What is in a Name? : Viewing Patent Infringement through the Prism of Anglo-American Doctrines

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A patent is nothing but a bunch of exclusive rights granted by the state to an inventor or his assignee upon satisfying certain conditions. This monopoly is given only for a fixed period of time in exchange for the public disclosure of certain details of a machine, method or composition of matter. The patent system in all countries promotes invention, disclosure and innovation by granting a temporary protection for the outcome of the inventor’s efforts. In India, the Patents Act 1970, governs the law dealing with patenting of inventions.

The exclusive rights which are given to the patent holder enable him to prevent or exclude others from making, using, selling, offering to sell or importing the claimed invention in the country where the patent is granted. The patent laws of all countries specify certain conditions for patentability and only upon meeting these conditions, the patent will be granted by the concerned authority.

Thus, to be granted a patent the applicant must furnish a written description of his or her invention with all the sufficient details so that any one skilled in the art can make and use the invention after the said patent expires. This written description is known as the patent specification, and in many cases it may be accompanied by drawings and diagrams which demonstrates the manufacturing and operation of the invention. At the end of the specification, the applicant should also provide the patent office with one or more claims that clearly state about the invention. Infact, it is the claim which is intended to provide the public with notice regarding precise scope of monopoly which the patent owner wants to enforce against third parties who may wish to make, use or sell the invention. In other words claims define in crystal clear terms what the patent will cover and what it will not. Thus, the claims must be written in a clear and succinct language and should be fairly based on the matter disclosed in the specification. To be simple, the function of the claims is to define clearly and with precision the monopoly claimed so that others may know the exact boundaries of the area within which they will be trespassers.

The interpretation of patent claims is very complex and infact the complexity of patent claim interpretation reflects the delicate balance of interests between the public and the inventor.

Interpreting claims too narrowly may unfairly deprive the inventor of his property rights, while overly broad interpretation may negatively affect the public by discouraging technological innovation.

Infringement

When a patent is for a product the patent holder has the exclusive right to make, use, sell, distribute such article or permit his agent to do so or issue a license. In case of a process patent, the patent holder has the exclusive right to use or exercise the method/process.
Another important feature of patent is that it is territorial in nature and thus all these rights will be valid only in the country where that patent has been issued.

If any person violates any of the patent holder’s rights then there will be infringement. If the infringing party has simply duplicated the invention in all respects then it is very easy to find out infringement and this type of infringement is known as literal infringement. The situation may be difficult if the infringer has introduced some minor changes and has produced a slightly different device. In such cases, called non–literal infringement, the Courts have to determine infringement by the interpretation of claims. Thus, the interpretation of claims plays a very crucial part in deciding whether there is infringement or not.

Courts in various jurisdictions have devised various mechanisms to deal with such infringement and the doctrine of equivalents is one such mechanism developed by the US Courts over a period of time to deal with non-literal infringement.8

Non-Literal Infringements in USA-Emergence of the Doctrine of Equivalents9

This doctrine has been around for about 153 years and it was in the case of \textit{Winans v Denmead} the US Supreme Court developed the doctrine of equivalence to deal with non-literal infringement. The Court had to determine whether the term ‘cylindrical and conical’ with respect to the body of a railroad car was wide enough to include the ‘octagonal and pyramidal’ railroad cars of the defendant. The decision was never a unanimous one and the majority opined that it would be unreasonable to literally construe the term ‘cone’ because ‘neither the patentee nor any other constructor has made, or will make, a car exactly circular’. Instead, the claim only required that the shape ‘be so near to a true circle as substantially to embody the patentee’s mode of operation, and thereby attain the same kind of result as was reached by his invention.’ But there was dissent also and the dissenting judges noted that, if such a construction were given, then there would be uncertainty in the scope of a patent which would ultimately give rise to ‘oppressive and costly litigation, of exorbitant and unjust pretensions and vexatious demands’. Thus, the dissenting judges argued that relaxation of this requirement for specificity will be very harmful, which may spawn costly and time consuming litigation.10

Interestingly in this case the word ‘equivalents’ was never used, but the Court accepted the need of going beyond the literal language of the claim by differentiating between form and substance of a claim.11 Later on the issues pertaining to equivalents came up in numerous cases and various tests were framed to help the Court in finding out whether an object is equivalent to the claimed invention.12 However, the landmark case dealing with the doctrine of equivalents came up before the US Supreme Court in the year 1950.13

The said case dealt with two electric welding compositions or fluxes: The patented composition, Unionmelt Grade 20 and the accused composition, Lincolnweld 660. Unionmelt contains silicates of calcium and magnesium. Lincolnweld's composition is almost the same as Unionmelt's, except that it substitutes silicates of calcium and manganese, for silicates of calcium and magnesium. In all other respects, the two compositions are the same and the mechanical methods in which these compositions are used are the same. Furthermore, both the compositions are identical in operation and produce the same kind and quality of weld.14

Thus, the main question which the Court was confronted was whether the substitution of the manganese in place of magnesium is a substantial change so as to make the doctrine of equivalents inapplicable. Expert chemists gave testimony to the effect that manganese and magnesium were similar in many of their reactions and this was corroborated by reference to recognized texts in inorganic chemistry. Thus, the Court finally held that although there was no literal infringement, the changes, which avoid literal infringement were colorable only and there was infringement by equivalents.14

The Court observed that to determine whether an accused device or composition infringes a valid patent, at the first instance the words of the claim should be interpreted in a literal manner. If accused matter falls clearly within the claim, infringement can be easily found. The Court also noted the following:

‘To permit imitation of a patented invention which does not copy every literal detail would be to convert the protection of the patent grant into a hollow and useless thing. Such a limitation would leave room for–indeed encourage - the unscrupulous copyist to make unimportant and insubstantial changes and substitutions in the patent which, though adding nothing, would be enough to take the copied
matter outside the claim, and hence outside the reach of law.\textsuperscript{15}

In the said case also there was dissenting opinion and the main concern expressed by the judges was that a manufacturer would no longer be able to rely on the language of patent claims to avoid infringement suits.\textsuperscript{16} This argument also has considerable merit because broad application of the doctrine of equivalents really undermines the notice function of patents by preventing the public from finding out the scope of a patent \textit{ex ante}.

If an infringing device performs substantially the same function in substantially the same way to obtain the same result as the patented device, then the former will be considered as an equivalent of the latter and there will be infringement.\textsuperscript{17} In other words, if two devices do the same work in substantially the same way and accomplish substantially the same result, they are the same, even though they differ in name, form, or shape.\textsuperscript{18} This is the rationale behind the doctrine of equivalence and this doctrine enhances the strength of a patent by giving the Courts the flexibility to expand the patent's scope beyond that of its literal terms.\textsuperscript{19}

\textbf{Prosecution History Estoppel}\textsuperscript{20}

Needless to say, patent prosecution is a time consuming procedure and during that procedure, patent applicants often amend the language and words of their proposed claims. It is a matter of debate whether the courts can consider the evidence of those changes in language in order to construe the resulting patent claims. In the context of patents, this debate has lot of significance because of the doctrine of equivalents, as the said doctrine makes uncertain the boundaries of any patent claim and one mechanism to address that worry is the rule of prosecution history estoppel.\textsuperscript{21}

Patent's prosecution history is a publicly available file that is being kept by the Patent Office, which memorializes the discussions between the examiner and the patentee during the prosecution of the patent. At the prosecution stage, it is quite common for the patent applicants to try to get the broadest claims they can, by covering any and all modifications to their inventions.\textsuperscript{22} Similarly, it is also common for the patent examiner to reject the claims, which are initially drafted by the patent applicant which may be based upon a number of grounds.

There can be a plethora of reasons for the examiner to reject claims under the Patent Act.\textsuperscript{23} Sometimes the rejection is because an examiner may feel that the claims are so broad that they would cover technology that was already known. In some cases, the rejection is because the claims are very obscure and in some instances it may be simply because of clerical reasons.\textsuperscript{24} In many cases, patent applicants amend the claims in order to overcome the rejection, whereas in some cases they try to convince the examiner about their viewpoints about the claim. But one thing is certain, the coverage of the claims that eventually become part of a patent will be much less than what the patentee originally sought. Thus, in other words the final claims cover only what the examiner in his wisdom had consented after complying with the statutory requirements. Thus, all the proceedings with regard to claims, its amendments etc will be known to the public by virtue of the prosecution history file which is kept by the patent office. Therefore, it is the prosecution history that allows the public to know why certain claims contain some limitations and what was the circumstance which prompted the examiner to impose that limitation.

Prosecution history estoppel is based on the very simple notion that a patentee cannot get coverage in Court that the patentee could not get before the Patent Office. Thus, it tries to limit the doctrine of equivalents by preventing a patentee from claiming equivalence with respect to subject matter the patentee surrendered during prosecution of the patent.\textsuperscript{24} The doctrine of prosecution history estoppel ensures that, patents mean what they say.\textsuperscript{25} It prohibits patentees from obtaining a patent by representing to the USPTO that the patent's scope is narrow and then arguing otherwise to the Court. Prosecution history estoppel is in tune with the notice function of patents because it allows third parties to rely upon the public document of the patent prosecution in order to exactly analyse a patent's scope and prevents the patentee's ability to invoke the doctrine of equivalents to expand that scope before a Court at a later stage.\textsuperscript{26}

One of the oldest cases where the US Supreme Court considered the prosecution history estoppel dealt with a patent application for a skirt protector, which stated that the skirt protector was formed in pleats.\textsuperscript{27} Subsequently, the applicant wanted to cover even non pleated skirt protectors. This application was rejected based upon a prior patent that made no reference to pleats. After rejection, the applicant filed an amended specification that described a skirt protector with a 'plaited or fluted border' and then the patent was granted.\textsuperscript{28}
Later on the patent owner brought a suit against a party who sold skirt protectors that did not have a plaited or fluted border and finally the case reached the Supreme Court. The Court made the following observation:

‘the file wrapper and contents … make it clear that the claim and specification of the Macdonald patent must be construed to include a fluted or plaited band or border as one of the essential elements of the invention. Without this element the patent would not have been issued……Where an applicant for a patent is compelled by the rejection of his application by the Patent Office to narrow his claim by the introduction of a new element, he cannot after the issue of the patent broaden his claim by dropping the element which he was compelled to include in order to secure his patent’

Another landmark case which dealt with prosecution history estoppel is *Exhibit Supply Co v Ace Patents Co*. The subject matter of the patent was for targets used in pinball machines. The patentee originally claimed that the target was ‘carried by the table,’ to which the patent office raised some objection. In order to overcome those objections made by the Patent Office, the claim was subsequently amended, and eventually issued as ‘embedded in the table.’

When the defendant came out with a target that was not embedded in a table, a suit was brought by the patent owner asserting infringement under the doctrine of equivalents. Here the Supreme Court invoked the prosecution history estoppel doctrine to deny infringement. The Supreme Court held that the inventor recognized and emphasized the difference between the two phrases and proclaimed his abandonment of all that is embraced in that difference. Thus, the inventor could not later on resort to the doctrine of equivalents to reclaim the abandoned material. Therefore, it became clear that, prosecution history estoppel would be invoked when an amendment was made to avoid prior art and this was subsequently followed in many cases.

The modern perspectives of prosecution history estoppel were initially articulated in Warner-Jenkinson and later on in Festo case wherein the Federal Circuit gave the doctrine of prosecution history estoppel a broad scope in order to limit the reach of the doctrine of equivalents. In the famous case of Warner-Jenkinson, Hilton Davis Chemical Company had a patent for purifying dyes by filtering the dye through a porous membrane at a certain pressure and pH level. During the prosecution of the patent application the examiner noted that the claims of the application did not mention a specific pH level for the dye and thus it was rejected. According to the examiner there was a prior patent that taught a similar filtration process at a pH level above 9.0 and thus his contention was that the Davis application was too broad to include a dye with a pH level above 9.0. Because of this rejection the Hilton Davis application was amended to claim a pH level between 6.0 and 9.0.

However, nobody knew why the lower limit of a pH of 6.0 was fixed and Hilton Davis failed to give an explanation why the lower limit was included. The Court found that putting the upper limit of a pH of 9.0 distinguished the previous patent from Davis application and thus the lower limit of a pH of 6.0 was unnecessary to get around the examiner's rejection. The Court held that there will be a presumption of prosecution history estoppel with respect to subject matter surrendered during prosecution of the patent. However, this presumption is rebuttable and thus any patent owner can rebut this presumption by demonstrating that a claim was amended for reasons unrelated to patentability. This would mean that if the patent-holder can prove that the reason for the amendment was not to limit the patent, then a finding of infringement based upon equivalents can still be made.

**The Landmark Case of Festo**

This case dealt with both the doctrine of equivalents and prosecution history estoppel. Festo was granted two patents, Stoll patent and Carroll patent, both relating to magnetically coupled rodless cylinders. After Festo marketed its device Shoketsu Kinzoku Kogyo Kabushiki Co Ltd, and SMC Pneumatics Inc, started marketing a similar product. After lots of twists and turns the case came up before the Federal Circuit which concluded that prosecution history estoppel can arise at any time when a claim is narrowed during prosecution in order to satisfy the requirements of the Patent Act and this is not limited to amendments being made to avoid prior art. The Federal Circuit also held that, when prosecution history estoppel is applicable, it will create a complete bar to the use of the doctrine of equivalents for that narrowed element. This is generally known as the complete bar approach.
Against this decision, Festo appealed before the US Supreme Court. The Supreme Court unanimously upheld the doctrine of equivalents. The Court concurred with the Federal Circuit that prosecution history estoppel can be applicable any time when an amendment is made to the application for reasons of patentability, not just when the amendment is made to avoid the prior art. But the Court rejected the complete bar approach followed by the Federal Circuit instead it favoured a flexible bar approach.

This time, the Supreme Court clarified that the prosecution history estoppel does not bar the inventor from asserting infringement against every equivalent to the narrowed element. Instead, the Supreme Court established a presumption by which the onus is on the patentee of showing that the amendment does not surrender the particular equivalent in question. The Court also spelt out three ways in which a patentee might rebut the presumption of surrender: i.e. by demonstrating that that the equivalent may have been unforeseeable at the time of the application; or that the reason behind the amendment bears only an indirect (tangential) relation to the equivalent in question; or some other reason. Thus, clearly the Supreme Court favoured a flexible bar approach and this approach strives to create a balance between innovation and certainty. After the Court's reasoning, the Court vacated the Federal Circuit's decision and remanded the case for proceedings consistent with the Court's opinion.

If the Federal Circuit's complete bar approach had been upheld by the Supreme Court then many patent holders would have been left in the lurch because they would not be in a position to claim equivalence for the claims which were narrowed for any reason. After the Festo case the Federal Circuit in many cases was called upon to analyse the scope of narrowing of claims. Although, there is no clear-cut answer to the crucial question on what constitutes a narrowing amendment, it becomes pretty evident that anything that narrows the scope of a patent will be considered by the Federal Circuit as a narrowing amendment.

Post-Festo Decisions: Emerging Trends

One of the leading cases decided by the Federal Circuit, after the Flexible bar approach, involved a leading Indian pharma conglomerate. Ranbaxy and Apotex were generic drug manufacturers who were manufacturing the drug cefuroxime axetil which was used as a broad-spectrum antibiotic used in treating respiratory tract infections. Apotex owned the process patent for preparing amorphous cefuroxime axetil. Ranbaxy wanted a declaratory judgment that its process, which used acetic acid, did not infringe the claims of the said Apotex patent. Apotex conceded that Ranbaxy did not literally infringe the claims but it sought to make Ranbaxy an infringer under the doctrine of equivalents.

The District Court denied Apotex's motion for a preliminary injunction, finding Apotex could not show a reasonable likelihood of success on the merits because of prosecution history estoppel. Apotex's originally filed patent application, which contained one independent claim and nine dependent claims. Independent claim one stated that, during the process to create the drug, the crystalline form of the cefuroxime axetil is dissolved in a highly polar organic solvent and adding the resulting solution to water. Dependent claims from three to seven had a limitation specifying the exact chemical to be used as the highly polar solvent like sulfoxide, dimethyl sulfoxide, dimethyl formamide, dimethyl acetamide, hexamethyl phosphoramid, formic acid.

In the first office action, the USPTO rejected claims 1, 8, and 10, stating that the phrase ‘highly polar organic solvent’ was indefinite and the examiner wanted to know the boundary between solvents that are highly polar and those that are less than highly polar. Furthermore the examiner objected to claims 3-7 for being dependent upon a rejected base claim, but said that they would be allowable if rewritten in an independent form. In response to this Apotex struck down claims 1-10 and submitted new claims 11-16 and Claim 11, was the only independent claim. Claim 11 read as follows:

Process of preparation of amorphous cefuroxime axetil which comprises the steps of:

(a) dissolving crystalline cefuroxime axetil in a volume of a highly polar organic solvent only sufficient to dissolve it, and adding the resulting solution to water; or

(b) dissolving crystalline cefuroxime axetil in a volume of highly polar organic solvent, only sufficient to dissolve it, adding water to the resulting solution and subsequently adding the resulting aqueous-organic solution to water, wherein the highly polar organic solvent is selected from the group consisting of a sulfoxide, an amide and formic acid.

The Federal Circuit observed that while Apotex was rewriting a dependent claim into independent form, it had substantial implication on the subject
matter. The dependent claims that were redrafted into independent form further defined and circumscribed an existing limitation for the purpose of putting the claims in condition for allowance.\(^{34}\) In other words, the additional language limited ‘highly polar solvent’ to a defined group of solvents like sulfoxides, amides, and formic acid. So the Court held that the patentee was presumed to have surrendered the equivalents that might have been encompassed by ‘highly polar solvent’.\(^{51}\)

On the next question whether Apotex can overcome the presumption that it has surrendered equivalents was also considered by the Federal Circuit. Apotex’s contention that acetic acid was unforeseeable at the time of application failed because the Court noted that formic acid and acetic acid, as homologs, were readily known by chemists to exhibit similar properties and was therefore equivalent.\(^{55}\) Thus Apotex was unable to invoke the doctrine of equivalence because of the prosecution history estoppel.

*Honeywell International Inc v Hamilton Sundstrand Corp* is another recent case which discussed the issue of flexible bar approach.\(^{56}\) The Honeywell patents deal with an aircraft auxiliary power unit (APU) usually located in the tail section of an airplane. It is the APU which generates electricity and incorporates a load compressor to provide compressed air needed both to start the aircraft's main engines and to control the environment of the aircraft's cabin during flight.\(^{57}\) During flight, the amount of compressed air required for these purposes fluctuates substantially. A valve is used to control the amount of air exiting the compressor through the main air duct, which supplies compressed air to the aircraft's systems.\(^{57}\) The Honeywell APU incorporates a more efficient design, which can avoid excess air bleeding in its control of surge. To reach this end, Honeywell's invention establishes a 'set point' that represents the minimum flow at which surge can safely be avoided.

By making a comparison of the set point to the actual output air flow from the compressor, the APU could calculate the proper amount of air to bleed and thereafter could adjust the surge bleed valve depending upon the conditions. In Honeywell's patent, the set point was calculated as a function of the air input that was controlled by adjustable inlet guide vanes. Defendant also made an APU device, the APS 3200, which also used an active surge control system that compared a flow-related parameter to a set point and adjusted the surge bleed valve in response.\(^{58}\) The said device establishes a set point that is dependent upon ambient air temperature and not on a measurement of inlet guide vane position which the Honeywell invention uses.\(^{58}\) Since Honeywell concedes that the inlet guide vane limitation is not literally met by the accused device, the only question is with reference to infringement under the doctrine of equivalents.\(^{58}\)

In this case, the Court noted that the original independent claims were rejected as obvious in view of the prior art. The rejected independent claims were cancelled and the dependent claims were rewritten into independent form in order to secure their allowance.\(^{59}\) The Court held that revoking an independent claim, which had no reference to the inlet guide vanes, and redrafting the dependent claims which contained the inlet guide vane limitation in independent form was a narrowing amendment. First, the Court held that the addition of a limitation to a claim would constitute a narrowing amendment.\(^{60}\) Secondly, the Court held that revoking an independent claim and redrafting a dependent claim that contained an additional limitation into independent form is nothing but an addition of a limitation and this would constitute a narrowing amendment.\(^{61}\) Finally, the Court held that there was no infringement by equivalents because the patent holder had made an amendment at the prosecution stage which narrowed the scope of the patent claims.

*Sheet Metal Workers Local 441 Health And Welfare Plan, et al v Glaxosmithkline Plc* is perhaps the most recent case where the Court had discussed about the doctrine of equivalence and prosecution history estoppel.\(^{62}\) The patent was for a substance known as bupropion hydrochloride (bupropion), which was known to act as an antidepressant. The said patent expired in mid-1991 and thereafter, GSK developed a sustained release version of bupropion, that used hydroxypropyl methycellulose (HPMC) as an excipient. This sustained release mechanism reduces the number of doses necessary.\(^{63}\)

In 1993, GSK filed an application with the USPTO seeking patent protection for the sustained release bupropion tablets it had developed. The application was rejected as the patent examiner found that the claim for patent protection was overly broad insofar as it would have covered any sustained release mechanism for bupropion. It was stipulated by the examiner to limit the claims to the specific sustained release agent it had developed and in 1995, the USPTO issued to GSK the patent for ‘Controlled sustained release tablets containing bupropion.’\(^{64}\) In
August 1999, several generic-drug manufacturers sought approval to market generic versions of sustained release tablets containing bupropion, which used hydroxypropyl cellulose (HPC) as an excipient. GSK filed an infringement case under the doctrine of equivalents. Here the defendants could successfully raise the plea of prosecution history estoppel and the Court held that the excipient (HPC), which defendants’ drugs use to achieve sustained release, had been recognized as a substitute for HPMC much before the prosecution of the patent application and GSK knew that HPC was a substitute for HPMC when it agreed to the narrowing amendments.

Thus it become clear that in all the important cases which came after Festo’s ‘flexible bar doctrine’, patent holders were not able to invoke the doctrine of equivalents, when they had narrowed down their claim during the prosecution of the patent.

**Pith and Marrow Doctrine in UK**

While in USA, the terms ‘literal’ infringement and the doctrine of ‘equivalents’, are common, UK uses the terms textual infringement and the doctrine of ‘pith and marrow’ to deal with infringements. Under the doctrine of pith and marrow, a court would examine the description and claim language to identify which elements the inventor considered to be essential and which elements he considered to be inessential; the essential elements constituted the pith and marrow of the invention. If an accused device has all the essential elements then there will be infringement of the patent, even if it excluded or included an equivalent for an inessential element. But if the device lacked an essential element literally, then there is no infringement.

In the landmark case of *Catnic Components Ltd v Hill & Smith Ltd* the plaintiffs held a patent for steel lintels. The defendants copied and manufactured a lintel, which differed slightly. When the case came up before the House of Lords, it was held that the patent specification should be given a purposive construction. Thus the question would be to find out whether a person skilled in the art would understand that strict compliance with a particular word in the claim was intended by the inventor as an essential requirement. If the answer was in the affirmative then any variant would be outside the monopoly, even though it could have no material effect on the way the invention functioned. Thus, after applying the said test the court found that the defendant’s lintel was covered by the plaintiff’s claim and held that the defendant had committed infringement.

In the famous case of *Improve Corporation v Remington Consumer Products Ltd*, the Court modified the principle that was applied in *Catnic* case. The patent was for an electronic hair removing device branded ‘Epilady’. The essential feature of the plaintiff’s device was a helical spring having an arcuate portion arranged so as to open the windings on the convex side and close them on the concave side. Rotation of the spring caused hair, which entered the windings on the convex side to be plucked from the skin as the windings closed together upon turning to the concave side.

Instead of using a helical spring, the defendants’ device used a flexible rod of elastomeric material with slits cut in it and bent so that the slits were open on the convex side and closed on the concave side. Rotation of the rod caused hairs entering the slits on the convex side to be caught on the concave side and plucked from the skin. The question on infringement was whether the elastomeric rod in the defendants’ device was within the claims of the patent as a mechanical equivalent of the helical spring.

The Court framed the following questions which is generally known as the improver test:

1. Does the variant have a material effect upon the way the invention works? If yes, the variant is outside the claim.
2. If no, would this fact that the variant had no material effect was obvious at the date of publication of the patent to a reader skilled in the art? If no, the variant is outside the claim.
3. If yes, would the reader skilled in the art nevertheless have understood from the language of the claim that the patentee intended that strict compliance with the primary meaning was an essential requirement of the invention? If yes, the variant is outside the claim.

After applying the test the Court held that there is no infringement. Thus in the UK the issue of infringement involves making a fairly straightforward assessment on whether the infringing product or process falls within the claim scope.

The attitude of English Courts towards the doctrine of equivalents is an unfriendly one. This was manifested in the famous case of *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd* and this doctrine has been criticized for lack of certainty. In the said case Kirin-Amgen Inc (Amgen), a Californian pharma company had a European patent relating to the production of erythropoietin (EPO) by recombinant
DNA technology. The discovery by Amgen of a method of making EPO artificially for use as a drug was a significant advance in the treatment of anemia, particularly when associated with kidney failure. This drug was marketed under the brand name Epogen.

Transkaryotic Therapies Inc (TKT), a Massachusetts corporation has also developed a method of making EPO, which it markets under the name Dynepo. Hoechst Marion Roussel Ltd (Hoechst) is the English subsidiary of a well-known multinational pharmaceutical company which has been proposing to import GA-EPO into the United Kingdom. In three consolidated actions, Amgen claims that GA-EPO infringes the claims of the patent in suit and TKT and Hoechst claim a declaration of non-infringement and revocation of the patent.

The essential difference between Epogen and GA-EPO is that the former is made by an exogenous DNA sequence coding for EPO which has been introduced into a host cell and the latter is made by an endogenous DNA sequence coding for EPO in a human cell into which an exogenous upstream control sequence has been inserted. The principal question of construction was whether the person skilled in the art would understand ‘host cell’ to mean a cell which was host to the DNA sequence which coded for EPO. The argument, put forward by Amgen, was that it could include a sequence which was endogenous to the cell, like the human EPO gene which expressed GA-EPO, as long as the cell was host to some exogenous DNA. In the defendant’s process (TKT process), it was host to the control sequence and other machinery introduced by homologous recombination. The House of Lords concurred with the defendant and held that the skilled person would not regard the TKT process of using an endogenous coding sequence to produce GA-EPO as one involving a host cell. Thus, there was no infringement.

The inclusion of Article 69 of the European Patent Convention into UK law ruled out the development of any English doctrine involving the extension of patent protection outside the wording of the claims, similar to the American doctrine of equivalents. As per Article 69 the extent of the protection conferred by a European patent shall be determined by the terms of the claims and the description and drawings shall be used to interpret the claims.

Although, under Article 69 it is not permissible to extend the scope of patent protection beyond the claims by using arguments about ‘equivalent’ elements, still there is some scope for equivalence when it comes to claim interpretation. In the words of Lord Hoffmann ‘there is no reason why it cannot be an important part of the background of facts known to the skilled man which would affect what he understood the claims to mean. That is no more than common sense’. Interestingly, this approach is also provided by the new Article 2 which was added to the Protocol by the Munich Act that revised the EPC in November 2000.

Indian Position

In India, there are very few cases dealing with patent infringement and thus there are fewer instances wherein the Court has discussed about the concept of doctrine of equivalents and pith and marrow. Recently, the Chennai High Court briefly discussed about these concepts in the case of Novartis AG v Adarsh Pharma and Anr. In the said case the plaintiff’s drug was ‘Beta Crystalline form of Imatinib Mesylate’, for which a patent application was filed. The plaintiff also got an Exclusive Marketing Right (EMR) to market the said drug. Defendants wanted to market a similar drug with a low percentage of ‘Beta crystals’. The plaintiff’s counsel tried to bring in the doctrines of equivalents and pith and marrow and argued that ‘Beta crystals’ were related to both the drugs and it was enough, without reference to the difference in percentage of the presence of such ‘Beta crystals’, to hold that there was an infringement. Since the case was at the interlocutory stage, the Court did not go into these arguments in detail.

Impact of Emerging Technologies

The emerging technologies are actually posing a big challenge to the doctrine of pith and marrow and equivalents. This was amply reflected in the Kirin Amgen discussed earlier. In the said case Amgen’s patent which pertained to production of erythropoietin (EPO) by recombinant DNA technology was circumvented by a technique called gene activation. This eventually led to lot of legal disputes in US and UK.

Amgen's patented process isolated the human EPO gene, introduced it into a cloning vector, and then inserted such vector into a host cell, Chinese Hamster Ovary (CHO) cells, so as to produce desired amounts of EPO. Here, the human EPO DNA is exogenous to the hamster host cell. Amgen got the patent for this process for producing EPO. Whereas in the case of TKT, it is not using any host cell from CHO or any
other non-human species to produce its human EPO. Instead it amplifies the ordinarily unexpressed human EPO gene in a human cell by inserting a promoter sequence, which then switches on the EPO coding gene. Thus it becomes clear that, TKT only uses an exogenous promoter to trigger the production of EPO from the endogenous EPO gene, while Amgen’s process involved the insertion of an exogenous DNA sequence into a host cell. This difference was considered crucial in UK and the House of Lords held that there was no infringement, while in US, the same process used by TKT was held to be infringing.

This really highlights the complexities of the modern day technologies and how they are actually testing the doctrines of equivalence and pith and marrow. Emerging technologies like nanotechnology raises many interesting questions. Nanotech inventors are uncertain about the extent of their patent rights with reference to those of inventors of traditional products. It is feared that patents with broad claims, that lack reference to scale, on traditional products might allow traditional patent holders to exact royalties from their nanoscale counterparts, using the doctrine of equivalents or pith and marrow. Such broad claims might cover the miniaturizing work of nanotechnologists even though those nanoscale counterparts are substantially different than the traditional products by virtue of the drastically different physical properties of matter at such small sizes. At present nanotechnology may be at its infancy, but this technology will surely test the doctrines of equivalents and pith and marrow in a big way.

Since India is aspiring to become a global leader in all emerging technologies, including infotech and biotech, disputes are sure to happen which may eventually be dragged to the Courts. Patent infringements very often involve complex technological issues and this is truer in the case of infotech, biotech and nanotech inventions. These emerging technologies are severely testing the doctrines of equivalents and pith & marrow in US and UK. Sooner than later, Indian Courts will be called upon to decide such complex issues involving claim interpretation, non-literal infringements etc. Thus our judiciary will have to seriously consider invoking these concepts whenever they deal with patent infringements.

**Conclusion**

It is incumbent upon the courts to interpret the Patent Act in such a way so as to promote the innovation and dissemination of new technologies so that the public can benefit. Courts in all jurisdictions have attempted to do exactly the same. While doing so, Courts have also accepted that premise that any patent holder should be having an adequate remedy against not only a literal infringer, but also those who design around the patent application and create nearly equivalent, versions. This has resulted in various proactive approaches being made by the Court, which we popularly term as doctrine of equivalents and pith and marrow.

Whether we call it ‘equivalents or pith and marrow’, one thing is clear; both the doctrines are very helpful in cases involving non-literal infringement. While doctrine of equivalents is equally balanced by the concept of prosecution history estoppel there is no such principle under the pith and marrow doctrine.

As it has been discussed earlier, under the doctrine of equivalents if two devices do the same work in substantially the same way, and accomplish substantially the same result, they are considered as equivalents. Needless to mention this has created some confusion which is manifested in various judgments given by the US Courts. Although the doctrine of equivalents in the United States brings some uncertainty into patent infringement practice, the cases discussed earlier show that the predictability of this doctrine is on par with pith and marrow doctrine. Even judges have admitted that both the doctrines were born of despair. Even then, both the doctrines have been of considerable help to the judges in determining colourable imitations and thus have played a very significant role in deterring the omnipresent copyist who will be waiting for the slightest chance to make unimportant and insubstantial changes and thereby remain outside the reach of patent infringement.

Had William Shakespeare been alive, he would have opined

'What is in a name?? Any doctrine which prevents the unscrupulous copyist from committing non-literal infringements may be called equivalents or pith and marrow'

**Acknowledgement**

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References

1 To be patentable an invention should have the following a) novelty b) inventive step and c) industrial application.
2 Section 48 of the Indian Patents Act 1970, deals with the rights of patent holders.
3 Section 3 of the Indian Patents Act 1970, deals with the non patentable subject matter.
4 Indian Patents Act 1970, Section 10.
5 Indian Patents Act 1970, Section 10(5).
6 Electric and Musical Industries Ltd v Lissen Ltd (1938) 56 RPC 23, 39.
8 This article will not be discussing about infringements dealing with ‘means-plus-function’ claims defined in 35 USC 112, paragraph 6.
9 The words equivalents and equivalence can be interchangeable used Along with the doctrine of equivalence there also exists the reverse doctrine of equivalence, wherein a person who has literally infringed a patent, may still escape liability for infringement According to this, the person is not liable for infringement if the ‘device is so far changed in principle from the patented article that it performs the same or a similar function in a substantially different way, even though it falls within the literal words of the claim Just as the purpose of the doctrine of equivalents is to prevent pirating of the patentee’s invention, so the purpose of the reverse doctrine is to prevent unwarranted extension of the claims beyond a fair scope of the patentee’s invention, Scrivs Clinic & Research Found v Genentech, Inc, 927 F 2d 1565, 1581 (Fed Cir 1991).
12 Notable among them are Union Paper-Bag Machine Co v Murphy (1877) 97 US 120 (Mem); City of Elizabeth v American Nicholson Pavement Co (1877) 97 US 126 (Mem).
14 339 US 605.
15 339 US 605, 608.
16 339 US 605, 617.
17 Sanitary Refrigerator Co v Winters, 280 US 30, 42.
18 Machine Co v Murphy, 97 US 120, 125.
20 The term ‘prosecution history estoppel’ was first used by the Federal Circuit in Hughes Aircraft Co v United States, 717 F 2d 1351, 1362 (Fed Cir 1983), the former term was ‘file wrapper estoppel,’ which simply referred to the ‘file wrapper’ that held the contents of a patent application in the USPTO.
22 Whitley Chandler T, Prosecution history estoppel, the doctrine of equivalents, and the scope of patents, Harvard Journal of Law & Technology, 13(3) (Summer 2000) 465, 471.
27 Sheppard v Carrigan, 116 US 593.
29 116 US 593, 597.
30 315 US 126.
31 315 US 126, 136.
32 315 US 126, 137.
33 The case of Christopher J Foster Inc v Newport News Shipbuilding & Dry Dock Co 531 F 2d 1243 (4th Cir 1975).
36 520 US 17, 21-22.
37 520 US 17, 32.
38 520 US 17, 33.
41 Festo Corp v Shoketsu Kinzoku Kogyo Kabushiki Co, 234 F 3d 558, 575 (Fed Cir 2000).
42 234 F 3d 558, 575.
44 122 S Ct 1831, 1839.
45 122 S Ct 1831, 1840.
46 122 S Ct 1831, 1842.
47 Although the Supreme Court favoured a flexible bar approach, Festo could not rebut the presumption and lost the case when issues were decided by the Federal circuit and the District Court.
50 Ranbaxy Pharmaceuticals Inc v Apotex Inc 350 F 3d 1235 (Fed Cir 2003).
51 350 F 3d 1235, 1237.
52 350 F 3d 1235, 1238-39.
53 350 F 3d 1235, 1238.
54 350 F 3d 1235, 1240.

a cell Generally such a gene would not express EPO Almost naturally present or by cells derived by replication from such a cell. The technique was the introduction of an exogenous DNA product been referred as ‘GA-EPO’ AMGEN isolated the patented genes.

It uses a process which it calls ‘gene activation’ and the product been referred as ‘GA-EPO’ AMGEN isolated the gene which coded for human EPO from a human donor cell. It uses a process which it calls ‘gene activation’ and the expression, Kirin-Amgen Inc v Hoechst Marion Roussel Ltd; [2004] UKHL 46, para 10.

Kirin-Amgen Inc v Hoechst Marion Roussel Ltd; [2004] UKHL 46, para 2.

Kirin-Amgen Inc v Hoechst Marion Roussel Ltd; [2004] UKHL 46, para 11.

Kirin-Amgen Inc v Hoechst Marion Roussel Ltd; [2004] UKHL 46, para 41, 49, 53, 57.


Article 2 states that ‘For the purpose of determining the extent of protection conferred by a European patent, due account shall be taken of any element which is equivalent to an element specified in the claims’.

2004 (29) PTC 108 (Mad), however there are some other cases like Thomason Brandt v The Controller of Patents and Designs, AIR 1989 Delhi 249, Raj Parkash v Mangat Ram Chowdhry and Ors, AIR 1978 Delhi 1, and Lalubhai Chakbhai Jariwala v Chinamal Chunjial and Co, (1935) 37 BOM L R 665, wherein the Court very briefly mentioned about applying the pitth and narrow rule to determine infringement.

India, as a member of World Trade Organization and by virtue of TRIPS Agreement, is under an obligation to consider granting product patent in all fields, including medicines and drugs with effect from 1 January 2005; by way of an interim measure, till the product patent application is taken up for consideration, provision has been made in the Patents’ Act for granting Exclusive Marketing Rights.

Basheer Shamnad, Block me not: How ‘essential’ are patented genes, University of Illinois Journal of Law Technology & Policy, 55 (Spring 2005) 89.


EPO is a hormone made in the kidney which stimulates the production of red blood cells by the bone marrow.

Kirin-Amgen Inc v Hoechst Marion Roussel Ltd; [2004] UKHL 46, para 1.

It uses a process which it calls ‘gene activation’ and the product been referred as ‘GA-EPO’ AMGEN isolated the gene which coded for human EPO from a human donor cell and then introduced it into a mammalian cell in culture which had been derived from the ovary of a Chinese hamster. As part of the hamster DNA, it expressed EPO. The essence of the technique was the introduction of an exogenous DNA sequence coding for EPO into a host cell in which it would be expressed. Whereas in TKT’s gene activation method, the EPO is expressed in a human cell by an endogenous gene naturally present or by cells derived by replication from such a cell. Generally such a gene would not express EPO Almost all human cells contain the full complement of DNA coding for all the proteins needed by the body but each cell will express only those proteins which its particular tissue requires. The rest remain inactive, disabled by the absence of a suitable regulatory which is needed to promote expression. TKT’s technique enables it to activate or ‘switch on’ the EPO gene in a human cell which would not ordinarily express that protein and then to select for commercial use those descendants of the manipulated cells in which the relevant genes have been amplified to produce a high level of expression.

Amgen, Inc v Hoechst Marion Roussel Inc (Amgen II), 314 F 3d 1313, 1358 (Fed Cir 2003).


In Russell Finex Ltd v Telsonic AG’s Patent, [2004] EWHC 474 (Ch), it was held that prosecution history should play no part in construing a patent and its claims.