

INDIA IPR - ENFORCEMENT

MONTHLY DIGEST — EDITION - SEP 2023



IMPORTANCE OF
INTELLECTUAL PROPERTY RIGHTS
IN
HEALTHCARE

MEDICAL
AND PHAR

Featuring Inside

- ⦿ Aug 2023 Raid Actions across India
- ⦿ Global Intellectual Property Rights Challenges in Healthcare
- ⦿ Brand Protection Challenges and Opportunities



TABLE OF CONTENTS

Preface	03
---------	----

Capt Sandeep Kumar Mehta

An Overview of Countering Counterfeiting	04-07
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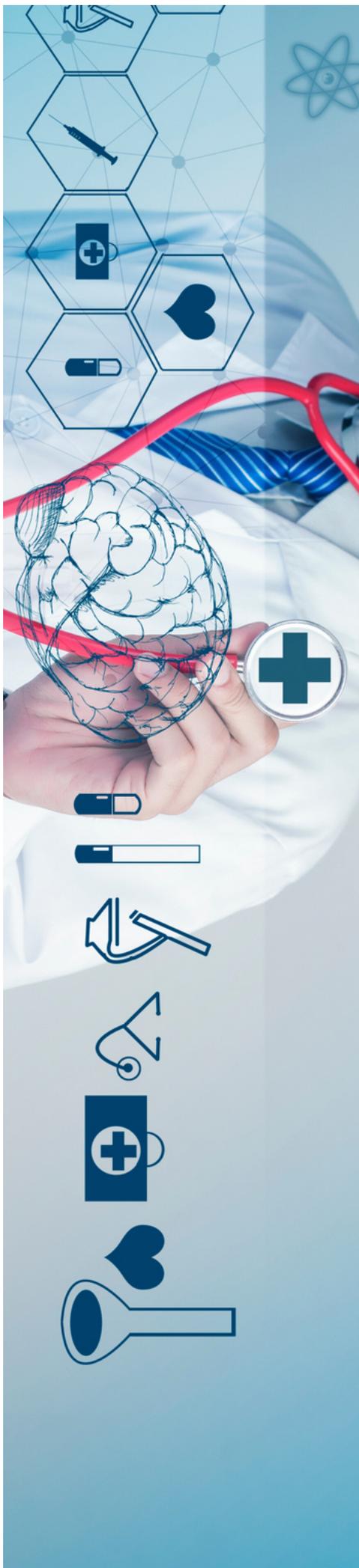
- Across Industries, Zones, and States
- Exploring Zone, State, and Industry trends
- Aug 2023 Raid Actions across India

Shaping & Safeguarding Healthcare with IPR	08-10
--	-------

- Global Intellectual Property Rights Challenges in Healthcare
- IP Considerations in the Telehealth Revolution
- Strategies Utilized by Pharma Companies
- Brand Protection Challenges and Opportunities

Upcoming Events	11
-----------------	----

About IIRIS Consulting	12
------------------------	----



P R E F A C E



**INTELLECTUAL PROPERTY IN
HEALTHCARE FORMS THE BASIS
FOR TRANSACTIONS IN
KNOWLEDGE ASSETS, ENABLING
THE TECHNOLOGY TRANSFER,
PRODUCTION PARTNERSHIPS,
AND COMMERCIAL
RELATIONSHIPS THAT COVERS
THE LIFECYCLE OF MEDICINES I.E.
INNOVATION FROM EARLY-STAGE
SCIENTIFIC RESEARCH OF
PRODUCT DEVELOPMENT AND
DELIVERY.**

Intellectual Property in healthcare forms the basis for transactions in knowledge assets, enabling the technology transfer, production partnerships, and commercial relationships that covers the lifecycle of medicines i.e. innovation from early-stage scientific research of product development and delivery.

Though the stake holders are governments, academia, businesses but it is consumers like you and me or general public at large across globe who are going to consume them.

Transparent and appropriately enforced Intellectual Property rules also help to control the menace of counterfeit medicines, to the patients who are in desperate need of specialized, specific, safe and effective medicines and therapies for leading a happy life.

Let us remain steadfast in this collective endeavor to combat counterfeiting and safeguard the fruits of creativity in the healthcare domain.

A life free from diseases and ailments - Let's keep fighting the counterfeiters & preserve humanity.

Capt Sandeep Kumar Mehta
Head - IPR, Brand Protection
IIRIS Consulting

COUNTERFEIT CASES IN JULY 2023 : AN OVERVIEW

Counterfeiting continues to be a pressing challenge in today's marketplace, posing serious risks to various industries and economies globally. The month of May 2023 saw a significant number of reported counterfeit cases, further emphasizing the importance of sustained efforts to combat this illicit activity. It is essential to remain vigilant in the face of counterfeiting, as it undermines consumer trust, erodes brand reputation, and leads to substantial economic losses. By analysing the distribution of these cases across different regions, states, and industries, we gain valuable insights into the magnitude of the problem and the areas that require targeted interventions. Effective measures, such as collaboration between law enforcement agencies, industry associations, and government bodies, along with public awareness campaigns, are instrumental in deterring counterfeiters and protecting intellectual property rights. Addressing the issue of counterfeiting requires a multi-faceted approach that encompasses stringent enforcement, proactive industry engagement, and robust consumer education.

The impact of counterfeiting extends beyond financial losses for businesses; it poses significant risks to consumer health and safety. Counterfeit products, ranging from counterfeit pharmaceuticals to electronics and luxury goods, can jeopardize consumer well-being and compromise the integrity of critical sectors. By understanding the overall landscape of counterfeit cases in May 2023, we can identify hotspots and vulnerable industries, allowing for targeted strategies and resource allocation to combat this illicit trade effectively. It is crucial for stakeholders across sectors to collaborate closely, leverage technological advancements for authentication and tracing, and promote awareness among consumers about the risks associated with counterfeit products. Together, we can foster a marketplace that upholds the value of intellectual property rights, safeguards consumer interests, and supports legitimate businesses in their pursuit of innovation and growth.

The information shared in the report is all statistical and has been compiled from third-party sources, which we believe are reliable.

INDUSTRIES AFFECTED BY COUNTERFEITING : INSIGHTS FROM RAID ACTIONS

The reported 225 counterfeit cases in Aug 2023 encompassed a wide range of industries, including FMCG, Currency, Alcohol, and more. Counterfeit products pose significant risks, from substandard quality and safety concerns to revenue losses for legitimate businesses. It is crucial for authorities, industry organizations, and consumers to work together in order to combat counterfeiting effectively.

At IIRIS, we understand the paramount importance of brand protection. With our comprehensive range of services, we strive to assist businesses in safeguarding their trademarks and combating counterfeiting effectively. Our expertise and dedication to brand protection make us the ideal partner for businesses seeking reliable and proactive solutions in the battle against counterfeit trade.

We have prepared four informative charts to enhance your understanding of the counterfeiting problem in India: The **first chart** provides a breakdown of enforcement actions carried out across the country's five zones, offering valuable insights into the geographic distribution of counterfeiting activities and highlighting zones that have witnessed heightened enforcement efforts. The **second chart** delves into raid actions conducted within various industries; The **third chart** identifies the top states in India with the highest number of reported counterfeit cases.

Finally, the **fourth chart** presents a comparative analysis of counterfeit cases reported in Aug 2022 versus Aug 2023 on a state-by-state basis, shedding light on any temporal trends and helping to identify states experiencing changes in counterfeit incidents.



AUG 2023 RAID ACTIONS – INDIA

Analysis of Counterfeit cases in Aug 2023 across different Zones

In Aug 2023, a total of 225 counterfeit cases were reported, providing valuable insights into the prevalence and distribution of counterfeiting across different zones. Among the zones, the North Zone had the highest number of cases with 113 reported incidents, highlighting the need for heightened enforcement measures and public awareness campaigns in this region.

The West, East, and South Zones followed with 31, 32 and 33 cases respectively, emphasizing the importance of combating counterfeiting activities in these commercial hubs.

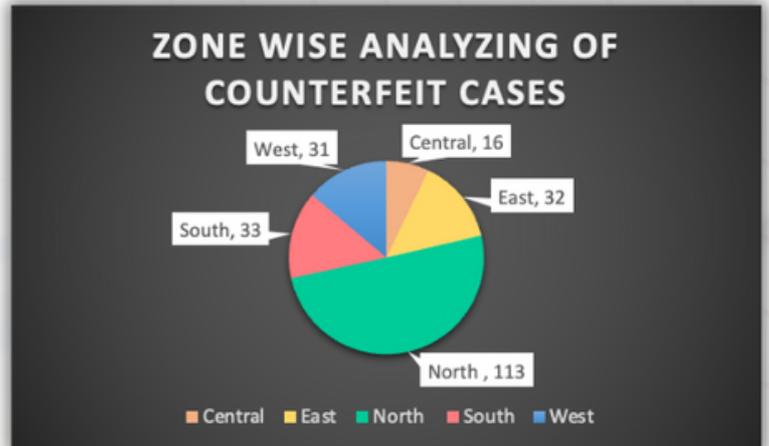


Exhibit 1: Pictorial Depiction of zone wise data shows the central zone registering lowest no. of cases in counterfeiting – Aug 2023

The Central Zone reported relatively lower numbers of counterfeit cases, but maintaining vigilance and proactive measures in these regions remains crucial. By analysing the distribution of counterfeit cases across zones, authorities and stakeholders can gain a better understanding of the geographical spread of counterfeiting activities. This knowledge allows for targeted strategies and resource allocation to effectively combat the trade of counterfeit goods. It enables enforcement agencies to focus their efforts in high-risk areas, enhance border control measures, conduct raids on illicit manufacturing units, and raise public awareness about the risks associated with counterfeit products.

Industry-Wise analysis of Counterfeit cases in Aug 2023

In Aug 2023, a total of 225 counterfeit cases were reported, providing valuable insights into the prevalence and impact of counterfeiting across various industries. The distribution of these cases highlights the challenges faced by different sectors and the need for targeted strategies to combat counterfeiting effectively.

Among the industries affected by counterfeiting, the FMCG industry had the highest number of reported cases with 68 incidents in Aug 2023.



Exhibit 2: Industry wise Enforcement action performed in the month of Aug 2023

Among the industries affected by counterfeiting, the FMCG industry had the highest number of reported cases with 68 incidents in Aug 2023. Counterfeit FMCG products pose risks to consumer health and safety, while also undermining the reputation and revenue of the FMCG products producers. Following closely behind, the currency industry reported 41 cases, signalling the persistent threat of counterfeit money in circulation. Counterfeit currency not only disrupts financial systems but also has serious economic implications. Other industries that experienced counterfeit cases in Aug 2023 included Alcohol with 21 cases, Fertilizers with 17 cases, and pharmaceuticals with 16 cases.

While several other industries reported a smaller number of counterfeit cases, they still face unique challenges. From tobacco and apparels to Cosmetics and toys, each industry must remain vigilant and take proactive measures to protect their brands, consumers, and revenues from the damaging effects of counterfeiting.



AUG 2023 RAID ACTIONS – INDIA

Mapping counterfeit cases in India: State-Wise Analysis for Aug 2023

In **Aug 2023**, India recorded a total of **225** counterfeit cases, providing insights into the distribution of counterfeiting across states. Uttar Pradesh had the highest number of reported cases with **48** incidents, followed by Maharashtra and Rajasthan with **23** and **15** cases, respectively. Assam and Bihar reported **14** and **13** cases respectively. Furthermore, the analysis reveals a broader picture, with moderate incidences spread across states such as Haryana, Telangana, Madhya Pradesh, Delhi, Uttarakhand, Tamil Nadu, Jharkhand, and West Bengal. While the number of cases may vary, it underscores the need for sustained vigilance and proactive measures to prevent the growth of counterfeiting in these regions and safeguard consumers' well-being and trust. It is crucial for authorities, law enforcement agencies, and industry stakeholders to collaborate in developing comprehensive strategies. These strategies should include strengthening enforcement efforts, enhancing border control measures, conducting regular market surveillance, and raising public awareness about the risks associated with counterfeit products. By leveraging technology, implementing authentication systems, and fostering a culture of respect for intellectual property rights, India can combat counterfeiting effectively, ensure a safe marketplace, and protect the integrity of its industries.

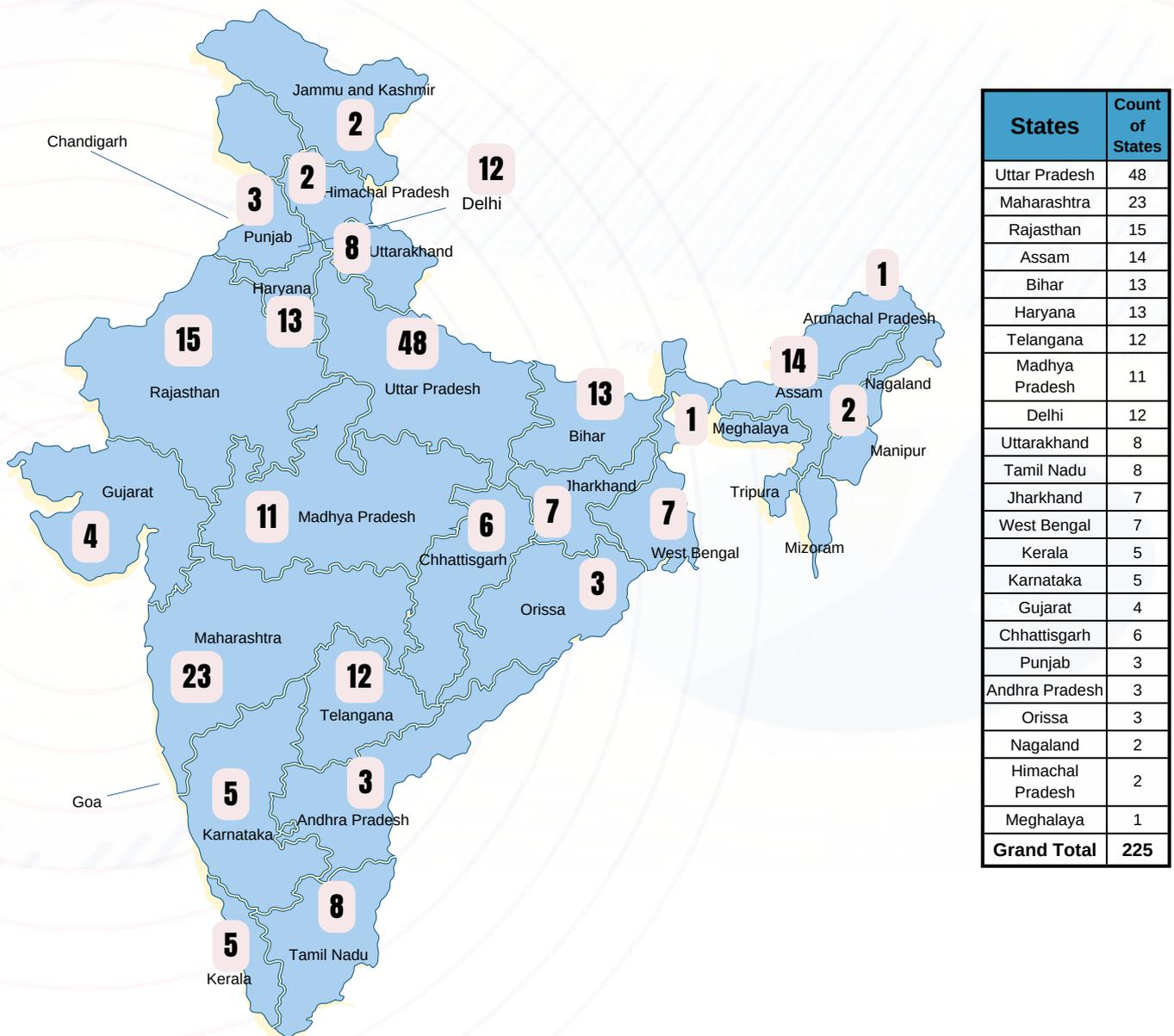


Exhibit 3: State wise bifurcation of IPR enforcement action – Aug 2023

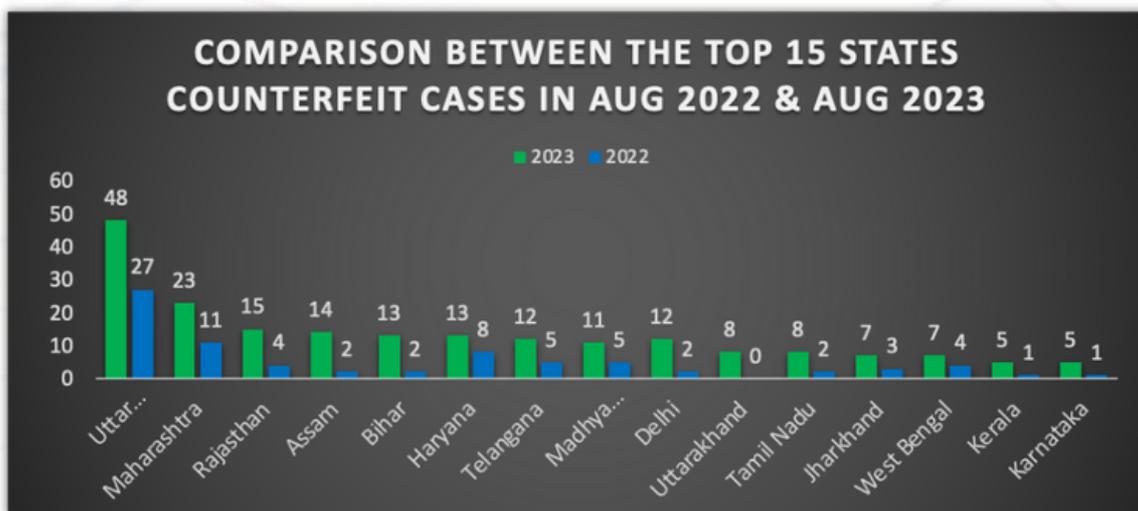
AUG 2023 RAID ACTIONS – INDIA

State-wise Comparison of Counterfeit cases: Aug 2023 vs. Aug 2022

Comparing the counterfeit cases reported in **Aug 2023** with those in **Aug 2022** provides valuable insights into the changing landscape of counterfeiting activities across different states in India. This analysis highlights the shifts in counterfeit case numbers and trends, offering a glimpse into the progress made in combating counterfeiting and the areas that require continued attention.

In **Aug 2023**, Uttar Pradesh witnessed a significant increase in counterfeit cases, rising from **27** cases in **Aug 2022** to **48** cases. This sharp rise indicates a growing prevalence of counterfeiting activities within the state, necessitating enhanced efforts to combat this illicit trade.

To provide a visual representation of the data, please refer to the chart below:



■ Total Cases 2022 = 77
■ Total Cases 2023 = 201

States	Bihar	Delhi	Gujarat	Haryana	Uttar Pradesh	Karnataka	Kerala	Madhya Pradesh	Maharashtra	Mizoram	Orissa	Punjab	Rajasthan	Tamil Nadu	Telangana
Aug-23	48	23	15	14	13	13	12	11	12	8	8	7	7	5	5
Aug-22	27	11	4	2	2	8	5	5	2	0	2	3	4	1	1

Exhibit 4: Pictorial depiction of comparison of total number of IP enforcement cases undertaken in Indian state in the month of **Aug 2022 and Aug 2023**

Disclaimer :

The report findings have been gathered, inter alia, using advanced research and methods using publicly available sources (that may or may not be pay-walled or accessible with reasonable technical acumen). Owing to such reliance, **IIRIS CONSULTING** cannot be held liable for any misrepresentation, fraud, theft, unethical practice, inaccuracies, or lacunae in the report that are attributable to sources that are not capable of further corroboration or supplementation.



SHAPING & SAFEGUARDING HEALTHCARE WITH IPR

THE VITAL ROLE OF IPR IN HEALTHCARE

Intellectual property rights play a crucial role in the field of healthcare, shaping the development and accessibility of life-saving drugs, medical technologies, and innovations. These rights provide creators and innovators with the legal framework to protect their inventions, fostering a conducive environment for research and development. From pharmaceuticals to medical devices, intellectual property rights are integral in incentivizing innovation, investment, and ultimately, the advancement of healthcare.

However, the intersection of intellectual property rights and healthcare also poses complex challenges, particularly in balancing the need for innovation with ensuring affordable access to essential treatments and technologies. In this article, we will explore the vital role of intellectual property rights in healthcare, examining its impact on innovation, accessibility, and the evolving dynamics of global health systems.

GLOBAL INTELLECTUAL PROPERTY RIGHTS CHALLENGES IN HEALTHCARE

- 1 Access and Affordability :** Balancing the need to protect intellectual property with the need to ensure widespread access to essential healthcare innovations, particularly in lower-income regions and marginalized communities.
- 2 Technology Transfer :** Addressing the complexities of transferring medical technologies and knowledge across borders while respecting intellectual property rights, especially in the context of global health crises and disparities.
- 3 Counterfeiting and Enforcement :** To combat the growth of counterfeit pharmaceuticals and medical items, robust enforcement measures are required to preserve intellectual property while also protecting patient safety and public health.
- 4 Differential Regulatory Frameworks :** Managing the complexities arising from variations in intellectual property and regulatory frameworks across different jurisdictions, impacting the availability and affordability of healthcare innovations on a global scale.
- 5 Global Collaboration and Equity :** Promoting international cooperation and equitable partnerships to address IPR challenges in healthcare, fostering a collaborative approach to drive innovation, accessibility, and affordability worldwide.

THE ROLE OF PATENTS IN PROTECTING PHARMACEUTICALS

In the world of pharmaceuticals, patents play a critical role in safeguarding the innovations that drive medical advancements.

These patents provide pharmaceutical companies with exclusive rights to their inventions, including new drugs and medical treatments.

By giving legal protection, patents enable companies to recover their investments in research and development, incentivizing further innovation. However, patents also have a profound impact on brand protection, influencing the strategies employed by pharmaceutical companies to maintain their competitive edge in the market.

BRAND PROTECTION AND PATENTS: THE INTERPLAY

For pharmaceutical companies, brand protection is paramount in establishing and preserving their identity in the marketplace. Patents serve as a cornerstone of brand protection, offering companies a period of exclusivity during which they can market their products without competition. This exclusivity provides a crucial window for pharmaceutical companies to establish brand recognition, build trust among healthcare professionals and patients, and

recoup the substantial costs of bringing a new drug to market.

The presence of a patent not only protects the pharmaceutical product from direct competition but also allows companies to command premium pricing due to the absence of generic alternatives. In this way, patents are instrumental in sustaining the financial viability of pharmaceutical innovation, driving further investment in research and development.

IP CONSIDERATIONS IN THE TELEHEALTH REVOLUTION

Telehealth, the use of digital communication technologies to deliver healthcare services remotely, has seen a significant increase in adoption and utilization, particularly in light of the COVID-19 pandemic. In the context of telehealth and intellectual property rights (IPR), several key considerations come into play

Patent Protection for Telehealth Technologies

As telehealth continues to evolve, innovations in telemedicine platforms, remote monitoring devices, and telehealth-specific medical devices have become the subject of patent applications. Intellectual property rights, particularly patents, are essential for protecting unique telehealth technologies, encouraging investment in research and development, and fostering continued innovation in this space



Copyright and Telehealth Content

Telehealth platforms often involve the creation of digital content such as software interfaces, educational materials, and teleconsultation tools. Copyright protection plays a role in safeguarding these creative works, ensuring that the original creators retain rights to their content and discouraging unauthorized use or reproduction by others

Data Protection and Telehealth Platforms

With the exchange of sensitive patient data and health information through telehealth platforms, data protection, privacy, and cybersecurity are critical aspects tied to intellectual property rights. Ensuring robust intellectual property protection for telehealth platforms includes safeguarding proprietary algorithms, data analytics methodologies, and patient data privacy technologies.

STRATEGIES UTILIZED BY PHARMA COMPANIES

Pharmaceutical businesses use a variety of techniques to maximise the benefits of their intellectual property while navigating the complicated landscape of patents and trademark protection.

their products to create a comprehensive web of protection. This strategy acts as a deterrent to potential competitors while fortifying the company's market position.

One common approach is to strategically file additional patents related to the original drug, encompassing formulations, dosages, delivery mechanisms, and potential new uses. This tactic, known as "evergreening," allows companies to extend their exclusivity period by offering incremental innovations around the core product.

Beyond defensive measures, companies also utilize patents as a basis for forming partnerships and licensing agreements with generic manufacturers.

Furthermore, pharma companies may engage in defensive patenting, which involves seeking patents for secondary or ancillary aspects of

Through these arrangements, pharmaceutical companies can leverage their patent portfolios to negotiate favorable terms, such as delaying generic market entry or receiving royalties from generic sales.

BRAND PROTECTION CHALLENGES AND OPPORTUNITIES

In the domain of brand protection within the healthcare industry, the advent of innovative technologies has ushered in a dynamic interplay of challenges and opportunities. One significant challenge revolves around counterfeit detection, propelled by advanced manufacturing methods and the intricate global web of supply chains. This has amplified the risk of counterfeit pharmaceuticals and medical devices. To counter this, the healthcare sector is actively embracing novel brand protection technologies such as sophisticated packaging solutions, serialization, and track-and-trace systems. The digital landscape has necessitated a broader scope for brand protection, leading healthcare companies to deploy cutting-edge technologies like automated tools, artificial intelligence-driven monitoring systems, and digital takedown procedures to combat online counterfeiting and trademark misuse. Blockchain technology, with its emphasis on secure and immutable record-keeping, is emerging as a powerful tool to fortify brand protection and supply chain transparency, enabling the tracking of pharmaceutical provenance and preventing unauthorized tampering. Moreover, in response to evolving regulatory landscapes, the industry is adopting advanced software solutions and digital platforms to ensure regulatory compliance in labeling, marketing materials, and product claims. This strategic incorporation of technology not only addresses the challenges but also fortifies brand protection, ensuring the integrity of healthcare brands amid the complexities of the digital age.

01 COUNTERFEIT DETECTION AND ANTI-COUNTERFEITING TECHNOLOGIES

With the rise of advanced manufacturing techniques, 3D printing, and the global nature of supply chains, the healthcare industry has faced an increased risk of counterfeit pharmaceuticals and medical devices. New brand protection technologies, including advanced packaging solutions, serialization, and track-and-trace systems, are being developed and implemented to combat counterfeiting and protect patient safety.

02 DIGITAL BRAND MONITORING AND ENFORCEMENT

The digital landscape has necessitated the expansion of brand protection efforts to online platforms. Healthcare companies are leveraging new technologies for monitoring and enforcing their brand rights in digital spaces, including automated brand protection tools, artificial intelligence-driven monitoring systems, and digital takedown procedures to combat online counterfeit sales or misuse of their trademarks.

03 BLOCKCHAIN AND SUPPLY CHAIN TRANSPARENCY

Blockchain technology is being explored as a means to enhance brand protection and supply chain integrity in the healthcare industry. By leveraging blockchain for secure and immutable record-keeping, companies can track the provenance of pharmaceuticals, medical devices, and healthcare products, ensuring authenticity, and preventing unauthorized diversions or tampering.

04 TECHNOLOGICAL SOLUTIONS FOR REGULATORY COMPLIANCE

New technologies are also impacting brand protection through heightened regulatory compliance efforts. Advanced software solutions and digital platforms are being employed to ensure adherence to regulatory requirements for labeling, marketing materials, and product claims, bolstering brand protection by minimizing the risk of non-compliant activities that could jeopardize brand reputation and legal standing.

In conclusion, the intersection of new technologies, including telehealth innovations, and intellectual property rights presents a complex landscape for the healthcare industry. As healthcare organizations and innovators continue to navigate this terrain, it is essential to strategically leverage intellectual property protections to safeguard telehealth advancements, combat counterfeiting, and ensure the integrity of healthcare brands in the digital age.

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Sr. Analyst-Brand Protection, IIRIS



UPCOMING EVENTS

INDIA AND THE WORLD

The 9th International Conference on Intellectual Property Rights (IPR) in 2023 marked a significant global gathering, building upon its successful legacy of eight prior editions. This event continued its tradition of attracting diverse participation, including representatives from countries such as Japan, the UK, USA, France, and more. The conference, strategically structured, aimed not only to facilitate interactions among international and domestic participants but also fostered engagement with governmental bodies. Held at Le Meridien Hotel in New Delhi, India, on November 7th-8th, 2023, the conference offered a platform for discussions, networking, and exploring new business avenues within the realm of intellectual property rights. Attendees seized the opportunity to exchange insights, explore emerging trends, and forge collaborations, thus furthering the global discourse on IPR and fostering new business opportunities.

Over the course of this year, IIRIS has been consistently and proactively undertaking strong enforcement measures within the pharmaceutical sector. These actions are pivotal in tackling instances of intellectual property rights infringement, thereby guaranteeing the authenticity and quality of healthcare products. The focus of our efforts is to preserve the integrity of the industry by safeguarding innovative solutions and upholding the ethical standards essential for the continued success of the healthcare sector. Our commitment is rooted in ensuring that healthcare products meet the highest standards, contributing to a trustworthy and sustainable industry that prioritizes both innovation and the well-being of consumers.

INDIA

-  The A-CAPP 2023 Anti-Counterfeiting Global Survey: Consumer Education | Webinar
6th December 2023
-  Annual STRIDE Meet
New Delhi, India
14th - 15th December 2023

INTERNATIONAL

-  Roundtable discussion: Tribes, intellectual property, and consumer protection | Alexandria, Virginia
30th November 2023
-  Trademarks and Brand Protection Masters 2023 | Ashburn, Virginia
05th - 06th December 2023



About IIRIS Consulting

IIRIS Consulting aka **Indus IntelliRisk & IntelliSense Services Pvt. Ltd.** stands committed as a value catalyst to corporates bringing in innovative, cutting edge technology aided, risk advisory and intelligence management solutions that help clients not only mitigate risks but also enable better business decisions.

IIRIS is an India born solutions and consulting firm, with wide operations across South Asia, Far East, USA, UK and Middle East. We operates in the fields of advisory, risk management, intelligence, digitization, and forensics.

Each of our services is delivered by experienced leaders using advanced methodologies that combine legally acceptable technological resources, on-the-ground intelligence collection, and data analytics.

Apart from helping clients make better business decisions, IIRIS also acts as an industry mentor that provide certification and skill building to help professionals be better future leaders.

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MARKET RESEARCH

SUPPLY CHAIN AUDITS

