CHAPTER VI

DOCUMENTATION OF IPR LEGAL CASES IN PHARMACEUTICAL INDUSTRIES

In light of increased competition, strict enforcement, new legal and regulatory developments and recent decisions, the pharmaceutical industry continues to face significant changes and challenges. Keeping up to date and evaluating the practical implication of recent case law and policy decisions is crucial to avoid unnecessary costs and also for staying on the right side. The present research work highlight the various cases regarding patents and related issues in the pharmaceutical industry.

1. Novartis Vs. Union of India & Others

Novartis v. Union of India & Others is a by a two-judge bench of the on the issue of whether could patent in India, and was the culmination of a seven-year-long litigation fought by Novartis. The Supreme Court upheld the Indian patent office's rejection of the patent application.

The patent application at the center of the case was filed by Novartis in India in 1998, after India had agreed to enter the and to abide by worldwide intellectual property standards under the agreement. As part of this agreement, India made changes to its patent law; the biggest of which was that prior to these changes, patents on products were not allowed, while afterwards they were, albeit with restrictions. These changes came into effect in 2005, so Novartis' patent application waited in a "mailbox" with others until then, under procedures that India instituted to manage the transition. India also passed certain amendments to its patent law in 2005, just before the laws came into effect, which played a key role in the rejection of the patent application.

Gleevec – Anti Cancer Medicine:

The patent application claimed the final form of Gleevec (the beta crystalline form of imatinib). In 1993, during the time India did not allow patents on products, Novartis had patented imatinib, with vaguely specified, in many countries but could not patent it in India. The key differences between the two patent applications, were that the 1998 patent application specified the (Gleevec is a specific salt - imatinib mesylate) while the 1993 patent application did not claim any specific salts nor did it mention mesylate, and the 1998 patent application specified the solid form of Gleevec - the way the individual molecules are packed together into a solid when
the is manufactured (this is separate from processes by which the drug itself is into pills or capsules) - while the 1993 patent application did not. The solid form of imatinib mesylate in Gleevec is beta crystalline.

As provided under the TRIPS agreement, Novartis applied for Exclusive Marketing Rights (EMR) for Gleevec from the Indian Patent Office and the EMR were granted in November 2003. Novartis made use of the EMR to obtain orders against some generic manufacturers who had already launched Gleevec in India. Novartis set the price of Gleevec at USD 2666 per patient per month; generic companies were selling their versions at USD 177 to 266 per patient per month. Novartis also initiated a program to assist patients who could not afford its version of the drug, concurrent with its product launch.

When examination of Novartis' patent application began in 2005, it came under immediate attack from initiated by generic companies that were already selling Gleevec in India and by advocacy groups. The application was rejected by the patent office and by an appeal board. The key basis for the rejection was the part of Indian patent law that was created by amendment in 2005, describing the patentability of new uses for known drugs and modifications of known drugs. That section, Paragraph 3d, specified that such inventions are patentable only if "they differ significantly in properties with regard to efficacy." At one point, Novartis went to court to try to invalidate Paragraph 3d; it argued that the provision was unconstitutionally vague and that it violated TRIPS. Novartis lost that case and did not appeal. Novartis did appeal the rejection by the patent office to India's Supreme Court, which took the case.

The Supreme Court case hinged on the interpretation of Paragraph 3d. The Supreme Court decided that the substance that Novartis sought to patent was indeed a modification of a known drug (the raw form of imatinib, which was publicly disclosed in the 1993 patent application and in scientific articles), that Novartis did not present evidence of a difference in therapeutic efficacy between the final form of Gleevec and the raw form of imatinib, and that therefore the patent application was properly rejected by the patent office and lower courts.

Although the court ruled narrowly, and took care to note that the subject application was filed during a time of transition in Indian patent law, the decision generated widespread global news coverage and reignited debates on balancing public good with monopolistic pricing and innovation with affordability. Had Novartis won and gotten its patent issued, it could not have prevented generics companies in India from continuing to sell generic Gleevec, but it could have
obligated them to pay a reasonable royalty under a grandfather clause included in India's patent law.

Many developing and poor countries rely on cheaper but quality generic medicines from India. The weakening of 3(d) would have delayed the generic availability of medicines for HIV and other diseases. Thus India can continue the production and export of generics while other countries continue to import from India. Other companies would not involve unnecessarily in ever greening patent persuasion and devote in innovative research. Even other developing countries can cite this precedence and amend their IPR laws to protect public health from undue exploitation of patents. This historic judgment of Indian Supreme Court against the Swiss pharma major Novartis ever greening patent attempt is a victory of millions and millions patients of the world.

2. THE BAYER Vs CIPLA CASE

(Nexavar – India) Bayer was granted a patent in India for Sorafenib in March 2008. (vide Patent No. 215758). The patent is schedule to expire in 2020. Bayer manufactures and markets its Sorafenib product as Nexavar in India. The background for the current case started when Cipla filed an application with the Drug Controller General of India (DCGI) for a license to manufacture, sell and distribute a generic version of Sorafenib. Bayer opposed it in the court citing a potential patent infringement in case Cipla’s application for marketing approval is accepted. Bayer particularly cited (a) its right to stop third parties to make, use, offer to sale, or import its patented product without its consent (Section 48 of the Patent Act) and (b) DCGI power not to approve the marketing right for a product that is ‘spurious’ (Section 2 of the Drugs & Cosmetic Act). Bayer’s contention was that an attempt by Cipla to manufacture Sorafenib will make Cipla’s drug a ‘spurious’ drug under the provisions of the Drugs & Cosmetic Act. Going further, Bayer demanded a Patent Linkage based system, wherein the DCGI does not approve the marketing rights for a drug for which a patent exists.

Cipla’s drug a ‘spurious’ drug under the provisions of the Drugs & Cosmetic Act. Going further, Bayer demanded a Patent Linkage based system, wherein the DCGI does not approve the marketing rights for a drug for which a patent exists. Cipla, along with the other respondents, the DCGI (represented by the Union of India), in its reply, relied on the logic that merely by granting a marketing approval the DCGI or Cipla, would not be infringing the patent rights accorded to Bayer in any manner as the act does not fall under the purview of making, using, offer to sale, or
importing its patented product. Further, an act of infringement is established only by a court of law and not merely by a statement by the patentee. In the present case, the DCGI was not a competent authority to decide if the drug for which the marketing approval was sought was infringing any existent patent or not. The mandate of the DCGI is only to assess the safety and efficacy data related to the drug and either approve or disapprove the drug for marketing within in the Indian territory based on these assessments. Whether or not, the drug in question would be potentially infringing any patented product in India, is something which is beyond the scope of DCGI. Also, the Patents Act provides that a drug manufacturer can conduct experiments on a patented drug to meet the requirements of a drug controlling body (Section 107A). Cipla went a step further to claim that the Bayer’s patent is invalid and that Cipla is ready to challenge its validity.

On the ‘spurious’ drug issue, Cipla contends that Bayer’s counsel has failed to rightly interpret the word ‘spurious’ in the actual context that it is purported to be used. The addition of ‘spurious’ drug, Cipla maintains, was to prevent any substitute drug that could be passed off as the original one by use of deceptive marks or packaging. Cipla, on the other hand, is making a generic copy of the drug and not trying to pass off its product over Bayer’s product.

Cipla’s contention also extended to Bayer’s plan to introduce the system of ‘Patent Linkages’ in India. The former came down heavily upon the latter by accusing Bayer to trying to introduce a new system in India, which is only possible by bringing legislative amendments.

Counsel for DCGI maintained that vide Section 107A of the Patents Act, a provision is made to experiment on the patented products for the purpose of submitting data to a drug controlling body. Further, it argued that a patent right, which is a private right, cannot be enforced by a public entity (DCGI). Hence, the idea that the DCGI should also peep in the patent status and then grant the approvals is also not sustainable. DCGI role is restricted to disallow spurious, adulterated and mis-branded drugs and allowing other drugs for market distribution if its meets other experimental requirements.

Based on the arguments of both the parties, Justice Ravindra Bhat of the High Court of Delhi, concluded the following:

1. The Drugs & Cosmetic Act and the Patents Act are divergent in their objectives and serves very different purposes. While the former was framed to avoid any spurious or adulterated drugs to enter into the market, the latter was framed to allow an innovator
company to stop third parties to commercialize their (innovator’s) product/process. The Officials enforcing the provisions of one Act is not technically competent to deal with the provisions of the other Act.

2. By accepting Bayer’s proposition to allow a Patent Linkage and stop Cipla/DCGI to approve the marketing rights for a drug, judiciary would be attempting to enter a legislative role, which it should not be doing.

3. Expecting DCGI to take patents into consideration while granting marketing approvals would not only be stretching too much of its normal reach but also an attempt to interpret the Drugs & Cosmetic Act beyond its intended boundaries.

4. The Patents Act has been amended many a times, latest being in 2005. Had there been any intention by the legislation to bring any changes relating to Patent Linkages, it would have found a place in the amended Act.

5. On the issue of spurious drug, Judge Bhat was in agreement with Cipla’s contention.

Justice Bhat concluded that the present case was an attempt by Bayer to ‘tweak’ public policies through court judgments. He came down heavily upon Bayer and dismissed the suit with costs.

**CURRENT STATUS:** Bayer filed an appeal before a division bench of the High Court. Later, the division bench ruled against Bayer, thus paving the way for the launch by Cipla. Bayer has now approached the Supreme Court.

Court observed that Cipla's generic version was a polymorph B variant of Roche's patented drug and did not infringe any patent in India.

**3. Roche Vs Cipla:**

India's generics giant Cipla has won a landmark patent case against Swiss drug maker Roche in the Delhi High Court. Roche had filed a patent infringement case against Cipla in 2008 for its generic copy of lung cancer drug Tarceva. The judgment in favor of the Indian company came after four years court battle. The court observed in its judgment that it has been scientifically proven that Cipla's generic version was a polymorph B variant of Roche's patented drug and that it did not infringe any patent in India. The court also said Roche's patent on the drug is valid. Roche had applied for a patent for the polymorph B version of erlotinib, which is the generic name of the drug, at the Indian patent office. But the application was rejected on the grounds that it doesn't qualify for a patent in India. Indian patent law doesn't qualify variants of a
basic drug molecule (erlotinib in this case) unless such versions demonstrate an enhanced therapeutic efficacy. The judgment comes at a time when all eyes are on India's patent system. The ruling comes ahead of the Supreme Court hearing of the Glivec case. Pharma giant Novartis has filed a case against the Indian patent office for the latter's refusal to grant it a patent for Glivec. In another case earlier this year, German company Bayer lost a trial when the Indian Patent Office granted compulsory licence to local generic manufacturer Natco Pharma for Nexavar in India.

4. MERCK Vs GLENMARK
On the same day as the Novartis judgment, Merck Sharp & Dohme (MSD), the third-largest pharma company in the world in terms of revenues, filed a patent infringement suit in the Delhi High Court against Glenmark, an Indian pharmaceutical company with a significant presence in branded generics. MSD sought a permanent injunction against Glenmark for launching generic versions of Merck’s top-selling anti-diabetes drugs Januvia and Janumet in the Indian market. MSD was granted a patent in India in 2007 for the compound sitagliptin which is the active ingredient in its branded products Januvia and Janumet, which were launched in India in 2007 and 2008, respectively, at a price-point that is the lowest in the world. MSD holds patents for sitagliptin in 102 countries of the world, apart from India.
In March 2013, Glenmark, subsequent to receiving a manufacturing license from the Food and Drug Administration of Sikkim (a small northeastern Indian state), launched similar drugs for Type-II diabetes. These are priced only 30 percent less than those of MSD’s, which is unusual compared to the typical differential of 80 to 90 percent between generics and patented drugs.
It is interesting to note here that while Section 3(d) of the Indian Patents Act worked against Novartis in its case to obtain a fresh patent of Glivec, it is also the clause that supports MSD’s claim that its patent for sitagliptin covers all of its compounds.
The patent litigation on the diabetes drugs is significant in the Indian context as the country has the world’s second-largest diabetic population after China, and the market is growing by at least 10 percent every year, according to IMS Health’s data, a pharmaceutical market research company.
5. **BAYER Vs IPAB’S**

MUMBAI: German drug major Bayer AG has challenged the Intellectual Property Appellate Board's (IPAB's) order of compulsory licence issued to domestic pharmaceutical company Natco Pharma in the Bombay High Court and has sought the court's intervention to protect its rights over patented cancer drug Nexavar.

"We introduce the product after years of research and investment, while companies like Natco merely copy and manufacture the product," said Ravi Kadam, senior counsel who is representing German pharmaceutical company in the case. "They (domestic companies) are making money while Bayer gets 7%, as royalty from the Indian pharma company."

In March 2013, India’s Intellectual Property Appellate Board upheld the country’s first compulsory license on a pharmaceutical product. The license was given to Natco Pharma, an Indian generic drug manufacturer; to legally make and sell a low – cost version of German pharma giant Bayer AG’s patented drug Nexavar, which is used to treat kidney and liver cancer. The license brought the price of the drug down 97 percent from over US$ 5,500 per month to US$ 175, and set a precedent for legally allowing the sale of generic versions of new medicines that are still under patent, to widen access to those in the country who need them the most.

6. **SUN PHARMACEUTICALS Vs ELI LILLY:**

Double-patenting issues arise when two commonly owned applications cover the same or similar inventions. The issues in this appeal revolved around an earlier patent claiming a composition of matter and describing a method for using that composition, and a later patent claiming that method of use.

Both of the patents in this case, Patent No. 4,808,614 (the '614 patent) and Patent No. 5,464,826 (the '826 patent) relate to gemcitabine, the active ingredient of Lilly's Gemzar® product. The '614 patent claims both gemcitabine itself, as well as a method of using it to treat viral infections. In addition, the '614 patent's specification discloses using gemcitabine to treat cancer. The '826 patent claims a method of treating cancer comprising administering a therapeutically effective amount of gemcitabine. The difference was important: the '614 patent expired on May 15, 2010, while the '826 patent does not expire until November 7, 2012.

The applications leading to both the '614 and '826 patents were filed on the same day, December 4, 1984. The '614 was a continuation-in-part of application No. 473,883 ("the '883
application"), which did not disclose using gemcitabine to treat cancer. That information was added as part of the continuation-in-part.

After filing an Abbreviated New Drug Application ("ANDA") for a generic version of Gemzar®, Sun Pharmaceuticals, sought a declaratory ruling that the '826 patent was invalid and not infringed. Lilly counterclaimed for infringement of the '826 and '614 patents. The '614 patent was not at issue in this appeal.

Applicants are barred from obtaining multiple patents covering the same invention by the doctrine of double patenting.

On appeal, the panel agreed with the district court and Sun that the latter type of double patenting occurred here, thus invalidating the asserted claims of the '826. The basis for the court's decision were two prior opinions, Geneva v. GlaxoSmithKline, 349 F.3d 1373, and Pfizer v. Teva, 518 F.3d 1353. In Geneva, the earlier patent claimed a compound and the specification disclosed its effectiveness for inhibiting beta-lactamase. The later patent claimed a method of using the compound to affect beta-lactamase inhibition. Similarly, in Pfizer, the earlier patent claimed several compounds and the specification disclosed their use in treating inflammation; the later patent claimed a method of using these compounds for treating inflammation. In both cases, the court ruled that the claims were not "patentably distinct," and thus the latter claims were invalid for obviousness-type double patenting.

7. **The Indian Network for People Living with HIV/AIDS Vs Boehringer**

The Indian Network for People Living with HIV/AIDS (INP) — a national network of people living with AIDS in India — and the Manipur Network of Positive People (MNP) have filed a pre-grant opposition to GlaxoSmithKline's patent application for Combivir.

The Positive Women Network (PWM) and INP are opposing Boehringer Ingelheim's patent application for Nevarapine, and DNP (Delhi Network of Positive People) along with INP, have filed a pre-grant opposition to Gilead Sciences' patent application for Viread. More recently, the Karnataka Network of Positive (KNP) and INP have opposed the grant of a patent for three of Abbott's products — Ritonavir, Lopinavir and Kaletra (soft gel). "The drugs for which pharma companies are seeking patent protection in India are not true innovations. They are old molecules, which have been slightly modified or patented for a new use, and these applications do not comply with Section 3(d) of the Indian patent law," said Loon Gangte, regional
coordinator, Collaborative Fund for HIV Treatment Preparedness (South-Asia) and president of DNP.

The legal provision at issue stipulates that modifications of already-known medicines cannot be patented unless such modifications make the drugs significantly more effective. It is designed to prevent a common practice in the pharmaceutical industry known as 'evergreening', whereby the company patents trivial modifications of already existing drugs to extend their monopolies beyond the 20-year period granted for the original patent.

"This is a life-threatening situation for HIV patients. Patenting of these drugs will dramatically reduce access to treatment as copies of the drugs for which MNCs are seeking patent protection are already available in India.

Patenting of anti-AIDS drugs in India could also have a considerable impact on accessibility of treatment not only in developing countries, but all around the world. "Many NGOs including MSF, the Clinton foundation, Pepfar (President's Emergency Plan For AIDS Relief) get more than 80% of their drugs from India. MSF, for instance, gets 84% of its anti-AIDS drugs from India. Once patented, these drugs will not be available anymore in most developing countries," said Leena Menghaney of the Campaign for Access to Essential Medicines, Medecins Sans Frontieres (MSF) — the world's leading independent organisation for medical aid, also known as Doctors Without Borders. The Indian patent office is expected to rule on these cases in the next few months. Glivec's case could be critical to the outcome of the latter. "Most cases against anti-AIDS drugs have been filed under Section 3(d) of the Indian patent law," said Mr. Gangte. Following the rejection of its patent application for anti-cancer drug Glivec, Novartis AG is now challenging the constitutional validity of a key provision in India's Patents Act, Section 3(d).

8. **SRS PHARMACEUTICALS Vs PFIZER**

Unasan, which is an antibiotic drug containing Ampicillin Sodium and Sulbactam sodium, manufactured by SRS Pharmaceuticals Inc., has won a alleged patent infringement case against, Unasyn, antibiotic drug, containing ampicillin sodium and sulbactum sodium, Manufactured by Pfizer Inc., USA.

Pfizer Inc. had filed an alleged infringement case against the defendants claiming that the acts of importing, distributing, marketing, offering to sell and selling the patented product
sulbactum of plaintiff's, were against the Patent No. 26810 issued by the intellectual Property Office in Philippines, in November 1992 to Pfizer Inc. for Unasyn.

According to the Philippines Republic Act No. 8293, Section 23, which qualifies the word "new" as "An invention shall not be considered new if it forms part of prior art." It was thus found out that the Unasyn patent is an invalid patent and is actually an extension of a Patent no. 21116 titled, "Penicillanic Acid derivatives, composition and process for the preparation", which expired on 15th July 2007.

The Presiding Judge, Cesar O. Unialan, of the Makati Regional Trial court, on March 31st 2009, thus declared that, "this court hereby denies the issuance of a preliminary injunction for plaintiffs (meaning Pfizer) miserably failed to prove of their right over the subject molecular ingredient/element or sulbactum sodium or sodium sulbactum for the simple reason the same ingredient had been subject of a prior art."

The case was thereby Dismissed by the court for a simple reason that there was nothing more to be done in the case considering the relief prayed for the plaintiffs under their Amended Complaint.

9. RESOLUTION CHEMICALS LIMITED Vs H. LUNDBECK

Resolution and Arrow were sister companies within the Arrow Group between 2001 and 2009. Arrow’s unsuccessful challenge to the validity of the Patent took place between 2006 and 2009. However Resolution was not asked whether it could or would supply Arrow (or any other company in the Arrow group) with escitalopram at the time of the escitalopram litigation. Nor was it asked to assist in the manufacture or supply of escitalopram at that time.

At first instance Arnold J reviewed the law on privity, confirming that what is required is "a sufficient degree of identification between the relevant persons to make it just to hold that the decision to which one is party should be binding in the proceedings to which the other is party" and that this may or may not be the case for group companies. Applying the law to the facts of the case, Arnold J found that Resolution had no interest in escitalopram at the time of the previous proceedings, and therefore concluded that there was no privity of interest between Resolution and Arrow with regard to those proceedings.

The Court of Appeal also reviewed the law on privity, with Floyd LJ concluding that "a court which has the task of assessing whether there is privity of interest between a new party and a party to previous proceedings needs to examine (a) the extent to which the new party had an
interest in the subject matter of the previous action; (b) the extent to which the new party can be said to be, in reality, the party to the original proceedings by reason of his relationship with that party, and (c) against this background to ask whether it is just that the new party should be bound by the outcome of the previous litigation”.

The Court of Appeal decided (with Floyd LJ giving the leading judgment) that Lundbeck had not established that Arnold J made any error of law. Whilst Arrow and Resolution were part of a group of companies under common control at the time of the 2005 proceedings, those proceedings had not been conducted by Arrow for Resolution's benefit. Floyd LJ explained that “Resolution had no concrete interest in the 2005 proceedings. It would be quite unjust to hold Resolution bound by the outcome. The judge was entitled to come to that conclusion”.

10. IPRS OVER PRODUCTS OF BIODIVERSITY

Neem:

In 1971, a timber company in the United States figured out that the neem tree's usefulness in acting as a pesticide and began planting neem tree seeds. He received a patent on it and, in 1988, sold the patent to the US based company. In 1992, W.R. Grace secured its rights to the formula that used the emulsion from the Neem tree's seeds to make a powerful pesticide. It also began suing Indian companies for making the emulsion.

The controversy over who has the rights to the Neem tree raised many questions. India claims that what the US Companies are calling discoveries are the actual stealing and pirating of the indigenous practices and knowledge of its people. The Indians and members of the Green Party in the European Union oppose big businesses owning the rights to living organisms, otherwise known as biopiracy, because they believe that the rights of poor farmers in developing countries will be harmed.

Basmati Rice Case

- In late 1997, an American company RiceTec Inc, was granted a patent by the US patent office to call the aromatic rice grown outside India 'Basmati'. RiceTec Inc, had been trying to enter the international Basmati market with brands like 'Kasmati' and 'Texmati' described as Basmati-type rice with minimal success. However, with the Basmati patent rights, RiceTec will now be able to not only call its aromatic rice Basmati within the US, but also label it Basmati for its exports. This has grave repercussions for India and Pakistan because not only will India lose out on the 45,000 tonne US import market,
which forms 10 percent of the total Basmati exports, but also its position in crucial markets like the European Union, the United Kingdom, Middle East and West Asia. In addition, the patent on Basmati is believed to be a violation of the fundamental fact that the long grain aromatic rice grown only in Punjab, Haryana, and Uttar Pradesh is called Basmati. According to sources from the Indian Newspaper, Economic Times, "Patenting Basmati in the US is like snatching away our history and culture."

The Rice Patent

RiceTec Inc, was issued the Patent number 5663484 on Basmati rice lines and grains on September 2, 1997.

In abstract, "the invention relates to novel rice lines and to plants and grains of these lines. The invention also relates to a novel means for determining the cooking and starch properties of rice grains and its use in identifying desirable rice lines.

In an official release, the government of India reacted immediately after learning of the Basmati patent issued to RiceTec Inc., stating that it would approach the US patent office and urge them to re-examine the patent to a United States firm to grow and sell rice under the Basmati brand name in order to protect India's interests, particularly those of growers and exporters. Furthermore, a high level inter-ministerial group comprising of representatives of the ministries and departments of commerce, industry, external affairs, Council for scientific and industrial research (CSIR), Agriculture, Bio-technology, All India Rice Exporters Association (AIREA), APEDA, and Indian Council of Agricultural Research (ICAR) were mobilized to begin an in-depth examination of the case. The contents and implications of the patent are currently being analyzed in consultation with patent attorneys and agricultural scientists. The government of India is particularly concerned about the patenting of Basmati because of an earlier case where the US granted a patent to two Indian-born scientists on the use of Turmeric as a wound healing agent. This case worked in favor of India because the patent was subsequently revoked after scientists of (CSIR) successfully challenged the patenting on the ground that the healing properties of Turmeric had been 'common knowledge' in India for centuries. There is a clause in US patent laws that will accept any information already available in published or written form anywhere in the world as 'common knowledge'. As a result, India was able to furnish published evidence to support their case that the healing characteristics of Turmeric is not a new invention and as such cannot be patented.
In the presence of widespread uprising among farmers and exporters, the nation of India as a whole feel confident of being able to successfully challenge the Basmati patent by RiceTec Inc. According to the Economic Times of India, the law firm of Sagar and Suri who won the Turmeric patent case and presently representing the government against RiceTec Inc. in existing cases, said; "RiceTec has got a patent for three things: growing rice plants with certain characteristics identical to Basmati, the grain produced by such plants, and the method of selecting the rice plant based on a starch index (SI) test devised by RiceTec Inc."

**Hill Turmeric:-**

- The news was greeted with disbelief and surprise by most people in India. From time immemorial Turmeric has been traditionally used in India for its many special properties in wound-healing. For instance, it is used as a blood purifier, in treating the common cold, and as an anti-parasitic for many skin infections. It is also used as an essential ingredient in cooking many Indian dishes. How could someone obtain a patent - i.e., an exclusive right to sell and distribute something that was so commonly known - was the disturbing question? This gave a striking blow to India. The biggest challenge before India was to prove its stand in the US courts.

- The claimed subject matter was the use of "turmeric powder and its administration", both oral as well as topical, for wound healing. As per the requirements of U.S. law, it was necessary to find adequate evidence in the form of printed and published information that would establish that the manner of use of turmeric as in the claimed invention, was known before the patent was claimed and, therefore, the patent was invalid. Despite the fact that the use of turmeric was known to every Indian household for ages, finding published information on the use of turmeric powder through oral as well as topical route for wound healing was a difficult task. We were fortunate enough that after an extensive researches 32 references were located, some of which were more than 100 years old, and in the languages of Sanskrit, Urdu and Hindi. The USPTO revoked the patent, stating that the claims made in the patent were obvious and anticipated, and agreeing that the use of turmeric was an old art of healing wounds. The patent on the "use of turmeric in wound healing" is but one of the many examples of how patents are being sought over various aspects of biological resources and products derived from the same. What complicates matters in such patents is that the various useful properties and knowledge regarding
biological resources is already known to many communities of the world in such circumstances proving our case over our traditional knowledge becomes difficult.

**Atta Chakkis:**

It looks like that the west is behind Indian traditional knowledge, again and again its making every product its patent victim. It is now turn for Atta chakkis. Hundreds of wheat exporters may fall into the trap being laid by a Nebraska-based company, ConAgra. The US Patent Office has granted patent rights to ConAgra Inc for the “method for producing an Atta flour”. It is clear from the declaration made by ConAgra that patent rights is not claimed over any novel innovation in the plant or machinery needed for processing flour, but on the very traditional method for producing Atta. *Monsanto's infamous patent on Indian wheat (EP0445929B1)* claims to have “invented” wheat plants derived from a traditional Indian variety, and products made with the soft milling traits that the traditional Indian wheat provides. Monsanto has repeated the biopiracy pattern earlier attempted by Ricetec, which had claimed to have invented Indian Basmati. With Greenpeace, RFTSE is now preparing a challenge against Monsanto's biopiracy of Indian wheat.

The first statement in Monsanto's patent remarks “This invention relates to plants and to products derived therefrom”. In this case, the plant is essentially derived from the traditional Indian wheats which Indian farmers have collectively evolved and conserved over millennia. Monsanto is claiming as its inventions the traits of Indian wheat evolved for India's food culture and cuisine, based on ‘rotis' and ‘chapattis'. The patent is thus a piracy not just of millennia of breeding by Indian farmers but also of millennia of innovation in food qualities.” Making India 's Food, Culture and Economy Invisible. Such false claims are made throughout the patent. Nearly 600 million Indians use soft milling low gluten wheat as a staple in the form of ‘chapatis or rotis'. For thousands of years, we have eaten wheats appropriate to our food culture. The alternative is available on a very wide scale in India in our daily food. This is the alternative Monsanto is attempting to pirate. Monsanto's claim covers wheat plants derived from Indian wheat varieties and products made from soft milling wheats.