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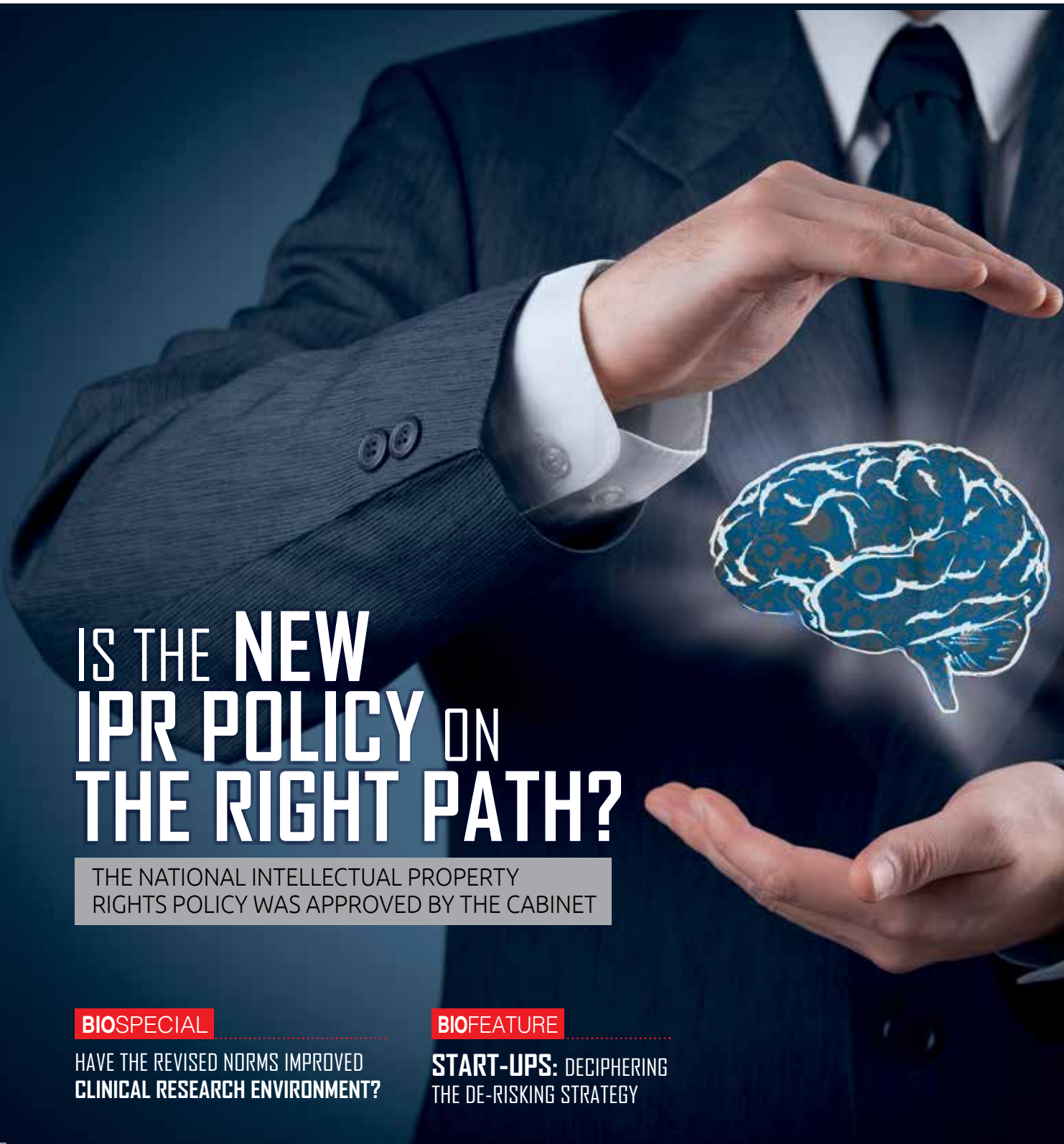

IS THE NEW IPR POLICY ON THE RIGHT PATH?

THE NATIONAL INTELLECTUAL PROPERTY RIGHTS POLICY WAS APPROVED BY THE CABINET

BIOSPECIAL

HAVE THE REVISED NORMS IMPROVED **CLINICAL RESEARCH ENVIRONMENT?**

BIOFEATURE

START-UPS: DECIPHERING THE DE-RISKING STRATEGY

A SUGAR PILL FOR THE INDUSTRY?

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India has once again found itself on the recent 'Special 301' Report's Priority Watch List along with eleven other countries such as China, Russia and Ukraine. The report, published by the United States Trade Representative, reviews the global state of IPR protection and enforcement and places countries with inadequate IPR protection on its watch list. What does this mean for a country with such a strong pharmaceutical and biotechnology sector?

There have been some major changes in the Indian legislative landscape over the years, and a stronger IPR regime had been in the pipeline for a while. The Department of Industrial Policy and Promotion has now released the National IPR Policy 2016 (NIPR), which is hoped to be a precursor to more concrete changes in the IPR law. The policy proposes to use IPR as a tool to promote innovation and development in the country. The NIPR, however, has not laid down a clear roadmap on the implementation.

In terms of benefits to the Indian pharmaceutical and biotechnology industry, certain objectives in the policy seem to stand out. The NIPR has suggested a study to examine the feasibility of IPR exchanges. The policy, through its encouragement of such exchanges, aims at facilitating investments in IPR driven industries and bringing investors and IPR owners together. India has already established one such exchange, which is one of the first in South Asia. With IPR being a major component of the pharmaceutical and biotechnology industry, such an exchange would help in easier and more convenient IPR commercialization for companies.

Another interesting concept that is touched upon in the NIPR is that of open source initiatives, which is designed to challenge the traditional incentivization theory of IP, which is based on monopoly rights. In an open source development framework, any IP generated is universally licensed without royalty. This IP is usually accompanied by an agreement that any subsequent IP created using the existing IP would also be universally licensed without royalty. A more pharma-centric open source concept is the Open Source Drug Discovery initiative (OSDD) developed by the Council for Scientific and Industrial Research, which the NIPR aims to encourage. OSDD is a collaborative open source model of discovery of drugs to treat diseases that affect a poorer population. Drugs discovered through this model would be free from IPR encumbrances and

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marketed as a generic drugs. Its successful implementation has led to 7,900 participants from 130 countries collaborating to fight diseases that afflict the poor in India and other nations. The encouragement of this program could change the landscape of the pharmaceutical industry and its approach to drug discovery.

India has an abundance of Traditional Knowledge (TK) that has been passed on from generation to generation. The need for the protection of TK had attracted international attention after several patent filings of Indian TK in the USA and Europe. A Traditional Knowledge Digital Library (TKDL) was developed in India in 2001, which serves as an evidence to refute the claims for patent registrations in foreign countries based on Indian TK. It has collated the TK of the nation in various languages such as Sanskrit and Urdu. The NIPR recognizes the richness of Indian traditional medicinal knowledge and stresses on the need to protect the same from exploitation. It also proposes to explore possibilities of using the TKDL for further research and development.

Access to affordable medicines and related healthcare solutions are also one of the objectives of the NIPR, with suggestions for cross-sector partnerships and collaborations between universities, public research facilities, the private sector and NGOs. While there may not be monetary incentives, private participants are hoped to be roped in with other incentives and benefits such as tax exemptions. Additionally, the NIPR suggests incentives for the domestic manufacturing of Active Pharmaceutical Ingredients so as to reduce the dependency on imports. Another recommendation in the policy is the revival of the long-buried Public Sector Undertakings in the health sector.

The NIPR has made some interesting and forward-looking suggestions, but closer examination reveals that many of these suggestions have already been in place for a while. Recommendations in the NIPR could still lead to an advancement in the Indian IPR regime and foster innovation and technology in the country, especially in the pharmaceutical and biotechnology sector. To implement these recommendations, however, they must ultimately be reflected in the law, and this is where the NIPR is unfortunately silent. The implementation of the policy is left up to the government departments with no timeframe or guidelines. It remains to be seen if these suggestions, while remarkable on paper, turn into something that actually addresses issues in the IPR law in the country. BS