THE PHARMACEUTICAL INTELLECTUAL PROPERTY AND COMPETITION LAW REVIEW

FOURTH EDITION

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PREFACE

Despite the industry's critically important response to the covid-19 pandemic, which saved millions of lives around the world, the attacks on industry – and science – continue. The pharmaceutical business is under unprecedented pressure – pricing is a constant focus of new legislation, patenting and business strategies are under continual scrutiny, and regulatory and compliance burdens are growing. Combine that complexity with the fact that pharmaceuticals are truly one of the most global industries, with many companies operating in dozens of countries with differing legal regimes and healthcare systems, and you have a 'perfect storm' for industry lawyers.

While there has been significant harmonisation in certain areas, the nuances of these local frameworks require careful attention from both a strategic planning and operational perspective in order to achieve business objectives across jurisdictions. Maximising the value of intellectual property can make the difference in deciding whether to pursue the development of an important new treatment, and in maintaining success in the marketplace. Similarly, a failure to carefully manage risks in dealings with competitors, such as generic and biosimilar companies, can result in huge civil and criminal liabilities. As companies are all too familiar, this is an area of significant enforcement activity around the world, with large fines being imposed and transactions thwarted if applicable legal constraints are not heeded. Moreover, the links between intellectual property, such as exclusivities, and drug pricing and affordability are a constant source of political scrutiny, as well as patient and physician concern.

Our objective in structuring this updated volume is to give practitioners in the field a one-volume introduction to these critical issues in an array of jurisdictions. It is hoped this book will reduce some of the burdens associated with bringing new treatments and cures to patients while achieving global business success. I would like to thank the authors for their renewed contributions to this edition of *The Pharmaceutical Intellectual Property and Competition Law Review*; they have produced what we believe is a very useful tool for managing global risks in this area.

Daniel A Kracov
Arnold & Porter
Washington, DC
August 2023

Chapter 6

INDIA

Arun Kumar and Manisha Singh[1]

I OVERVIEW

This chapter offers a review of 'product hopping' practised by Indian pharmaceutical companies and investigates the connections between Indian competition law, intellectual property law and drug regulations. Furthermore, it tries to provide a broad summary of product hopping's anti-competitive behaviour. It looks at how Indian legal systems try to strike a balance between promoting innovation, dealing with patent disputes and the entry of competitors into the market, and accounting for product-hopping strategies.

Product hopping is a tactic used by pharmaceutical product developers and manufacturers to counter the competition that generic drug manufacturers pose to their patented products nearing the expiry of the term. Patients are made to switch to another patented drug product made by the same company that is roughly equivalent to the drug they were previously using for the same category of disease. By employing the strategy of product hopping, the branded pharmaceutical manufacturing businesses transfer their patients to another drug product with a current patent, preferably far in advance of the parent or original drug product's patent term expiration. Said method influences generic manufacturers to gain attention when releasing the drug product's generic form.[2]

'Product switching' is another name for product hopping. A 'hard switch', in which the previous product is removed from sale, and a 'soft switch', in which the older product is kept on sale alongside the new one, are the two ways to perform product hopping. In either case, the business will focus its marketing efforts on the novel or fresh product to reduce the market for any knockoffs of the original product.[3]

Product hopping is the practice of a pharmaceutical firm reformulating its medication and enticing physicians to prescribe it in place of the original medication. A brand manufacturer engages in product hopping when they do both of the following:

a reformulate the product in such a way that a generic version of the original product is not interchangeable; and

b encourage physicians to write prescriptions for the reformulated version of the product rather than the original version, namely, switch the prescription base from the original to the reformulated version.[4]

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1 Arun Kumar is a senior consultant and Manisha Singh is the founder and managing partner at LexOrbis.

2 Jessie Cheng, 'An Antitrust Analysis of Product Hopping in the Pharmaceutical Industry', *Columbia Law Review* Vol. 108, No. 6 (October 2008), pp. 1471–1515.

3 Drug Pricing and Pharmaceutical Patenting Practices (https://www.everycrsreport.com/reports/R46221.html).

4 Michael A Carrier, 'Product Hopping', *Journal of Commercial Biotechnology* (2017) 23(2), 52–60.

Product hopping happens because of one (or more) of several kinds of reformulations. Changing from a capsule, tablet, injection, solution, suspension or syrup to another form, such as any of the aforementioned formulations, as well as extended-release capsules or tablets, orally dissolving tablets and chewable tablets. For instance, the makers of the cholesterol-lowering drug TriCor and the antidepressant Prozac shifted from capsule to tablet form, while the developers of the anxiety-treating drug Buspar switched from tablet to capsule.[5]

A second method of reformulation involves adding or removing compounds to modify moiety components (sometimes referred to as 'moieties'). Technically speaking, a manufacturer can change from one enantiomer to another, which is one of the pairs of chemical compounds that are mirror imaged. A manufacturer can switch from a chemical compound that is an equal mixture of each enantiomer, only one of which contains the active ingredient, to a compound that contains only the active enantiomer of the ingredient. This is an example and foreshadows the change discussed below from heartburn-treating Prilosec to Nexium. Switches from the antidepressant Celexa to Lexapro, the heartburn drug Prevacid to Kapidex, and the allergy treatment Claritin to Clarinex can all be attributed to chemical alterations.[6]

A third type of reformulation entails the blending of two or more previously separately sold medication formulations. Combinations include the migraine medication Treximet, which combines Imitrex and Naproxen Sodium, and the high blood pressure drugs Azor, Caduet and Exforge, which combine Norvasc and Benicar, Lipitor and Diovan, respectively.[7]

II LEGISLATIVE AND REGULATORY FRAMEWORK

i Regulatory framework

The pharmaceutical regulations in India are controlled by the National Regulatory Authority (NRA). The Central Drugs Standard Control Organisation (CDSCO) under the Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India is the NRA of India. The objective of the NRA is to ensure that medicinal products are of acceptable quality, safety and efficacy; are manufactured and distributed in ways that ensure their quality until they reach the patient or consumer; and that their commercial promotion is legally and morally valid.[8]

ii Legislative framework

The legislative framework for the marketing, authorisation and pricing of pharmaceutical products in India (including generic drugs) consists of:

a the Drugs and Cosmetics Act 1940 (DCA), the Drugs and Cosmetics Rules 1945 (the DCA Rules), the Drugs (Control) Act 1950 and the New Drugs and Clinical Trial Rules 2019, which in combination regulate the manufacturing and distribution of pharmaceutical products;

5 id.

6 id.

7 id.

8 https://cdsco.gov.in.

b the New Drugs and Clinical Trial Rules 2019, which specifically look after investigational new drugs, new drugs and subsequent new drugs, clinical trials, bioequivalence studies and bioavailability studies;

c the Drugs (Price Control) Order 2013 (DPCO), which regulates the pricing of certain essential medicines listed therein and framed under the Essential Commodities Act 1955;

d the Pharmacy Act 1948 and the Pharmacy Practice Regulations 2015 (the Pharmacy Regulations), which prescribe conditions and qualifications, upon satisfaction of which a person can be authorised to handle or dispense medicines;

e the Medicinal and Toilet Preparations Act 1955, which imposes an excise duty on medicinal preparations that contain alcohol, narcotic drugs or narcotics; and

f the Drugs and Magic Remedies (Objectionable Advertisements) Act 1954, which controls the advertisement of drugs in India.[9]

The legislative framework for the distribution of pharmaceutical products consists of:

a the Drugs and Cosmetics Act (DCA) and the DCA Rules, which govern the import, production, distribution and sale of drugs in India;

b the Narcotic Drugs and Psychotropic Substances Act 1985, which controls the circumstances under which certain drugs may be sold, and in what quantity;

c the Pharmacy Act and the Pharmacy Regulations, which specify the requirements that must be met before a person can be permitted to handle or dispense medications; and

d the Draft Guidelines on Good Distribution Practices for pharmaceutical products-Reg 2018 (the Draft Guidelines) have been proposed to apply to all persons and organisations involved in any aspect of the storage and distribution of pharmaceutical products, along the entire supply chain, between the manufacturer and the patient.[10]

III NEW DRUGS AND BIOLOGICS

In India, the drug regulation system operates at both central and state level. To achieve uniformity in the enforcement of the Drugs and Cosmetics Act, the CDSCO has been given primary responsibility for approving new drugs, clinical trials conducted in the nation, establishing drug standards, monitoring the quality of imported drugs, coordinating the efforts of state drug control organisations and offering expert advice.[11]

i Drugs

According to Section 3(b) of the Drugs and Cosmetics Act 1940, the term 'drug' includes:

> *(i) all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on the human body to repel insects like mosquitoes;*

9 Pharmaceutical Antitrust 2019 – India, https://www.azbpartners.com/bank/pharmaceutical-antitrust-2019-india/?utm_source=Mondaq&utm_medium=syndication&utm_campaign=LinkedIn-integration.

10 id.

11 New Drug Approval Process in India, 20 March 2021; https://www.apifirst.in/2021/03/20/new-drug-approval-process-in-india/.

(ii) such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of [vermin] or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette;

(iii) all substances intended for use as components of a drug including empty gelatine capsules; and

(iv) devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board.[12]

With the publication of GSR 227 (E) on 19 March 2019, India has issued a new set of regulations that apply to all sorts of new pharmaceuticals, investigational novel medications for human use, clinical trials, bioequivalence studies, bioavailability studies and ethics committees. These regulations are officially titled the New Drugs and Clinical Trial Rules 2019.[13]

According to the New Drugs and Clinical Trials Rules 2019, 'new drug' means:

(i) a drug, including active pharmaceutical ingredient or phytopharmaceutical drug, which has not been used in the country to any significant extent, except under the provisions of the Act and the rules made thereunder, as per conditions specified in the labelling thereof and has not been approved as safe and efficacious by the Central Licencing Authority concerning its claims; or

(ii) a drug approved by the Central Licencing Authority for certain claims and proposed to be marketed with modified or new claims including indication, route of administration, dosage and dosage form; or

(iii) a fixed-dose combination of two or more drugs, approved separately for certain claims and proposed to be combined for the first time in a fixed ratio, or where the ratio of ingredients in an approved combination is proposed to be changed with certain claims including indication, route of administration, dosage and dosage form; or

(iv) a modified or sustained release form of a drug or novel drug delivery system of any drug approved by the Central Licencing Authority; or

(v) a vaccine, recombinant Deoxyribonucleic Acid (r-DNA) derived product, living modified organism, monoclonal antibody, stem cell-derived product, gene therapeutic product or xenografts, intended to be used as a drug.

Explanation: The drugs, other than drugs referred to in sub-clauses (iv) and (v), shall continue to be new drugs for four years from the date of their permission granted by the Central Licencing Authority and the drugs referred to in sub-clauses (iv) and (v) shall always be deemed to be new drugs.[14]

Given the above provisions of the Drugs and Cosmetics Act 1940 and rules, even drugs that are a modified form of old drugs may get approval from the Central Drug Licensing Authority.

Pharmaceutical companies must follow the appropriate regulatory routes if the drug substance or drug product that is intended for introduction in the Indian market falls under the definition of a new drug as stated above. The following key elements are necessary for regulatory pathways to work:

12 id.

13 id.

14 id.

a Nature of drug substance or drug product. Determining the process for approving new drugs is greatly influenced by the type of the drug product. According to the definition of a new drug, a vaccination, a product derived from recombinant deoxyribonucleic acid (r-DNA), a living modified creature, a monoclonal antibody, a product derived from stem cells, a product for gene therapy or xenografts intended for use as drugs will always be considered to be a new medication. Therefore, before considering applying for marketing authorisation, every manufacturer who plans to introduce any of these categories of pharmaceuticals must first complete significant non-clinical and clinical trials, as appropriate, to demonstrate their safety and efficacy.[15]

b Type of formulation. The type of formulation has a significant impact on the process of approving new drugs. According to the definition of a new drug, any drug licensed by the Central Licencing Authority in a modified or sustained release form or with a novel drug delivery mechanism is always considered to be a new drug. Each producer must therefore complete clinical trials, bioavailability and bioequivalence (BA-BE) studies, or both, as appropriate, before applying for marketing authorisation for any of these categories of medications.[16]

c Drugs already approved in the country. The Central Licencing Authority's licence to market a medicine as a new drug is valid for four years after that date, according to the New Drugs and Clinical Trial Rules 2019. To create a new drug for sale and distribution during this time, a manufacturer must also apply for the approval of the new drug.[17]

d Investigational new drug. Extensive research and tests, both clinical and non-clinical, are needed for these kinds of drugs. Phase I of the clinical trials is followed by phase II and phase III. The regulatory authorities must receive the generated data for them to grant marketing authorisation.

e Orphan drugs. Depending on the circumstances, different restrictions may be relaxed in the case of orphan pharmaceuticals; however, this requires Central Licencing Authority approval. In these situations, it is advised to meet with CDSCO officials before submission so that the pathway can be reviewed and mutually agreed upon.[18]

f New molecules, new combinations, new dosage forms, new indications, new dosage, new route of administration. Before applying for marketing authorisation, every manufacturer that plans to introduce any of these types of medications must first complete clinical trials, BA-BE studies, or both, as appropriate.[19]

Data exclusivity

There has been a great deal of debate surrounding the subject of data exclusivity recently. There have been attempts to conflate the concerns of data protection with data exclusivity. When viewed in light of Article 39.3 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS agreement), clinical test results produced by the innovator companies have acquired a unique relevance. The provisions in Article 39.3 give countries freedom, enabling them to interpret the clause however they see fit. According to proponents of data exclusivity, the regulatory authority cannot approve second or subsequent

15 id.

16 id.

17 id.

18 id.

19 id.

applications for the same product based on data given by the innovator companies. The country's generic pharmaceutical industry will be impacted by data exclusivity, which would also raise prices. Article 39.3 of TRIPS does not require data exclusivity, and it may not currently be in India's national interest to grant data exclusivity to pharmaceutical drug data, according to the Satwant Reddy Committee, which the Indian government established to study these issues. The same position that India does not currently need to allow for data exclusivity as a matter of policy has been supported by a report from the Parliament. Since multinational companies are vehemently advocating for the same, the matter has been at the centre of controversy.[20]

ii Generic or subsequent new drug

'Generic drug' has not been defined or specified in Indian legislation or regulation, which is important to note. According to Rule 122-A, the initial applicants for the registration of a new drug in India are required to present information, including the findings of clinical studies. However, subsequent applicants seeking registration of the same drug are only required to submit data from BA-BE and comparative dissolution studies, in accordance with Appendix I-A of Schedule Y (data required from applicants of a new drug already approved in the country) and are not required to submit the outcomes of clinical trials.

The registration of a subsequent new drug is done by the 'subsequent new drug division', which deals with applications for approval of an already approved new drug (within four years of its first approval) and a drug already approved by the Licensing Authority mentioned in Rule 21 for certain claims, which is now filing an application to be marketed with modified or new claims, namely, indications, dosage, dosage form (including sustained release dosage form) and route of administration.[21]

Subsequent new drug applications can be made for the following cases:

a bulk drug already approved in the country (approved within four years of original bulk drug);

b new drug (formulation) already approved in the country (approved within four years of original new drug formulation);

c a drug already approved and proposed to be marketed with new indication;

d a drug already approved and proposed to be marketed as a 'new dosage form or new route of administration';

e a drug already approved and proposed to be marketed as a 'modified release dosage form'; and

f a drug already approved and proposed to be marketed with additional strength.[22]

iii Similar biologics

Similar biologics are subject to regulation under the Drugs and Cosmetics Act of 1940, the Drugs and Cosmetics Rules of 1945 (as amended from time to time), and the Rules for the manufacture, use, import, export and storage of hazardous microorganisms/genetically engineered organisms or cells of 1989 (Rules, 1989), which were notified under the Environment (Protection) Act of 1986. Examples of applicable guidelines are given below:

20 Competition Law and Indian Pharmaceutical Industry; Centre for Trade and Development (Centad), New Delhi, 2010; https://www.cci.gov.in/public/images/marketstudie/en/docs1652437987.pdf.

21 See footnote 8.

22 id.

a Recombinant DNA Safety Guidelines 1990;
b Guidelines for Generating Preclinical and Clinical Data For rDNA Vaccines, Diagnostics and Other Biologicals 1999;
c CDSCO Guidance for Industry 2008:
    - submission of clinical trial application for evaluating safety and efficacy;
    - requirement for permission of new drug approval;
    - post-approval changes in biological products: quality, safety and efficacy documents; and
    - preparation of quality information for drug submission for new drug approval: biotechnological and biological products;
d Guidelines and Handbook for Institutional Biosafety Committees (IBSCs) 2011; and
e Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India 2012.

The following are the appropriate authorities engaged in the approval process of similar biologics:

a Institutional biosafety committee (IBSC). Any person, including research organisations handling dangerous microbes or genetically modified organisms, constitutes an IBSC. An IBSC is in charge of conducting an initial examination of applications and recommending them to the Review Committee on Genetic Manipulation (RCGM) in addition to maintaining biosafety on-site. The IBSC is also tasked with reviewing and approving the firm for the exchange of the aforementioned organisms for research purposes.
b RCGM. The RCGM is operated by the Department of Biotechnology, Ministry of Science and Technology, Government of India. The RCGM is in charge of approving research and development activities for similar biologics, as well as the exchange of genetically modified cell banks for research and development purposes and the review of data up to preclinical evaluation.
c Genetic Engineering Appraisal Committee (GEAC). The GEAC serves as a legislative body within the Ministry of Environment and Forests for the examination of applications and approval of activities where the final drug product involves genetically modified organisms or living modified organisms.
d CDSCO. For similar biologics, CDSCO is in charge of approving clinical trials, as well as granting licence for the manufacturing and marketing of products and for the import and export of clinical samples for biochemical and immunological examination.

Only after a product has been thoroughly characterised in comparison to the reference biologic and confirmed to be similar can it be classified as a similar biologic. Only once the similar biologic's quality resemblance to a reference biologic has been established should further product development be taken into consideration. Only once a reference biologic has been authorised, using a full data package in India, can it be used as the benchmark when developing similar biologics. If India does not have an official authorisation for the reference

biologic, it should have been licensed, approved and sold in a country that is a member of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use.[23]

IV PATENT LINKAGE

Multinational pharmaceutical corporations have made an effort to introduce the concept of patent links to India's drug regulatory system. The practice of connecting medicine approval to a patent's status is known as 'patent linkage'. Pharma giant Bayer tried to prevent generic rivals from obtaining marketing permission for their version that violated patents. This was an attempt to integrate patent linkage into the Indian regulatory system for pharmaceuticals. The stance that a drug regulating agency cannot be utilised to enforce patents has been resolved by a High Court ruling, and as a result, the idea of linkage cannot be interpreted as per the Drugs and Cosmetics Act or the Patents Act 1970. Since test data may not be used after the patent expires, patent linkage can have significant effects on generic entry.[24]

V COMPETITION LAW AND COMPETITION ENFORCERS

The Competition Act of 2002 and its related rules serve as India's competition law framework. The Competition Act aims to prevent practices that have an adverse effect on competition and strives to promote and sustain competition in the markets and protect consumer interests.[25]

The Competition Commission of India (CCI) oversees enforcement of the Competition Act. The National Company Law Appellate Tribunal (NCLAT) hears appeals of the CCI's rulings. The Supreme Court of India is the proper forum for a further appeal of the NCLAT ruling. The CCI has been enforcing the Competition Act for nearly two decades and has received over 50 cases involving the pharmaceutical and healthcare industries.[26]

The principal provisions of the Competition Act that apply to the pharmaceutical industry are as follows:

a anticompetitive horizontal agreements and anticompetitive vertical constraints (Section 3 of the Competition Act);

b abuse of dominant position (Section 4 of the Competition Act); and

c combinations (Sections 5 and 6 of the Competition Act).[27]

Any strategy or practice adopted by the innovator pharmaceutical company to delay the generic drug's market entry or to foreclose the market may come under the radar of the Competition Act if it causes or is likely to cause an appreciable adverse effect on competition (AAEC) on the Indian drug market.[28]

23 Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India, 2016; https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTU0NA==.

24 See footnote 20.

25 The Competition Act 2002.

26 id.

27 id.

28 See footnote 9.

While assessing whether any activity or agreement results in an AAEC, the CCI must consider several considerations that are prescribed by the Competition Act. These factors include:

a putting up barriers to new entrants in the market;
b driving out existing competitors;
c hindering entry into the market;
d foreclosure of competition;
e accrual of benefits to consumers;
f improvements in production or distribution of goods or provision of services; or
g promotion of technical, scientific, and economic development through production or distribution of goods or provision of services.[29]

VI INTERSECTION OF DRUG REGULATIONS WITH COMPETITION LAW

Drug regulation (in terms of costs, intellectual property rights or patent rights, safety, and efficacy) is either directly or indirectly related to pharmaceutical market competitiveness. The Drug and Cosmetic Act 1940's primary goal is to guarantee the efficacy, safety and quality of medicines. However, there may be some impact on competition while regulating the production, sale and distribution of medications and awarding marketing approval or authorisation. The Drugs and Cosmetics Act makes it very clear that its requirements must be followed in addition to any other drug-related legislation already in place.[30]

The elements of the drug regulatory framework mentioned above that pertain primarily to the application of competition law in the pharmaceutical industry are as follows:

a the DPCO, which gives the Indian government the authority to set a price ceiling for specific scheduled formulations, allowing manufacturers to set maximum retail prices that take into account local taxes;
b the Essential Commodities Act, which gives the government the authority to regulate the production, supply and distribution of essential commodities, including pharmaceutical products; and
c the Pharmacy Act, which lays out the requirements and qualifications that must be met to be authorised to handle or dispense medications.[31]

In 2018, the CCI published a policy note titled 'Making Markets Work for Affordable Healthcare' that discussed the role of middlemen in the rise of drug prices, the perceptions of quality driving the growth of branded generics, vertical arrangements in healthcare services and the lack of transparency and regulation in the pharmaceutical industry.[32]

29 id.
30 See footnote 20.
31 See footnote 9.
32 Policy Note on 'Making Markets Work for Affordable Healthcare'; https://cci.gov.in/public/events/All/details/33.

VII ANTICOMPETITIVE BEHAVIOUR

i Is product hopping anticompetitive?

Product hopping may or may not be anticompetitive as it is purely based on the approach or strategy of the innovator pharmaceutical company manufacturing a drug product. This can be understood based on two cases where competitive scrutiny for product hopping differed significantly in their outcomes.

In the first case, *Abbott Laboratories v. Teva Pharmaceuticals USA, Inc*,[33] the defendant, Abbott, was alleged to have introduced a slightly modified product, in an approach to hinder its generic competitor's entry into the market. Since Abbott's product hopping involved withdrawing its existing drug from the market by introducing its new slightly modified drug, resulting in the reduction of consumer choice, the court found the strategy of product hopping anticompetitive. However, in the second case, *Walgreen Co v. AstraZeneca Pharms LP*,[34] AstraZeneca was accused of adopting the anticompetitive strategy of product hopping by the introduction of a slightly modified drug that was identical to an existing drug. The court dismissed the complaint on the grounds of being anticompetitive since AstraZeneca retained production of the original drug, not leading to a reduction in consumer choice. Said court conclusions would help infer that product hopping combined with the withdrawal of an existing brand product from the market may be anticompetitive because of the reduction in consumer choice and scope of generics entry into the market.[35]

It has been strongly argued that product hopping should not be considered anticompetitive. Introduction of a new drug is generally pro-competitive, and its competitive legality should not be based on a court's decision, whatever the evaluation of the drug's merit.[36]

But the changes in the physical form of a drug or formulation prepared thereof are hardly considered innovative. Moreover, it has been stated by courts that an accepted product claiming monopoly should be considered anticompetitive until the monopolist coercively reduces the customer choice in hand. This has been observed in the matter of *New York v. Actavis*.[37,38]

Actavis restricted the use of its drug Namenda IR (immediate release) by switching to its slightly modified version Namenda XR (extended release). Actavis restricted the entry of generic players much before the expiry of Namenda IR, forcing doctors and patients to switch to a costly newer version, making the strategy of Actavis competitive. Under such coercive circumstances, the product-hopping strategy has negative consequences for consumers and their healthcare plans. Product-hopping strategy is considered competitive when combined with coercive and predatory conduct because these circumstances reduce competition and social welfare. In other words, 'the strategy of product hopping is not the product introduction itself, but the associated conduct, that supplies the competition act violation'.[39]

33 *Abbott Laboratories v. Teva Pharmaceuticals USA, Inc* 432 F Supp 2d 408, 416, 423-24 (D Del 2006).

34 *Walgreen Co v. AstraZeneca Pharms LP*, 534 F Supp 2d 146, 148-51 (DDC 2008).

35 Vikram Iyengar, 'Should Pharmaceutical Product Hopping be Subject to Antitrust Scrutiny?', *JPTOS* 664–689.

36 id.

37 *New York v. Actavis, PLC*, No. 14-Civ-7473, 2014 WL 7015198.

38 Michael A Carrier & Steve D Shadowen, 'Product Hopping: A New Framework', *Notre Dame Law Review* Vol. 92:1.

39 id.

ii If product hopping is anti-competitive, should Indian competition law be applicable?

Cases concerning product switching or product hopping have not yet been handled by the CCI. The CCI will need to strike a balance between the legitimate rights of patent holders to take action to protect and use their intellectual property, including the potential for engaging in product switching, and the likely restriction on new market entry, as in other cases involving the interplay between patent rights and antitrust.[40]

It is likely to be more difficult to examine incidents of product switching from an antitrust perspective. A patent holder has the legal right to prevent anyone from using the underlying patent that is employed in the medicine for the duration of its patent term. A patent holder is free to select the most effective strategy for their patent rights during this exclusivity period. It would be well within its rights to license its patented medication as an authorised generic before the expiration of its patent period. The CCI may, however, consider whether this conduct may be viewed as an anticompetitive market-leveraging practice where the patentee uses its dominant position in the patented market to gain entry and market share in the alternative market for generic versions of that drug if it believes that such product switching is being used to deny market access to other generic manufacturing companies. A violation of Section 4 of the Competition Act, which deals with abuse of dominance behaviour, may result from such anticompetitive leveraging.[41]

While the Competition Act's abuse of dominance rules do not expressly call for the effects test, the CCI may also take into account whether the advantages of releasing a generic medication before the patent's expiration offset any potential market denial that such conduct may otherwise entail. The likelihood of antitrust violation would rise if such pre-term licensing between the patentee and a generic producer was the result of collusive behaviour to block the entry of an otherwise more capable and stronger generic manufacturer.[42]

It is noticeable that the Competition Act provides a very narrow scope for patent holders to escape from antitrust liabilities for their anticompetitive agreements executed under the influence of their patent rights. However, the same agreements would not help the patent holder to escape from antitrust liabilities if the execution of those agreements was under the influence of a dominant position.[43]

VIII OUTLOOK AND CONCLUSIONS

The Drugs and Cosmetics Act is one of the key regulatory frameworks that actively decides when a pharmaceutical product can enter the Indian market. The introduction of a new pharmaceutical product in the market, subject to complying with the Drugs and Cosmetics Act, does not seem inherently anticompetitive under the Competition Act. The CCI needs to look at the patent holder's overall conduct when launching a new product, as well as the impact on the final consumer and the market, to determine whether this strategy of launching a new product is a legitimate use of its patent rights from a competition perspective.

40 See footnote 9.

41 id.

42 id.

43 id.

Further, the CCI needs to conduct a more thorough investigation of the pharmaceutical and healthcare sector after observing that there is an asymmetry in available information while making decisions in the circumstances of product hopping or product switching.