生存或毁灭：印度强制许可制度
Compulsory licensing in India and the 'big pharma' debate

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《TRIPS 协议》还规定了“强制许可”概念，这一机制旨在抑制专利权滥用，特别是国家严厉的专利制度下医药巨头对于专利机制的滥用。以下是关于印度强制许可制度的简要概述：

许可：最后一招

强制许可是指国家允许仿制药品生产公司以较低价格生产和销售专利药品相应仿制药的一种法定许可。这种仿制药品的销售经常受到专利权人的反对。印度专利管理局可以根据具体情况决定专利权人是否可以根据《1970 年印度专利法》第 87 条就仿制药品的销售取得专利权使用费。

申请取得强制许可被认为是在无法向专利权人取得自愿许可之后的最后一招。如果专利药品生产商不同意给予仿制药生产商自愿许可，那么根据法律要求，仿制药公司在申请取得强制许可时必须证明三个情况：在专利权被授予之日起三年后，(1) 专利生产商无力向公众提供专利发明产品，(2) 公众无法以合理的价格获取专利发明产品，或 (3) 专利发明没有在印度领土上实施。

追溯历史

印度历史上授予的首个强制许可，是 2012 年就专利药多吉美（Nexavar）授予 Natco 仿制药公司的许可。在请求专利权人给予自愿许可遭到拒绝后，Natco 公司根据《印度专利法》第 84 条提出强制许可申请。这项强制许可决定受到了专利权公司的强烈反对，制药行业的巨头纷纷认为印度是“反专利”支持者。这家专利权公司本身拥有大量的专利发明，尤其以药品专利为多，因此他们害怕印度就多吉美授予的首个强制许可会使他们蒙受严重损失，毕竟他们为这些专利药的发明投入了大量的金钱。

自从授予有关多吉美的强制许可以来，印度由于被认为偏袒仿制药生产商，一直受发达国家和跨国制药企业的密切留意。不过，有关多吉美的强制许可完全符合《TRIPS 协议》下的国际规则。为了在保护公众利益的同时也确保创新企业受到激励不断创新，专利局在授予强制许可时也表现得非常谨慎。专利局最关心的是创新企业的权益不会因为授予强制许可受到妨碍。

在授予有关多吉美的强制许可后，其他几家印度仿制药生产商针对专利药达沙替尼（Dasatinib）、沙格列汀（Saxagliptin）和曲妥单抗（Trastuzumab）提出强制许可申请。印度专利局拒绝了这三项申请，认为他们没有就授予强制许可提出确凿的表面证据。专利局拒绝了这些申请，证明专利局对印度知识产权法的高度重视，在兼顾社会大众集体利益的同时，也全力捍卫创新企业的合法权益。

公众的机会

从本质上说，强制许可是不情愿的卖家与自愿的买家在国家的强制命令下签署的合同，目的在于确保有足够数量的拥有专利发明的生产商为满足社会需求从事生产，反过来，也会刺激竞争和消费者福利。

许多人一直极力主张强制许可伤害了创新积极性以及创新的潜在诱因。由于这种观点，多吉美强制许可被授予后，令国际市场感到讶异，受到了持续的关注。不过，制药企业对强制许可的强烈抗议反映出他们仅仅为了获得垄断和利益，而不惜霸占对人类生命极其重要的产品。

潜在的研发障碍?

印度拥有庞大的药品制造业，药品生产量居全球第三。制药业与从事仿制药生产制造的许多印度制药企业都依靠专利不断发展。与其他高研发水平的国家相比，印度的研究与开发水平既不均衡也不高，尽管外国制药企业在印度的投资有着惊人的增长速度。印度需要为技术和品牌提供更多前沿的研发方案，为国内外消费者获得基本药物创造更多机会，令强制许可程序更有意义。

强制许可会阻碍创新是一种常见的误解。其实，强制许可制度可以成为制药行业的推动力，从而推动其在国家研发蓝图中的地位。

立法意图

每部法律背后的主要目的都是为了提供公共福利。强制许可制度也有同样的立法意图，该制度可以提高公众获得药品的机会，从而提升公共健康和福利。■

> “强制许可会阻碍创新是一种常见的误解”

A patent enshrines not only a bundle of rights given to an innovator or inventor, but also provides them with a timeframe for monopoly as given under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) regime.

TRIPS also provides for the concept of "compulsory licensing", the mechanistic formula in order to check the abuse of patent rights, especially by pharmaceutical giants, which flows from the rigidity of a country's patent system.

The following is a brief overview of compulsory licensing as practised in India.

Licence: the last resort

A compulsory licence (CL) is a statutory licence provided by the government by way of which a generic company is allowed to manufacture and sell a generic version of the patented drug at a cheaper price. The sale of this generic drug is generally a move opposed by the patentee.

The controller of the Patent Office can decide, on a case by case basis, whether the patentee will receive royalties for sales of the generic drug as per section 87 of the Indian Patent Act, 1970.

Seeking a grant of a CL is considered as a last resort, made only once prior attempts to obtain a voluntary licence from the patentee have failed.

Once the manufacturer of a patented drug does not agree to permit a voluntary licence to the generic manufacturer, the generic company must, as per the statutory requirements, prove three contentions when seeking a CL.

They must prove that, three years following the grant of the patent in question: 1) the patented manufacturer is not able to make the patented invention available to the public; 2) the patented invention is not available at a reasonable price; or 3) there has been a lack of working of the patent within the territory of India.

Step back into history

The first CL ever granted in India was to generic drug manufacturer Natco for the patented drug Nexavar in 2012.

Natco filed its request for the CL under the provisions of section 84 of the Indian patent law, after it unsuccessfully approached the patentee for a voluntary licence for the drug. The innovator companies themselves held a wealth of patented inventions, specifically pharmaceutical drugs, hence, dreading that the CL for a generic Nexavar, as the first CL to be enforced by India, would put them in loss considering that they spent a huge sum of money on inventing the patented drug. The grant of this CL was thus vehemently opposed by the innovators and the pharmaceutical giants, who felt that India was an "anti-patent" enthusiast.

> *"[It is a] usual misconception that a CL impedes innovation"*

Under scrutiny

Ever since the CL for Nexavar was granted, India has been under the scrutiny of developed nations and multinational pharmaceutical companies for bias toward its generic drug makers.

However the grant of CL to Nexavar is in total compliance with the international rules as provided by TRIPS.

The Patent Office also demonstrated extreme caution while proceeding with the grant of the CL so as to benefit the public and assure that the innovators would be encouraged to invent more. It was of utmost concern to the office that the interest of the innovators not be hampered with the grant of the CL.

Following the CL grant of Nexavar, three additional CL applications were filed for the patented drugs Dasatinib, Saxagliptin and Trastuzumab by various Indian generic drug makers.

The Patent Office rejected all three applications, citing that they failed to establish a *prima facie* case for the granting of a CL. The rejections testify that the office places supreme importance in the intellectual property laws of India and guards the rights of the innovators with full force, as well as reaffirming the collective interests of the public at large.

Greater public access

A CL is, at its essence, an unintended contract entered into by an unwilling seller and a willing buyer under the mandate of the state, ensuring that a decent amount of producers or manufacturers of a patented invention are catering to the needs of the society, in turn, spurring competition and consumer welfare.

It has been strongly argued by many that the CL leads to discouragement of innovation and underlying inducement to innovate.

The Nexavar CL raised a number of eyebrows internationally when it was granted because of this apprehension, thereby garnering attention.

But the outcry of the pharmaceutical companies against CLs imply their intention to usurp important and vital supplements for human life with the sole aim of monopolizing and profiting from them.

Potential R&D roadblock?

India is home to a massive pharmaceutical industry, ranking third worldwide in terms of production volume. And the pharmaceutical industry thrives on patents with the majority of the Indian pharmaceutical industry engaged in manufacturing and producing generic drugs.

The research and development (R&D) is unevenly low when compared with other countries. This is despite an alarming growth rate in foreign pharmaceutical houses investing in India.

The country needs to produce more cutting-edge R&D solutions to technologies and brands so as to enable a meaningful CL procedure that creates better access to essential drugs, domestically as well as internationally.

In contrast to the usual misconception that a CL impedes innovation, employing CLs would serve as an impetus for growth in the pharmaceutical industry, thereby topping the charts for R&D in the country.

Legislative intention

Behind every law the main intent is to provide for public welfare. Harbouring similar intentions, a CL would promote access to medicine, thereby promoting public health and welfare. ■

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