NO PATENTS ON PREVENTION!

CAN PATENTS AFFECT ACCESS TO TB PREVENTIVE TREATMENT?

FIND OUT BELOW.

FAQ ON PATENTS

WHAT IS A PATENT?

A patent is a temporary exclusive right given to a person/entity for an invention. This exclusive right means that the person who is the patent holder can stop others from making, using, selling,or importing the patented product or process, in the country where the patent is granted.

WHAT CAN BE GRANTED A PATENT?

A patent is granted for inventions. These can include products and processes or method of making something. These products/ processes have to be new or 'novel'. They must not be in existence already.

WHY IS A PATENT GRANTED?

Primarily to reward and encourage innovation and further research, it is granted for a limited period of time. After this period of time, the patent expires and the invention becomes available in the public domain for all to use. However, experience is increasingly showing us that patents are not always drivers of innovation.

WHO GRANTS A PATENT?

In India, the patent is issued by the central government through the Indian Patent Office.

HOW LONG DOES THE PATENT RIGHT EXIST?

In India, the patent right is given to the creator or owner of the invention for a period of 20 years from the time of making an application to patent the invention.

IS A PATENT GRANTED IN INDIA VALID IN OTHER COUNTRIES?

No. Patent is a territorial right. This means a patent granted in one country cannot be used to claim patent rights in another country. Similarly, a patent granted in India cannot be enforced in any other country.

FAQ ON PATENTS AND MEDICINES

CAN A PATENT BE GRANTED FOR A MEDICINE OR A DIAGNOSTIC TOOL?

Yes, patents can be granted for medicines and medical devices (diagnostic tools). A patent can also be granted for a process of making medicines.

WHAT HAPPENS WHEN A PATENT IS GRANTED FOR A MEDICINE?

On grant of a patent for a medicine, the patent holder receives exclusive right over that medicine for 20 years (i.e. the license). This means, the patent holder can stop any other person from making, using, selling or importing that medicine in the country where the patent has been granted. That is, the patent holder has a monopoly in the market for 20 years. This gives them the power to set a price of their choice for that medicine.

ARE THERE EXAMPLES OF HIGH PRICES OF MEDICINES IN THE MARKET DUE TO PATENT RIGHTS?

In the 1990s the HIV triple combination treatment was still protected by patents in different countries. The companies that held the patents on these medicines were selling them at about USD 15,000 per person month (that's about INR 11 lakh today)!

At the same time, in countries like Brazil, Thailand and India, where there were no patents on these medicines, companies producing generic pharmaceuticals could manufacture, use and sell these medicines. With multiple companies making these medicines, the competition increased and prices started decreasing. Within a few years the price of these medicines went down by 99%. Thanks to the competition in the market.

The same pattern is seen in various other medicines including for Tuberculosis Preventive Treatment (TPT). The price (before intervention by civil society) for rifapentine in one full patient course of 3HP was USD45 (about INR 3,270). The new price, result of advocates challenging the pharmaceutical patent, is $15 (about INR 1090) for rifapentine in one full patient course of 3HP.

ARE PATENTED MEDICINES BETTER THAN GENERIC MEDICINES?

No, both have equal effect. Generic medicines have the same active pharmaceutical ingredients (APIs) and the same chemical reactions in the body as the patented medicines. For instance, the Tuberculosis medicine rifapentine was sold by the patent applicant Sanofi under the brand name Priftin™. When combined with isoniazid, rifapentine formed the 3HP TB preventive treatment regimen. Today, a combination of isoniazid and rifapentine can be manufactured and sold by different companies and would be sold under different brand names with the same chemical properties and preventive effects.

WHAT ARE SOME OF THE STRATEGIES THAT PHARMACEUTICAL COMPANIES USE TO SECURE ADDITIONAL PATENTS ON THE SAME MEDICINE?

The patent holders at times use strategies to prolong the patent protection on the same medicine to give them longer monopoly in the market. This is done by making slight modifications to the medicine and filing application for patent on these modifications.These modifications can take various forms such as, using the medicine for treating a different disease, different dosing schedule for the medicine, different form of the medicine such as salts, esters, ethers, polymorphs, and particle size. These are also known as secondary patents.

WHAT IS EVERGREENING OF PATENTS?

Companies who own patents over medicine file several applications - after the first patent - to cover simple modifications of the same invention. These modifications could be a new form or use of a known medicine or process (e.g. changing a tablet to a syrup).

If the patent application covering the modifications is granted, it would extend the monopoly of the company holding the first patent with respect to these medicines. Instead of the original 20-year protection, they can get an additional 20 year patent, prolonging their monopoly in the market on that medicine. This is called evergreening of patents.

SHOULD WE BE CONCERNED ABOUT EVERGREENING OF PATENTS?

Yes! Worldwide, people continue to struggle to access essential medicines. Patent evergreening allows patent holders to extend their monopoly in these market and therefore allows them the right to fix prices, often making the medicine more expensive. This poses a barrier to access the essential medicines at affordable prices. Every person has the right to enjoy the highest possible standard of health, under the right to health. Access to affordable medicines is one of the aspects of right to health. Where countries do not regulate evergreening of patents, there is a potential of creating unnecessary barriers to access to affordable medicines.

DOES INDIA'S PATENTS ACT ALLOW PATENT EVERGREENING?

No. India's Patents Act has strong provisions in place that disallows grant of patents to subject matter that are mere modifications, unless certain conditions have been met. For instance, the Patents Act disallows grant of patent to a new form of a known substance unless enhanced therapeutic efficacy is shown. Combining inventions that were previously known is also not allowed and cannot be granted a patent in India. For example, a combination of the known TB drugs, isoniazid and rifapentine cannot be granted a patent, because these medicines are already known to be effective treatment against TB.India also does not allow new use of known invention. For example, given that isoniazid is known to be useful in treatment for TB, a patent cannot be again granted to isoniazid for treatment of another disease.

IF INDIAN LAW PROVIDES PROTECTION FROM PATENT EVERGREENING, WHY SHOULD WE BE BOTHERED?

Given the technical nature of patent applications, and the huge number of applications to be processed, the patent office may erroneously grant patents to some applications that should not be granted. For instance, it was recently reported that 72% of the patents granted by Indian Patent office to pharmaceuticals were wrongly issued. Therefore, it is important that interventions are made at the patent office to object to wrong grant of patents.

WHAT KIND OF INTERVENTIONS CAN WE MAKE TO PREVENT WRONG GRANT OF PATENTS??

In order to supplement and assist the assessment of the patent application, the Patents Act has included provision for opposition.The Patents Act provides that an opposition may be raised by any person to the grant of a patent to an application, this is called pre-grant opposition. A pre-grant opposition can be raised on certain grounds provided in the Patents Act. These include the invention not being new, the invention being known to public, the invention leading to evergreening , to name a few. A pre-grant opposition can be filed by any person before the patent office.

The legislation also has a provision for opposition after the grant of a patent. This is called post-grant opposition. A post-grant opposition may also be filed on the basis of grounds of granted patent not being new, being known to public even before the patent application was filed, or that the patent is actually a form of evergreening. A post-grant opposition however has to be filed within one year of grant of patent before the patent office.

There is also a provision for seeking revocation of a patent that may already have been granted and can be filed before appropriate courts.

HAVE PATIENT GROUPS AND COMMUNITY-BASED NETWORKS RAISED OPPOSITIONS AGAINST GRANT OF PATENTS?

Yes. In the case of several medicines, the patient groups and community-based networks in India have filed oppositions against patent applications covering essential medicines. Some of these medicines include HIV drug lopinavir, the Hepatitis C drug sofosbuvir, the drug-resistant tuberculosis drug bedaquiline, and the TB preventive treatment combination of rifapentine-isoniazid,just to name a few.

IS THE GRANT OF PATENT SAME AS PERMISSION TO PRODUCE AND MARKET THE MEDICINE?

No. A patent is simply a right to exclude others from making, using, selling or importing the patented product or process. Grant of patent does not grant the patent holder the permission to manufacture or sell the medicine in the market. In order to be able to manufacture or sell the medicine, a separate approval has to be sought from the Drug Controller General of India, Central Drug Standard Control Organisation (CDSCO).

WHAT IS TUBERCULOSIS PREVENTIVE THERAPY OR TPT?

Tuberculosis preventive therapy or TPT is a treatment for preventing tuberculosis. It includes administration of one or more anti-tuberculosis medicines. This treatment is given to those who may have been exposed to the TB bacteria, or those who have low immunity due to existing conditions such as affected by HIV, diabetes, or silicosis.

WHICH MEDICINES ARE INCLUDED IN THE TPT?

The World Health Organisation indicates that isoniazid is the most widely used TPT regimen in the world; this is sometimes referred to as IPT, or isoniazid preventive therapy. Rifampicin and rifapentine are other two drugs that are important part of TPT. When combined with isoniazid, rifampicin and rifapentine form so-called short-course TPT regimens that prevent TB in less time and with fewer side-effects than the longer IPT regimen. Of these short-course regimens, the most commonly used is a 12-week regimen of rifapentine-isoniazid called 3HP.

FAQ ON TPT- PATENT AND REGULATORY BARRIERS

ARE THERE PATENTS ON DRUGS THAT ARE ESSENTIAL FOR TPT?

Rifapentine is an old drug whose first use dates back to the 1960s. The original patent on Rifapentine has also expired. Similarly, Isoniazid is also an old medicine that is known from the 1960s. Isoniazid was never patented.

However, in 2014, a company called Sanofi filed patent applications in several countries for a combination formulation of isoniazid and rifapentine. Sanofi was trying to patent a combination of medicines that was known for decades, and establishing market monopoly over them!. If a patent was granted for this combination for Sanofi, it would result in wrong grant of patent, as the patent on these known medicines had long expired.

Rifampicin is another medicine that is used in TPT. This drug is also an old drug discovered in 1965. Patent on this medicine has expired.

WHAT HAPPENED TO SANOFI'S PATENT APPLICATION ON THE COMBINATION FORMULATION OF ISONIAZID AND RIFAPENTINE?

In 2019, a TB survivor and HIV network in India, filed a pre-grant opposition against the applications seeking patents on known medicines Isoniazid and Rifapentine. The pre-grant opposition filed raised technical grounds showing why the application is not eligible for a patent.

On notice of these oppositions, Sanofi withdrew its patent applications related to Isoniazid and Rifapentine in India.

Sanofi eventually withdrew its patent application related to the isoniazid-rifapentine combination in Indonesia, European Union, and all other countries where the application had been submitted. Sanofi also committed to not enforcing its patent rights in the few countries that had already granted a **patent** to the applications **(Australia, China, Russian Federation, South Africa, and the United State).**

This is a clear example of the power of the community of coming together and successfully opposing the grant of patent that could have resulted in evergreening.

ARE THERE ANY REGULATORY BARRIERS IN ACCESSING TPT IN INDIA?

For manufacturing or selling a medicine in India, a permission has to be granted by the Drug Controller General of India,and the medicines have to be approved by the Central Drug Standard Control Organisation (CDSCO).

In India, use of Rifapentine (150 mg) and isoniazid as a 12-week once-weekly regimen for the treatment of latent tuberculosis infection has been approved by the CDSCO. There are several sellers in the market offering this medicine for purchase.

The regimen containing isoniazid and rifapentine combination however is yet to be approved by the CDSCO. While there are companies such as Macleods that have developed a combination formulation of rifapentine and isoniazid, one would have to wait for them to receive approval for manufacture and marketing.

ARE THERE OTHER PATENTS ON TB PREVENTION DRUGS THAT SHOULD BE OPPOSED?

A company called Janssen Pharmaceutica NV has filed a patent application in India to patent long-acting form of Bedaquiline which could also be used in TB prevention. The patent application for this form of Bedaquiline was opposed together by a network of HIV affected person and a TB survivor in March 2021, stating that the application is not eligible for grant of patent.

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