Data Exclusivity

Drug manufacturers are required to carry out clinical trials in order to establish drug efficacy and efficiency. The clinical trial data generated to demonstrate efficacy and efficiency for New Chemical Entities (NCEs) is the subject matter of monopoly that data exclusivity (DE) offers. Thus, generic drugs that are required to show bio-equivalence will not be allowed to use this data in order to exhibit efficacy and efficiency.

DE gives the owner an extended monopoly over the data besides a granted patent. Therefore, the Indian government, policy makers and generic drug manufacturers are of the view that it is a TRIPS plus provision which if included in the Indian IP regime will be a retrogressive step for the generic drug manufacturers.

India has seen a strong lobby against inclusion of data exclusivity provisions for pharmaceuticals on the premise that it is a TRIPS plus provision. Not providing data exclusivity for pharmaceuticals and agro-chemicals is believed to be in the interest of the generic pharmaceutical industry, since the same will have a huge impact in delayed entry of generic drugs in the market.

Inclusion of the data exclusivity provision in the Indian IP regime will also bring with it the concept of patent term extension, since the protection allowed by data exclusivity will be in addition to the term of a granted patent, which in India is 20 years as per TRIPS provisions.

Further, the generic pharma industry in India is of the view that inclusion of data exclusivity will only grant an extended short-term monopoly and introduce adverse pricing which in turn will weigh against public health.

A committee was set up by the Indian government, known as the Satwant Reddy Committee in 2007 that recommended a fixed period of data protection for a period of five years for pharmaceuticals and a fixed period of three years for agro-chemicals.
However, the report is still under consideration and the position of data exclusivity still remains unclear in the Indian scenario.

The proponents of data exclusivity in India have put forth the proposition that drugs specifically for India will be manufactured with ease if data exclusivity laws are place. They are of the view that the big pharma players will view India as an amiable market for investment and work on drugs endemic to India. However, the opponents strongly recommend for a no data exclusivity policy.

Therefore, at present India has no statutory protection for Data exclusivity unlike the corresponding United States legislation, the Hatch Waxman Act.

### Patent Term Extension

India has been a giant in the generic drug market arena for over a decade now and has also become an important supplier of active ingredients to the third world countries. It was in 2005 when in order to comply with the TRIPS Agreement, products were extended patent protection along with processes for a term of 20 years.

However, patent term extension did exist in the erstwhile Indian *Patents and Designs Act of 1911* (hereinafter referred to as the Act of 1911), it was done away with in the year 2005 with the inclusion of product patents in order to make the legislation TRIPS compliant.

With the *Patents (Amendment) Act of 2005* (hereinafter referred to as the Amendment Act), Section 3 (d)\(^1\) was amended to bear stricter patenting standards for pharmaceutical and agro-chemical products.

Further, the Indian Supreme Court passed a spearhead judgement last year, Novartis v. Union of India, which clearly stated that the amendment to Section 3(d) was an attempt to prevent evergreening and extended monopolies to patent products, which in turn is a win for public health.

It was clearly laid down in the judgement that Section 3(d) clearly sets up a second tier of qualifying standards for chemical substances/ pharmaceutical products in order to leave the door open for true and genuine inventions but at the same time, to check any attempt at repetitive patenting or extension of patent term on spurious grounds.

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\(^1\) Section 3: The following are not inventions within the meaning of this Act:

(d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

Explanation: For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.
While patent term extension may seem appropriate for the developed countries, the developing countries at this stage may feel the pinch on the issue of affordability and public health concerns.

Concluding the above, it is safe to say that since a vast majority of the Indian pharmaceutical industry are generic drug manufacturers, the inclusion of data exclusivity laws and patent term extension may not be conducive in the present times. On the contrary, India may witness a steep decline in innovator companies establishing their grounds in this volatile market due to the absence of statutory provisions for data exclusivity and patent term extension.

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**Tarun Gandhi** - Attorney at Law and Patent Attorney

Chadha & Chadha, India

Tarun Gandhi is a Managing Associate at Chadha & Chadha. His niche area of expertise is prosecuting Life Sciences related patent applications. He is also actively involved in trademark litigation and prosecution. He is an active member of INTA, AIPLA, APAA, AIPPI and BiO.