

Contributory Patent Infringement and the Pharmaceutical Industry†

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Article details the laws in different countries on contributory infringement. It highlights various legal issues involved in this area by discussing and analysing different cases and decisions given by Courts in different countries. It concludes with some suggestions for the development of the relevant laws in India.

Intellectual property protection laws have existed since a very long time. These laws have been formulated to protect the rights of the inventors to their inventions. Most of the countries, through various statutory provisions have recognized and protected economic and moral rights of the inventor in their inventions. Such rights are aimed at promoting innovation, creativity and the dissemination of the knowledge for the benefit of society and the application of its results for the economic and social development of mankind.

Infringement

Infringement is generally defined as an act of making, using, selling or offering for sale without the authority of the patentee, any patented invention, within a

State where a patent is in force, or unauthorized importation into such a State, any patented invention, during the term of the patent.

Infringement of a patent can be:

- (a) direct
- (b) induced
- (c) contributory, or
- (d) through colourable imitations or equivalents.

Direct Infringement

Direct infringement occurs when someone who, without authority, makes, uses or sells a patented invention in the country where the patent is valid and is enforceable.

Induced Infringement

Induced infringement occurs when a person actively and knowingly aids and

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abets direct infringement of a patent by another person.

Contributory Infringement

A Contributory infringement occurs when any person, without authority from the patentee sells or offers to sell within the patent granting States, or imports in such States, a component of a patented machine, manufacture, combination or composition, or a material or apparatus, for use in practising a patented process, or machine constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in the infringement of such patent, and not a staple article of commerce suitable for substantial non-infringing use.

Infringement under Doctrine of Equivalence

Under the doctrine of equivalence, an accused device is considered infringing if it performs “substantially the same function in substantially the same way to (achieve) substantially the same product as claimed in a patent”.

The fundamental guiding principle is to prevent the ‘unscrupulous copyist’ from escaping liability for infringement simply by making minor modifications, without having any novelty, in such a manner that would take the copied invention outside the scope of the claims made in the original patent for that invention.

Varying Concepts of Contributory Infringement

The concept of contributory infringement varies from country to country. Also in many countries including India, the law is not well developed.

Broadly, the definition of contributory infringer is applicable in all major countries where the laws of patent are well defined. However, there are substantial differences, from country to country, in the scope, premises, and interpretation of the law regarding contributory infringement.

In general there is an agreement in most of the countries that the production, sale or offer for sale of an article will constitute contributory infringement only if the said article is not a staple article of commerce. This means that the article in question does not have any other substantial commercial use except for producing the patented article.

There are differences among various countries regarding necessary conditions required to prove contributory infringement. In the US, UK, Australia and Malaysia it is required to prove direct infringement first in order to get relief for contributory infringement. However, in South Korea it is not required to prove direct infringement, whereas the statute is not very clear in some other countries like France and Germany.

According to the US Supreme Court, the infringer must have knowledge that the article in question was patented and his use of such invention to make, use, sell or offer to sell will constitute infringement¹. However, in some countries notably South Korea, such knowledge is not mandatory and the mere act of producing components that could only be used to produce a patented article contribute to contributory infringement².

Difference also exists among countries on whether or not, the importation of the

components of the article, which have no other known use other than in the patented invention, into a country where the invention is protected by patent, constitutes contributory infringement. In the US and in many other countries, such an act will constitute contributory infringement. But in UK, the place from where the supply is made of the material or its part and the place where the invention is carried out, should be within UK in order to constitute contributory infringement. Thus, foreign suppliers of materials or parts, which are brought into UK by the direct infringer, are excluded. Also excluded are the British manufacturers who make components or parts of the patented invention in UK but complete, the manufacture of the patented product or operate the patented process abroad³.

Contributory Patent Infringement and the Pharmaceutical Industry

Patent protection is very important for the pharmaceutical industry in order to generate revenues for continued research for new drug product to bring to the market. For chemical and pharmaceutical products the question of induced and contributory infringement becomes quite complicated in certain situations. In different countries, the courts have delved in great details, the different facets and issues involved in contributory infringement and have pronounced some landmark judgements. We would now critically examine some of these judgements.

Beecham vs Bristol: The Hetacillin Case⁴

In this case, Beecham held the British

patents on the antibiotic ampicillin, as well as on processes for its manufacture. Bristol held the US licence for its manufacture, and used Beecham's patented manufacturing processes in the synthesis of hetacillin, a derivative of ampicillin made by adding acetone. In the presence of water, hetacillin converts freely and reversibly into ampicillin and acetone, that is to say, the acetone can readily be generated from Hetacillin leading Beecham counsel to describe the new drug as "ampicillin with a hat on." Bristol marketed the new antibiotic in the UK, and Beecham brought suit for infringement.

The decision of the House of Lords in the case was that the act of selling the prodrug did in fact infringe the product claim which covered the parent drug ampicillin.

Though the decision was based on the doctrine of "pith & marrow" of a claim, it was also the first instance where a suit for contributory infringement could have been successfully brought.

Zenith Laboratories vs Bristol Myers-Squibb Co.⁵: *The Cefadroxil Case*

This case involved a new form of Cefadroxil.

The Zenith Laboratories, Inc. ("Zenith"), filed a declaration in federal district court, seeking judgement in its favour that its product, cefadroxil DC, a structurally new form of the compound cefadroxil (an antibiotic, whose patent had expired) did not infringe the claims in a current patent owned by Bristol-Myers Squibb Co. ("Bristol") (for a different form of cefadroxil).

Cefadroxil DC (“Zenith”), and drug, cefadroxil monohydrate (“Bristol”), differ only in the number of water molecules paired with each cefadroxil molecule. At trial, Bristol did not contend that cefadroxil DC infringed its patent in its manufacturing or at preingested state. Rather, it asserted that after ingestion, Zenith’s compound converted to cefadroxil monohydrate inside the body (or *in vivo*) and that such a conversion rendered cefadroxil DC an infringement to cefadroxil monohydrate of Bristol.

The district court held that Zenith had not directly infringed Bristol’s patent because:

Its manufactured product differed from Bristol’s patented compound. However, it found that cefadroxil DC did convert *in vivo* to cefadroxil monohydrate. It also reasoned that, if subsequent “absorption of the converted drug into the bloodstream constitute [d] a ‘use’ within the meaning of 35 U.S.C. s 271(a), then the person ingesting cefadroxil DC would contributorily infringe [Bristol’s] patent. Consequently, any sale of cefadroxil DC by Zenith for human consumption . . . would constitute a direct and knowing inducement of that infringement.”

The Court of Appeals for the Federal Circuit (the “CAFC”) reversed the trial court’s finding of induced infringement based on its findings that the evidence provided at trial was insufficient to confirm that the patented product actually formed in the human body (and, therefore, that a literal, direct infringement had taken place). In addition, the CAFC held that:

No direct infringement occurred under the doctrine of equivalents because the compound formed in the stomach performed a different function than did the patented product. Because no direct infringement had been shown, the manufacturer of the accused product could not be found liable for induced infringement.

However, had the CAFC concurred with the district court’s finding that the evidence conclusively proved that the patented product actually formed in the human body, some serious questions would have arisen.

(1) Does the metabolic conversion of a non-patented product into a patented product inside the human body constitute “making” according to the statutory provisions of the term?

(2) Would the subsequent absorption of the chemical into the blood stream constitute the “using” of the patented product within the statutory meaning of that term?

(3) Does the providing of unpatented chemicals necessary to “metabolize” into a patented product in the human body, through the sale of a pharmaceutical drug, constitute induced infringement, contributory infringement, or both?

In interpreting the term “make,” as it relates to patent infringement, courts have adopted the ordinary usage of the word “to create by putting together component parts.” In analysing for infringement, courts have used synonyms for “make” such as “assemble”, “build”, “construct”, “fabricate,” and “manufacture.” All these terms imply a process that culminates when the accused invention has

reached a point wherein it is identical or equivalent to the patented invention.

Based on the concept of end-user's assembling of a patented product may constitute infringement, people tend to argue that the metabolic conversion of a non-patented product inside the body into a patented product should constitute infringement. However, this seems extending the definition of "making" too far.

Our body is a complex structure, which performs countless different operations for sustaining ourselves. The process of metabolizing any ingested substance is a natural action of the body, which it performs, based on its own logic in most cases independent of external intervention. A particular action might be done by our body for fulfilling certain requirements and in the process if a particular drug gets converted to some other form without any external intervention but due to the normal functioning of the body should not be construed as an act of "making" or "assembling"

The next question, which arises, is what constitutes a "use" within the meaning of the statute.

It is logical to interpret that the purpose of the use must be the same as claimed in the patent and the manner of the use must be the same.

According to this interpretation, the use of the drug in the body is different from that claimed in Bristol-Myers application. Hence, the metabolic conversion as described above should not constitute an "use" as required by the statute.

The third and most interesting question is whether Zenith by selling a product which "metabolizes" in the human body

into a patented product became a contributory infringer?

The formation of a patented product within a person's body would not constitute a "sale" within the meaning of law. However, such a sale may constitute contributory infringement on the pretext that the sold product is being "used" to "make" a patented product inside the body.

Since, the use is different from the usage described in the patented invention, whether Zenith should be considered, as a contributory infringer will become clear if we consider the judgement in the terfenadine case.

The Terfenadine Case

The famous Terfenadine case was decided in the Courts of Germany, UK and the USA.

Merrel Dow had a patent for Terfenadine⁶, an antihistamine. This patent expired in 1992. After expiry of this patent many companies started selling Terfenadine, viz. H.N. Norton & Co. Ltd, Penn Pharmaceuticals Ltd and Generics (UK) Ltd in UK, MundiPharma in Germany & M/S Geneva Pharmaceuticals and M/S Baker Pharmaceuticals in the USA. All of them were sued by Merrel Dow & Marion Merill Dow Ltd, alleging infringement of the substance and use claims of a new and much later patent⁷, which claimed the metabolite of Terfenadine (the metabolite patent). Tests have conclusively proven that Terfenadine undergoes 99% fast pass metabolism and gets converted into the patented metabolite and this actually accounts for the anti-histamine activity of

Terfenadine.

The defendants argued that they did not produce the active metabolite substance in the manufacturing plant and they were manufacturing and selling a product whose patent has expired.

The trial Court in Germany accepted the defendant's argument that the substance claim of the metabolite was not being infringed by the selling of Terfenadine.

However, the Court felt that there was a more valid case of contributory infringement against the defendant though it could not decide in favour of contributory infringement.

A similar ground was taken by the District Courts in USA.

However, in the UK, the matter moved to Court of Appeal, which passed a very significant judgement⁸.

The plaintiff claimed contributory infringement under section 20(2) of the Patents Act 1977. The Court made a very interesting observation, that if the plaintiff was correct, and they had discovered that inside some organ of the human body aspirin gets converted to hitherto unknown compound, they could patent it and thereby preclude anybody from selling aspirin! This is a very ludicrous supposition.

According to the Court, the fundamental question to be answered was whether, given the prior publication of Terfenadine patent, and the prior use of Terfenadine, a claim to the acid metabolite (not limited to acid metabolite produced by other means) is valid, regardless of who the patentee of Terfenadine was. The Court held that the disclosure to the public of a

method of anti-histamine treatment comprising the administering of Terfenadine into the human body discloses to the public (even if not fully understood), for the sake of patenting, each step of the precise chemical happenings within the human body. The subsequent discovery of more information of how the process works within the body does not have the effect of then removing the process, or any part of it, from public domain. The metabolite thus is one step in the process of administering Terfenadine in the human body described in the Terfenadine patent. The plaintiffs were free to seek a patent for the acid metabolite when made otherwise than as part of the disclosed process (the use as described in the Terfenadine patent).

This judgement is very significant as it aims to limit extending the life of a patent. It also aims at stopping double patenting in as much as it intends to stop taking out from the public use processes or products already made available to the public.

Based on the judgement in the Terfenadine case, one can draw the conclusion in the Cefadroxil case. Since Bristol-Meyers patent on Cefadroxil described its prior use by ingestion of the compound, it should disclose to the public, all precise mechanism of action, chemical changes which take place inside the body and chemical identities of all metabolites, derivatives so formed including Cefadroxil monohydrate, which is the active metabolite. Hence the subsequent patent on Cefadroxil monohydrate should have been struck down based on prior public disclo-

sure.

AstraZeneca vs Genpharm and Cheminor: The Prilosec (omeprazole) Case

This case could have been that of contributory infringement.

AstraZeneca claimed that Genpharm and Cheminor infringed a patent for active metabolites of omeprazole called sulphenamides (US 4636499, which expires in 2006.) because it would convert to the patented drug in the body and the patent covered the *in vivo* produced sulphenamides in addition to the synthetic ones.

Genpharm and Cheminor countered that the *in vivo* formation of sulphenamides was disclosed in the basic compound patent on Prilosec (US 4255431) and in numerous prior art references published more than a year before [AstraZeneca's] application for the US 4636499 patent.

The judge ruled that:

“By claiming patent protection for sulphenamides formed *in vivo* after the oral administration of omeprazole, [AstraZeneca] has merely attempted to patent the unpatentable”

“Had [AstraZeneca] demonstrated that the mechanism of omeprazole and sulphenamides *in vivo* had changed since the publication of the prior art sources, it would have been relevant to the anticipation analysis because it would have created a factual issue with respect to what occurred in the prior art.”

Had the prior art not referred the *in vivo* formation of sulphenamides, this case could have been that of contributory infringement concerning the active me-

tabolites of a drug.

The Taxol Case

The judicial interpretation of the law on contributory infringement was laid in the famous Taxol⁹ case by the Full Court of the Federal Court of Australia.

Bristol-Myers Squibb Co. (“Bristol-Myers”) held two Australian patents for methods of administering the drug “taxol” to patients for the treatment of cancer.

FH Faulding & Co. Ltd (“Faulding”) supplied taxol to medical practitioners in Australia along with instructions regarding the administration of the drug in the treatment of cancer. By following the instructions provided by Faulding, the medical practitioner would infringe the patents held by Bristol-Myers. Consequently, Bristol-Myers brought an action against Faulding for infringement of its two patents. In addition to other grounds, the ground of contributory infringement was also alleged.

The Full Court applied a purposive construction to the provisions and found that infringement of the patents had occurred by the supply of taxol for the purpose of performing the claimed method of treatment and found Faulding guilty of contributory infringement.

Hoffmann-La Roche Inc. vs Promega Corp¹⁰

It was alleged that Promega contributorily infringed three of Roche's patents viz. US patent nos. 4,889,818¹¹; 4,683,195¹²; and 4,683,202¹³ all related to DNA technology. Hoffman-La Roche Inc. (Roche) was the assignee of these three patents from Cetus Corporation.

The 4,889,818 patent claims a purified thermostable enzyme (Taq) that could be isolated directly from a natural organism (nTaq). The 4,683,195 and 4,683,202 patents claimed a process known as Polymerase Chain Reaction (PCR), which involves the detection of infinitesimal quantities of specific sequences of DNA and the subsequent 'amplification' of them into billions or trillions of copies.

Cetus had also developed a '10X PCR Buffer,' a specific formulation of components that provides a chemical environment 'optimally' suited for using Taq in PCR. Subsequently, separate tubes of the magnesium chloride component of the buffer were sold to allow customers greater flexibility in varying concentrations of magnesium chloride to optimize PCR performance all of which was licensed to Roche in 1991.

In 1990, defendant Promega Corp. was granted a non-exclusive licence under the 4,889,818 patent to manufacture, use and sell nTaq specifically for uses other than PCR applications. Promega sold nTaq as a generic kit, allowing customers to use nTaq for various applications. Promega later also developed a '10X Reaction Buffer' for its nTaq kit, and announced that 'it would provide the magnesium chloride component of the buffer in a separate tube to allow users to vary the levels of that element depending on their needs'. Roche sued Promega, alleging that it breached its license and contributed to the infringement of its PCR process patents when it packaged nTaq in a 'PCR optimized' kit that was marketed to the scientific community. Promega argued that because Roche admitted in its

complaint that nTaq could be used for nTaq and DNA sequencing, nTaq was therefore suitable for 'substantial non-infringing use' which was a sufficient ground to deny relief in a suit of contributory infringement in USA (discussed above).

However, the Court disagreed with this argument on the ground that that Promega assumed that the 'substantial non-infringing use' analysis was directed only at then Taq ingredient, which was not correct. Even if nTaq had non-PCR uses, the court explained, Promega's packaging of nTaq with other ingredients may constitute contributory infringement if the package, as a whole, was unsuitable for substantial non-infringing use. Hence it was imperative to show that such a package should have a substantial (which should include economical considerations) 'non-infringing use'. Since Promega could not prove such substantial 'non-infringing use' the Court decided that *prima facie* there was sufficient ground for considering that Promega has contributorily infringed Roche's patent.

This is a classic case where one of the fundamental provisions in defining contributory infringement was taken into consideration while deciding the merits of the case.

Another important aspect of contributory infringement, which was decided in the USA was the liability of foreign manufacturer's using a patented process and allowing it to be imported to the US. In a recent case¹⁴ United States District Court for the Southern District of Indiana found that an Australian corporation had contributorily infringed a product patent

when it sold devices to its American subsidiary, knowing that the subsidiary would resell them in the United States.

The court applied the test for contributory infringement and found that the device was especially adapted for use in infringing the patent and was not a staple article suitable for substantial noninfringing use. Thus, the requirement in section 271(c) that the defendant made the sale knowing that the article was “especially made or especially adapted for use in an infringement of such patent” can mean simply that there was a sale in which the seller knew of the buyer’s intent to import the article into the United States.

The act of importation is the infringement, and the article is the “*especially made*” key to accomplishing the infringement.

Pfizer Inc. vs Aceto Corp.¹⁵

It was held that a foreign manufacturer that does not itself import the product into the United States is not liable under 35 U.S.C. § 271(g) (which imparts infringement liability on the importation, sale, or use within the United States of a product manufactured abroad using a process that is protected by an unexpired United States patent) when a buyer of its product imports that product into the United States. The court stated that there is no liability under section 271 (g) even if the manufacturer could foresee such importation.

However, the court did not address the issue of whether the foreign manufacturer may be liable for actively inducing infringement or for contributory infringement when the manufacturer can foresee

importation into the United States. According to our view the manufacturer should not be liable for contributory infringement, as otherwise, it would mean increasing the judicial authority of a particular country beyond its borders which is totally against the basic principle of patent right which is territorial.

These case laws clearly bring out the various issues involved in establishing a determining criteria for contributory infringement though some aspects like whether a metabolite of the patented product can be considered to be contributorily infringing etc. still require to be resolved.

Conclusion

In India, the doctrine of contributory infringement is not well established. In fact, Indian Patent Act does not contain any specific provisions in this regard. Also, there has been no significant judicial pronouncements or interpretations on this subject. Even the present Patent amended Act (2002), is silent on this issue. All it states is what constitutes infringement and who is an infringer. However, this broad definition does not help in interpreting the finer issues involved in an analysis of contributory infringement. There are also no judgements available in India on this issue. But, with India’s signing of GATT and TRIPS Treaty and the advent of product patent era (in drugs & pharmaceuticals), coupled with India’s leading position in software technologies we have to incorporate in details all aspects of infringement. Since the concept of contributory infringement is not at all

defined, sufficient diligence should be taken in framing its provisions.

Some of the areas which should require special attention are:

1. What constitutes contributory infringement?

2. The scope of contributory infringement specially third party liability. These should include specific statutes in the following areas:

(i) who are infringers?

(ii) whether it is required to show that the material in dispute is not a staple article of commerce in order to establish contributory infringement.

(iii) whether patent misuse can be used as a defense against an allegation of contributory infringement.

(iv) is it mandatory to establish direct infringement in order to establish a case of contributory infringement?

(v) whether repairing of a patented article constitutes infringement

(vi) whether one who manufactured components of a combination patent and then shipped them abroad for reassembly was guilty of contributory infringement.

(vii) whether there will be any pre-issuance liability on potential infringers.

(viii) whether manufacturing of a patented product for regulatory approval constitutes infringement.

3. Appropriate remedies.

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