsuperscript{947} See: The Act Section: 103 Reference to High court of disputes as to use for purposes of government.
\textsuperscript{948} See: Ibid Section: 94 Termination of compulsory license.
patent comes into picture only in case of infringement of patent. Only patented inventions can be enforced against infringement. Inventions, which are not patented, cannot be enforced against infringement. A person having compulsory license over a patent can also institute infringement suit as if he is the owner of the patent. Enforcement of patents guarantees the owner monopoly over the patent for during the term of the patent.