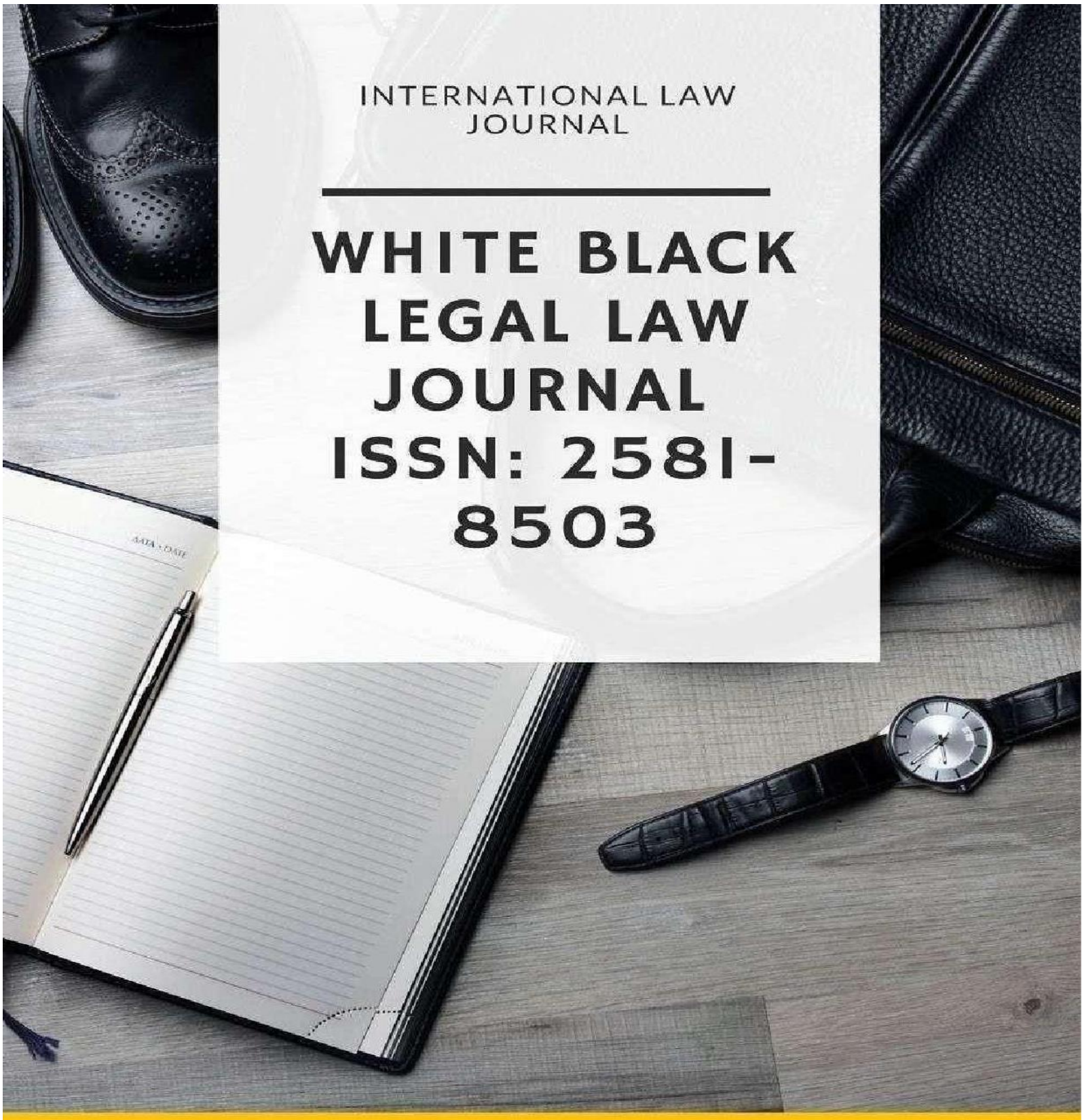

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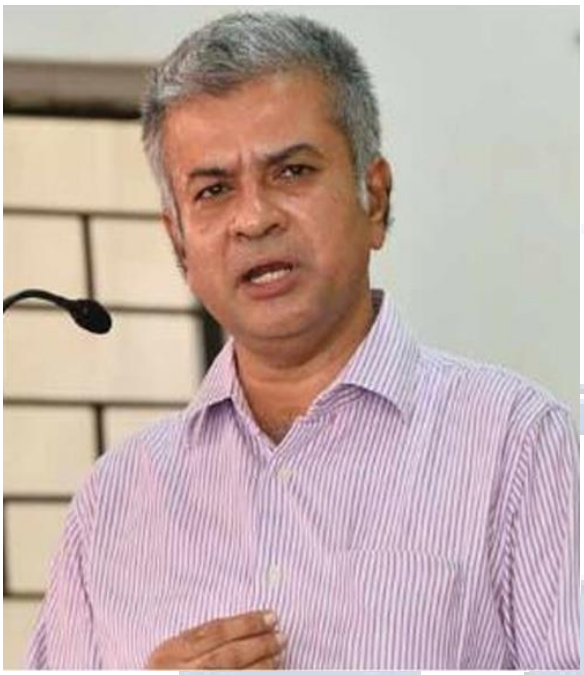

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WHITE BLACK LEGAL is an open access, peer-reviewed and refereed journal providededicated to express views on topical legal issues, thereby generating a cross current of ideas on emerging matters. This platform shall also ignite the initiative and desire of young law students to contribute in the field of law. The erudite response of legal luminaries shall be solicited to enable readers to explore challenges that lie before law makers, lawyers and the society at large, in the event of the ever changing social, economic and technological scenario.

With this thought, we hereby present to you

"Market Competition and Innovation: The Effect of Patent Law on Antitrust Laws"

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ABSTACT

The Indian pharmaceutical industry is one of the most significant industries in the world. It is characterized by a high demand for prescription medications, a large market share, and a lack of research and development. In this paper, we review the history of India's pharmaceutical industry, with a particular focus on the manufacture and sale of prescription medications. This paper also discusses antitrust concerns pertaining to the pharmaceutical sector, with particular emphasis on the manufacturing and selling of generic medications, including both brand-name and generic goods. We also discuss some of the key issues that need to be addressed in this sector from the perspectives of public policy and research, with an emphasis on emerging countries like India.

INTRODUCTION

The economics of the pharmaceutical sector are uncommon, and the way that regulation, patent law, and antitrust law connect is unique. The industry's supply side consists of wholesalers, retail pharmacy services, and both brand-name and generic prescription and over the counter (OTC) pharmaceuticals. The unique characteristics of each of these industries influence how competition law is applied. Prescription medications that are originators require a great deal of research and have a large potential market share because of insurance coverage, regulatory exclusivities, and patent protection. Depending on entrance and insurance reimbursement conditions, the generic industry—which may include copy products and pure generics—may have structural competition. Retail pharmacies and wholesalers are two examples of distribution industries that may be structurally competitive. In most countries, regulations play a major role in shaping each of these supply sectors. In some countries, however, the influence of public and commercial insurers, who serve as intermediaries and third-party payers for patients—the final consumers—also plays a balancing role. The way in which competition operates and the ultimate costs of pharmaceuticals are determined by the interplay of regulatory, patent, and antitrust laws, as well as payers' countervailing power.

Since pharmaceuticals are very complicated technological products with a substantial yet unobservable risk to health, they are regulated extensively in all nations. Prescription

medications must meet safety, effectiveness, and manufacturing quality standards as stipulated by market access regulations to be made widely available to consumers. Requirements that medications be prescribed and dispensed by registered doctors and pharmacists further restrict access to medications, which tends to give these patient agents more market power. There is extensive price regulation, first as a reaction to insurance, which weakens consumer price sensitivity and forges strong governmental payers, and then as a response to the public health concern that medications be reasonably priced.

This essay discusses antitrust concerns pertaining to the pharmaceutical sector, with a particular emphasis on the manufacture and sale of prescription medications, including both brand-name and generic goods. OTC products are included, although not by much. Section II delineates the principal economic attributes of the pharmaceutical sector that bear on antitrust policy, encompassing patent and regulatory frameworks, as well as the functions of insurers, physicians, and retail pharmacies serving as patient/customer representatives. As mentioned in Section II, there are some differences in these economic traits between originator and generic sectors as well as high-income and middle- and lower-income nations. An outline of the primary situations in which antitrust lawsuits have been filed in the pharmaceutical sector is given in Section III. The case law from the US and the EU, which have comparable market access regulations but differ in the role of private vs. public insurance, payer use of countervailing power, and other areas, is described in Sections IV and V, respectively. In Section VI, antitrust issues are briefly examined, and conclusions are drawn for nations with less developed regulatory frameworks and outpatient medication markets that are primarily self-pay.

AN OVERVIEW OF INDIA'S PHARMACEUTICAL INDUSTRY'S HISTORY.

There are three main periods in the history of the Indian pharmaceutical sector. Global multinational firms dominated the Indian pharmaceutical business in its initial era, which began shortly after independence. The Patents and Designs Act, 1911, a statute that was passed in British India and guaranteed a robust system of product patent protection, is credited with creating the current system. [1]Global firms with the technological capacity

[1] "Competition Law and Indian Pharmaceutical industry," (2010), Center for Trade and Development (Centad), New Delhi

introduce new medications to the market found it easy to enter the Indian market, but the cost of these medicines was prohibitive for the local populace (average drug prices in India were among the highest in the world).

During this period, there were very few significant domestic manufacturers, and eight of the top ten pharmaceutical companies were MNC subsidiaries (Greene 2007). India's underdevelopment is the reason that foreign nations have been the source of the majority of issued patents. More significantly, observers at the time seemed to believe that most of these patents were idle and that foreign patent holders were more interested in stopping the use of protected innovations than in making sales in India. As a result, even for those who were prepared to pay such exorbitant amounts, access to these things was not assured, despite their extremely high price. Furthermore, India was heavily dependent on the import of pharmaceuticals at this period.

Concerned by this situation, the Indian government appointed Justice N. Rajagopala Ayyangar to a one-man commission in 1957 to review the country's patent and design laws. The Committee concluded that the current patent system, established by the Patents and Design Act of 1911, did not advance the interests of the country and was the reason for the exorbitant cost of pharmaceuticals. The Committee suggested implementing the then-current German process patent system, which granted pharmaceutical product inventors the sole right to produce and market their creations using a specified procedure. Following the Ayyangar Committee's suggestions, the Indian government drafted the Patents Act, 1970, allowing pharmaceutical items to be protected by method patents for seven years after the date of filing. Evidently, the goal of this act was to promote a dynamic competitive environment in the industry and to establish and support domestic manufacturing of vital medications.

One may argue that the Patents Act, 1970 marked a turning point in the development of the Indian pharmaceutical sector. The result was the growth of the indigenous pharmaceutical sector, which is today focused on bulk drug reversal engineering. Furthermore, the Foreign Exchange Regulation Act (1973) required that the majority of the bulk drugs (intermediate products) that are used in formulations (products sold to retail customers) be produced in India rather than imported, and it restricted foreign ownership of Indian companies to 40% with the exception of a few exceptional cases. Furthermore, under the National Drug Policy of 1978, pricing limits were implemented in the form of Drug pricing Control Orders

(DPCOs). Due to these series of events, international multinational corporations were no longer incentivized to market their goods in India; instead, local pharmaceutical enterprises with a focus on producing generic versions of copyrighted medications emerged. The Indian government's research and development efforts aided the domestic businesses. Significant research and development were conducted by two public sector enterprises, Hindustan Antibiotics Ltd. (HAL) and Indian Drugs and Pharmaceuticals Ltd. (IDPL). These organizations' R&D efforts were transferred to the private sector through a variety of channels, most frequently the transfer of scientists. Furthermore, the pharmaceutical business received numerous technological inputs from the research activities of institutes including the National Chemical Laboratory (NCL), Indian Institute of Chemical Technology (IICT), and Central Drug Research Institute (CDRI) (Joseph, 2011).

The local enterprises were first limited to manufacturing just for the home market, but subsequently they acquired the capacity to manufacture off-patent generic copies of branded medications for the global market. Additionally, they produced bulk pharmaceuticals that were outsourced to India by multinational corporations that produced formulations, which led to exports. But in the majority of situations, the local pharmaceutical businesses lacked the technological know-how and made insufficient R&D investments to become leaders in the creation of novel treatment approaches and novel medications. Furthermore, under the current patent law, which only provided process patents for a seven-year duration, they lacked the incentives to do so. The price of medication development, which we will explore later, may also affect Another major disincentive would have been the expense of drug discovery (which we address later). Although the business expanded throughout this time, it did not become significant enough to warrant an independent evaluation in the nation's Annual Economic Surveys until around 2004–2005. throughout this time, it was infrequently listed as a component of the chemical industry. Nonetheless, the Indian pharmaceutical sector generated USD 3 billion in export revenue and USD 4 billion in domestic sales by 2004–05.[2]

When India joined the World Trade Organization (WTO) in 1995, the pharmaceutical sector in that country entered a new era. India was obligated to provide a scheme for product patents as part of it, and this regime also applied to pharmaceutical firms. Thus, in order to comply with WTO requirements, the Indian Patent Act was modified in 2005. One immediate effect of this

[2] Economic Survey of India, 2004 – 05

is that the Indian pharmaceutical industry's prior strength—reverse engineering a patented drug and manufacturing it using a different process to sell in nations that permitted it—was rendered moot, forcing the sector to find a new approach to competition (Greene, 2007). The establishment of product patents was intended to stimulate increased research and development (R&D) activity in India by both foreign and domestic companies. Although that didn't always happen, the domestic industry did find another avenue of growth: many pharmaceuticals that were about to lose their US patent protection allowed Indian companies to sell generic drugs in the US if they could get regulatory approval. The export of worldwide generics was the primary driver of the industry's continuous expansion.

Particularly for international firms doing business in India, the anticipation that the companies will make significant investments in R&D was not fulfilled (Chaudhuri, 2014). However, since the beginning of the new patent regime, Indian firms' R&D spending as a proportion of total sales has stalled (Joseph, 2011). This may be because they were intimidated by a few high-profile failures. Dr. Reddy's two medications, ragaglitazar and balaglitazar, were licensed to Novo Nordisk but were withdrawn from clinical studies because of unfavourable side effects or lack of efficacy (Singh and Datta, 2006). Few Indian businesses invest more than ten percent of their earnings on research and development.

Particularly for international firms doing business in India, the anticipation that the companies will make significant investments in R&D was not fulfilled (Chaudhuri, 2014). On the other hand, since the new patent regime went into effect, Indian firms have not increased their R&D spending as a percentage of overall sales (Joseph, 2011). This may be because they were intimidated by a few high-profile failures. Dr. Reddy's two medications, ragaglitazar and balaglitazar, were licensed to Novo Nordisk but were withdrawn from clinical studies because of unfavourable side effects or lack of efficacy (Singh and Datta, 2006). Few Indian businesses invest more than 10% of their earnings on research and development.[3]

As a result, Chinese companies are now fierce rivals of Indian companies in the bulk medication market, which presents a serious risk to small and medium-sized businesses in this industry that rely more heavily on API sales. To "formulate a long-term policy and strategy for promoting domestic manufacture of APIs/Bulk Drugs in the country," the Katoch Committee was established. It suggested establishing suitable infrastructure, developing industrial

[3] Press Trust of India, 2015, www.businessstandard.com/article/printerfriendlyversion?article_id=115022500808_1

clusters, reviving public sector organizations, and offering financial incentives to those involved in this industry.

Distinctiveness Of The Pharmaceutical Sector

Since the pharmaceutical sector has a significant impact on everyone's life and well-being, reaching end users is crucial. This makes it the most significant component of the industry. A customer may decide not to utilize a good or service that is out of their price range for most other goods and services they purchase in a marketplace. A medicinal medication that is too expensive for a certain customer may frequently have unfavourable effects, including death. Due to the extremely inelastic demand for some life-saving pharmaceutical medicines, prices for these items may become unaffordable for a significant portion of the customer base if market forces are allowed to take their full course.

However, the pharmaceutical industry also relies on large costs of research and development for development of a successful product, and oftentimes the success rate for any given R & D project is rather low. It is estimated that out of 10,000 molecules that pass the stage of basic research and are patented, only about 1 is marketed successfully, and the current cost of bringing in a successful product to the market is estimated at more than USD 2.5 billion.[4] Once produced, intellectual property is open to everybody for commercial production in the absence of any protection. An adequate incentive must be given to the manufacturer to participate in the R&D activity in the first place, considering the costs and dangers involved and the fact that the pharmaceutical firm bearing most of the risk bears during the research and development process. Hence, product patents, which grant a company or inventor exclusive profits on a product for a set amount of time, are awarded for unique inventions. However, the production expenses of such pharmaceuticals are quite inexpensive if they are licensed for sale in the market and prove to be effective.

One salient feature that sets the pharmaceutical industry apart from other sectors is that end consumers have no say over the medications they buy. Physicians make the decision, except for the over the counter (OTC) market. This might lead to an agency problem because doctors

[4] (UNCTAD, 2015), See http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014..pdf

may not always have their patients' best interests in mind when writing prescriptions for pharmaceuticals. The pharmaceutical corporations make significant efforts to maintain a sales team to raise physician knowledge of their drugs. Later, we go into great depth on how this aspect's competitiveness is affected.

THE PROCEDURE FOR INTRODUCING A MEDICINE INTO THE MARKET AND THE LEGAL STRUCTURE.

Bringing a drug to market involves a complex process that includes research and development, clinical trials, regulatory approval, manufacturing, marketing, and distribution. Here's an overview of the typical steps involved in bringing a drug to market, along with an examination of the regulatory framework and antitrust laws that govern the pharmaceutical industry:

1. Research and Development (R&D):

- Drug discovery: Scientists identify potential drug candidates through research, often targeting specific diseases or medical conditions.
- Preclinical testing: Candidate drugs undergo laboratory testing and animal studies to assess their safety, efficacy, and potential side effects.

2. Clinical Trials:

- Phase I: Small-scale trials in healthy volunteers to evaluate safety and dosage.
- Phase II: Trials in a larger group of patients to assess efficacy and further evaluate safety.
- Phase III: Large-scale trials to confirm efficacy, monitor side effects, and compare the drug to existing treatments.
- Regulatory submission: After successful completion of clinical trials, the pharmaceutical company submits a New Drug Application (NDA) or Biologics License Application (BLA) to the regulatory authority (e.g., FDA in the United States, EMA in Europe).

3. Regulatory Review:

- Regulatory authorities review the submitted data to evaluate the drug's safety, efficacy, and quality.
- Approval or rejection: Based on the review, the regulatory authority decides whether to approve the drug for marketing. Additional studies or modifications may be required before approval is granted.

4. Manufacturing:

- Once approved, the drug is manufactured according to Good Manufacturing Practice (GMP) standards to ensure quality, safety, and consistency.
- Regulatory inspections: Manufacturing facilities are subject to regular inspections by regulatory authorities to ensure compliance with quality standards.

5. Marketing and Distribution:

- The pharmaceutical company launches the drug in the market, often with marketing campaigns targeting healthcare professionals and consumers.
- Distribution networks are established to supply the drug to pharmacies, hospitals, and other healthcare providers.

6. Regulatory Framework:

- Regulatory agencies, such as the FDA in the United States, EMA in Europe, and CDSCO in India, oversee the approval and regulation of drugs.
- These agencies enforce regulations to ensure the safety, efficacy, and quality of pharmaceutical products.
- Antitrust laws, such as the Sherman Antitrust Act in the United States, aim to promote competition and prevent anticompetitive behavior in the pharmaceutical industry.
- Antitrust enforcement may involve investigating practices such as price-fixing, market allocation, and monopolistic behavior that harm competition and consumers.

THE INDIAN PHARMACEUTICAL INDUSTRY AND THE CHARACTER OF ITS MARKET

As previously said, one of India's most significant businesses is the pharmaceutical sector, and several Indian companies are now major participants on the international stage in the generic formulations market. As of 2013–14, the pharmaceutical market in India was projected to be worth USD 34 billion, including exports.[5]

Generics hold a 72 percent market share in terms of sales in India, as would be expected. While over-the-counter pharmaceuticals make up 19% of the market, patented drugs only account for 9% of the total, which is nearly completely provided by multinational corporations. With 20 percent of global generic medicine exports by volume, India is also the world's largest exporter of these medications (IBEF, 2015). India's overall exports were valued at USD 10.1 billion as of 2013. As of 2009, 95% of India's medical requirements were met by Indian companies (Gouri, 2009).

Speaking about the pharmaceutical market is a bit naive, despite the fact that the pharmaceutical sector is frequently discussed. Markets must be defined in terms of therapeutic categories since a pharmaceutical industry medicine cannot be substituted for another drug unless it is in the same therapeutic class. Thus, the pharmaceutical sector is divided into several markets. Furthermore, a company introducing a new medicine to the market will have extremely few or no substitutes due to patent protection. Hence, markets for patented medications will often be quite concentrated, and pricing will typically be very high. There are far less expensive generic alternatives for formulations without patent protection, and competition among generic manufacturers often assures a very low and

- **Price rivalry:** One significant aspect of the Indian pharmaceutical sector is the rivalry in prices between generics. Although this usually results in cheap pricing, there may be cases of high prices and a significant price dispersion for a certain molecule even in

[5] Annual Report, OPPI, 2013 – 14

situations when there are several providers of the same medication. A unique characteristic of the Indian market—which is absent from most industrialized markets—is the presence of branded generics, which we will address later. Thus, intra-molecule rivalry exists amongst brands. In certain cases, this leads to artificial distinction, when companies invest in marketing and promotion to raise spending on their goods (Bhattacharjea & Sindhwani, 2014). As a result, they may demand high prices for their goods even if they have large market shares. One significant aspect of the Indian pharmaceutical sector is the rivalry in prices between generics. Although this usually results in cheap pricing, there may be cases of high prices and a significant price dispersion for a certain molecule even in situations when there are several providers of the same medication. A unique characteristic of the Indian market—which is absent from most industrialized markets—is the presence of branded generics, which we will address later. Thus, intra-molecule rivalry exists amongst brands. In certain cases, this leads to artificial distinction, when companies invest in marketing and promotion to raise spending on their goods (Bhattacharjea & Sindhwani, 2014). As a result, they may demand high prices for their goods even if they have large market shares. Price restrictions and price competition coexist. Under the Essential Commodities Act of 1955, pharmaceutical prices have been regulated by the DPCO since 1970. The DPCO of 1979 regulated the pricing of 370 pharmaceuticals at first, but by 1995, the number of drugs under control had decreased progressively to 74. But compared to the 74 molecules under the DPCO 1995, a significant number (348) of local generic formulations became under the purview of price control under the DPCO 2013, accounting for an estimated 30% of the total domestic market (Yes Bank - Assocham, 2015). Thus, rather than using competition laws to control the market, direct pricing now controls a sizable piece of it.

- **Cost Advantages**: One of the primary advantages enjoyed by the Indian producers is low-cost but quality manufacturing of drugs. According to Greene (2007), the cost advantages stem from lower labour costs (approximately one-seventh of that in the US), lower infrastructure costs and fixed costs compared to the USA and Western Europe, large number of FDA-approved plants and availability of technical personnel. While some bulk drug producers have been able to maintain cost advantage and thrive with process innovations that usher in greater efficiency11 , Indian bulk drug manufacturers are increasingly facing competition in this segment from the Chinese producers of bulk drugs, who have greater cost efficiency in production of bulk drugs. While most of the established Indian pharmaceutical companies have moved away

from bulk drug productions to formulations, where the pharmaceutical companies enjoy higher profit margins, other bulk drug producers have targeted regulated markets where the margins are somewhat protected. [6]However, Indian firms continue to enjoy cost advantages in formulations, and thus can sell a lot of off-patent generic drugs. Other areas where firms operating in India potentially enjoy cost advantages are contract research and clinical trials. Thus, there exist incentives for many domestic firms to partner with multinational firms for the conduct of clinical trials, which would lead to reduction in costs in clinical trials.

- **Product Innovation:** Historically, Indian businesses have focused more on process innovation than on actual product innovation. Thirteen This is because, from 1970 to 2005, the Indian pharmaceutical business flourished in a sheltered environment devoid of product patent recognition. It is commonly asserted that only around one of every 5,000 to 10,000 molecules granted a product patent is effectively sold. Because of this, the pharmaceutical sector has high fixed costs and advanced technology, making it extremely difficult for businesses to enter the new product development space. The ability of Indian companies to produce novel pharmaceuticals is restricted by their R&D expenditures. It's thought that creating a new medication requires an expenditure of more than $1 billion USD.[7] The newly combined Sun Pharma (which therefore includes Ranbaxy Laboratories) spent 20 billion Indian rupees on research and development in 2015. This is the greatest R&D investment by an Indian company, yet it is significantly less than the yearly expenditure by worldwide new drug producing corporations. Furthermore, India lacks the technical expertise in biology and chemistry as well as the necessary infrastructure to support an atmosphere conducive to world-class R&D. However, there have been a few initiatives by Indian companies to create novel medications. Dr. Reddy's Laboratory created two compounds in the 1990s, balaglitazone and ragaglitazar, and Novo Nordisk was granted an out-licensing agreement for both. Dr. Reddy has received payment from Novo Nordisk for the license to test and, if successful, commercialize the product. Unfortunately, Novo Nordisk

[6] "From bulk drugs to formulations," P. Vikram Reddy, The Hindu, Jan 19, 2004, and "API Market loses out to formulations," Sushmi Dey, Business Standard, August 27, 2012.

[7] This segment borrows heavily from Joseph (2011).

was unable to effectively.

bring either of these medications to market, and Rheoscience was unable to successfully conduct human clinical studies for balaglitazone after 2005.[8]

- **Marketing Practices:** Pharmaceutical companies are not allowed to actively market or sell pharmaceutical products to consumers in India or most other countries of the world, except for over-the-counter medications. Instead, a doctor writes a prescription for a specific medication, which the patient purchases from a drugstore. Because of this phenomenon, doctors are effectively the consumer's agent, and pharmaceutical corporations target doctors in their marketing and advertising campaigns. A 2011 survey conducted in conjunction with OPPI and IMS Consulting Group found that most businesses prioritize their sales force when it comes to spending on promotions, with doctors being the main target audience (Udeshi and Bahri, 2011).

- **Distribution Channel:** In India, medicines are distributed through retail pharmacies to patients upon production of a prescription from a doctor for any other type of medicine other than the OTCs. However, the medicines would first need to be taken from their place of production (plants and pharmaceutical companies) to the place where they could be sold (retail pharmacies). As described in Jeffrey (2007), due to peculiarities in Indian tax system where inter-state sale of goods are taxed by Central Govt. but inter-state movement of goods are not, Indian pharmaceutical companies maintain Carrying (or Clearing) and Forwarding Agents (CFAs) to maintain stocks of their products in every state they intend to sell. This replaced an earlier arrangement prior to mid-nineties where companies themselves maintained depots and warehouses in each state. The CFA earns a percentage margin of total revenue.

Comparative Analysis of Global Competition Authorities

A comparison of competition authorities across different jurisdictions reveals varying approaches to regulating market competition. These authorities, tasked with safeguarding fair

[8] "Dr. Reddy"s Struggles for Homegrown Hits to Escape Rival Clones," Abhay Singh and Mrinalini Datta, December 5, 2006, Bloomberg.

competition, exhibit differences in their mandates, enforcement mechanisms, and regulatory frameworks. Understanding these divergences is crucial for comprehending the global landscape of competition law and its impact on markets and industries worldwide.

European Union - In the European Union (EU), home to several major innovating drug manufacturers, the European Commission oversees competition concerns within the pharmaceutical industry. Notably, branded manufacturers have been observed employing various strategies to delay the entry of generic drugs into the market. These strategies, including pay-for-delay settlements, evergreening, product-hopping, and abuse of data exclusivity, aim to prolong the exclusivity of branded drugs and hinder generic competition. While these tactics may prevent generic companies from capitalizing on data produced by originator companies, they can also result in delayed availability of generics following the expiration of patent exclusivity.

The European Commission has taken regulatory action against companies engaging in anticompetitive behaviour. For instance, fines have been imposed on companies like Sanofi Aventis for allegedly providing misleading information about generic versions of their blockbuster drugs, AstraZeneca for making misleading representations to patent offices, and Lundbeck for engaging in reverse payment settlements. Additionally, Schering-Plough faced penalties for offering excessive discounts to impede generic entry in France. In Italy, Pfizer was fined for activities deemed an abuse of dominant position aimed at blocking generic entry.

Regarding pricing policies, EU member states have varying approaches. While some countries implement free pricing for generic products, others operate under regulated pricing systems. Under regulated systems, pricing may be determined through external reference pricing or by setting a price ceiling relative to the original price of the branded drug. The reference pricing system, notably employed in Germany, establishes reimbursement levels for interchangeable medicines. Generally, countries with more liberal pricing systems tend to experience higher average medicine prices alongside increased generic penetration.

USA: The Hatch-Waxman Act of 1984 allows pharmacists to lawfully fill a prescription for a branded medication with its generic equivalent. It also combines patent protection with affordability through IPR protection, straightforward guidelines for the introduction of generic medicine once the patent protection expires, and simple regulations for patent protection.

Frequent FDA inspections of pharmaceutical facilities across the globe guarantee that the high-quality generic medications are interchangeable with branded medications once

patent protection ends. However, a strategy known as "pay-for-delay" might be used by originator and generic corporations to collude and undermine the brand-generic rivalry. A branded medication manufacturer that is losing its exclusivity may file a lawsuit against a generic competitor.

Usually, this leads to a settlement where the original manufacturer pays the generic competitor in exchange for their willingness to postpone the release of the generic product. Although the US Federal Trade Commission (FTC) has attempted to challenge these exclusion payments in several situations, their efforts have not always been successful. Nonetheless, the Supreme Court decided in 2013 that these settlements might go against antitrust laws (Dwyer, 2013). The FTC also pursues anti-competitive behaviour in the generic vs generic market, which is essential to price reduction. W.P. No. 2015-11-02 Page No. 23 Companies have occasionally signed contracts to provide the market with the same medication at various dosages, each of which focuses only on a distinct dosage (UNCTAD, 2015). Another issue is "product hopping," in which well-known companies release a new formulation as the patent is about to expire that has no appreciable therapeutic advantage over the previous formulation (for example, a capsule is introduced in place of a tablet), then remove all versions of the previous formulation (the tablet) from distribution to move doctors and patients to the new formulation prior to the release of generic versions. Because the chemical is now accessible from the branded manufacturer in the form of capsules, it can occasionally be difficult for pharmacists to replace it with the generic medication because the generic is only available in the outdated formulation, for which a doctor may not issue a prescription.

Other Emerging Markets: We take into account the other BRICS nations in other emerging markets. Different kinds of price restrictions are in place in nearly all of these nations. HIV/AIDS patients in South Africa have access to essential medications thanks to the practices of compulsory licensing (where a product of an innovative company can be produced by the generic producers upon payment of a royalty) and parallel importing (which can result in the importation of a drug under patent protection by the country's authorities from places where it carries a lower price). There are legal ways to encourage the replacement of generic medications for certain branded ones at the point of sale. Authorities also use price control tools

like single exit price (SEP) to stop manufacturers from giving hospitals excessive rebates. It has also handled issues involving mergers and acquisitions and accusations against firms for charging exorbitant prices for pharmaceuticals. The Russian Federation has exerted significant pricing control over pharmaceutical businesses; yet, it has been observed that this has led to the disappearance of numerous pharmaceuticals from pharmacies. Additionally, there is inefficiencies in the drug procurement process, which drives up the cost of medications.[9]

Brazil has had to cope with problems that are somewhat comparable to those in India in that there have been instances of retail competition being subverted. A pharmacy cartel that chose which days of the week would give discounts on was sanctioned by the Administrative Council for Economic Defence of Brazil (CADE). It was also among the first nations to employ compulsory licensing, having done so since 2007 (Smith, 2013). China has handled instances of supply chain vertical agreements. In order to produce the ingredients for hypertension medications known as "compound reserpine tablets," two pharmaceutical distribution companies, Shuntong and Huaxin, entered into agreements with suppliers of promethazine hydrochloride. These agreements forbade the suppliers from supplying to compound reserpine tablet manufacturers without authorization from the aforementioned pharmaceutical companies (UNCTAD, 2015).[10]

THE PHARMACEUTICAL INDUSTRY AND THE COMPETITION COMMISSION

This section examines the latest competition legislation implemented in India and the steps taken by the CCI to fulfill its mission regarding competition-related matters pertaining to the country's pharmaceutical industry.

After the Competition Act of 2002 was passed and further revised in 2007 and 2012, the Competition Commission of India was established in 2003. "...eliminate practices having adverse effect on competition, promote and sustain competition, protect interests of consumers and ensure freedom of trade in the markets of India" is one of the CCI's responsibilities.26 Furthermore, CCI is mandated to "administer competition advocacy, raise public awareness, and provide training on competition issues in addition to giving opinion on competition issues on a reference received from a statutory authority established under any law.

[9] (Federal Antimonopoly Service of Russia, 2013).

[10] http://www.chinalawinsight.com/2011/12/articles/corporate/antitrust-competition/ndrc-fined-two-pharmaceutical-companiesfor-abusive-conducts/.

The CCI consists of a Chairperson and between 2 to 6 full-time members at all time, who are appointed by the Central Govt. The CCI is served by a Director General (DG) who conducts "inquiry into contravention of any of the provisions of (the Competition) Act**.** While the strength of the personnel to assist the DG in his/her investigations is unknown, the Competition Act provides for engagement of experts and professionals as is deemed necessary to assist the Commission in the discharge of its functions.[11]

The Central or State governments, or any other statutory authorities, may submit matters to the CCI for investigation, or it may act "on its own motion" in response to information received by the agency from any interested or impacted parties. Following the receipt of information, the CCI has two options: it can conclude that there is no prima facie evidence and close the matter, or it might find that there is and order the DG to launch an inquiry. Following an investigation, the DG makes a recommendation about potential violations of the Competition Act. After receiving the DG's recommendations, the CCI requests any objections or recommendations from interested parties. Following review of all submissions, the CCI may decide to pursue additional investigation on its own or with assistance from the DG, or it may decide to close the case and render a decision. The Competition Commission of India (CCI) has the authority to stop a suspected anti-competitive behavior and to fine a party up to 10% of the average revenue for the three previous fiscal years if it decides that the party has violated the Competition Act. The CCI forbids anti-competitive behavior in three distinct areas: agreements, abuse of dominant position, and combinations, which are essentially mergers and acquisitions. The CCI has the authority to send parties involved in mergers and acquisitions show-cause notices, and it may disallow the M&A on grounds that it will adversely affect competition, or it may propose changes if it is satisfied that minor changes to the proposed merger will be acceptable. The CCI also has an appellate tribunal that aggrieved parties can approach in case of an adverse ruling by CCI.

Evaluation of Anti-Competitive Behavior: Identifying the Market and Calculating Market Power

Any study of the competitive landscape in any industry begins with the identification of the relevant market. The amount of market power held by the current enterprises must be addressed after the market has been defined. The Herfindahl-Hirschman Index is one of the most often

[11] The Competition Act, 2002

used instruments to assess market concentration or power (HHI). HHI may be simply defined as the total of the squares representing the market shares of different companies in the relevant market. HHI is ten thousand (square of hundred) if the market is monopolistic, meaning that one company controls all of the market.

Conversely, when the market approaches competitive levels, multiple firms have small market shares and the HHI approaches zero. Markets having an HHI of more than 2500 are deemed extremely concentrated by the US Department of Justice (DoJ), whereas markets with an HHI of between 1500 and 2500 are deemed moderately concentrated.[12]

Mergers that result in an increase in HHI beyond a typical threshold are typically discouraged because they enhance market concentration, and these thresholds depend on the pre-merger concentration in the market.[13]

The concept of an acceptable market is often far more nuanced when it comes to the pharmaceutical industry than it was in the case of Coke and Pepsi. Defining the market at the molecular level is an easy technique to determine the right market. As a result, every brand connected to that chemical enters the pertinent market. It is also reasonable to expect that consumers will switch to other brands of a given chemical if a brand's price increases by a tiny amount. As a result, HHI is just the total square of the market shares of all the brands that are offered for that chemical. But this method is probably going to define markets quite narrowly. This is due to two little differences that are specific to the pharmaceutical market.

The competition between the pharmaceutical companies is the first important issue in the marketplaces. General manufacturers and multinational companies (MNCs) are the innovators. Here, it's important to know whether customers see a chemical made by a generic producer as a ideal replacement for the chemical produced by the inventor. According to recent study, customers in India favor innovator brands (multinational firms) above native brands, while all other factors remain similar.[14]

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[12] http://www.justice.gov/atr/herfindahl-hirschman-index

[13] http://www.justice.gov/atr/horizontal-merger-guidelines-08192010#5c

[14] See Chatterjee, Kubo and Pingali (2015) in the case of oral anti-diabetic marke

Evaluation of Acquisition and Merger Activities by the CCI: Sun- Ranbaxy Merger Case

The Competition Commission of India (CCI) plays a crucial role in assessing merger and acquisition activities to ensure they do not result in anticompetitive outcomes in the market. One notable case that garnered attention was the merger between Sun Pharmaceuticals and Ranbaxy Laboratories.

The Sun-Ranbaxy merger case involved Sun Pharmaceuticals, one of India's leading pharmaceutical companies, acquiring Ranbaxy Laboratories, another major player in the Indian pharmaceutical industry. The merger was announced in April 2014 and completed in March 2015, making Sun Pharmaceuticals one of the largest pharmaceutical companies in India and globally.

The CCI closely scrutinized this merger to evaluate its potential impact on competition in the pharmaceutical market. The primary concerns revolved around the possibility of the merged entity gaining significant market power, which could lead to reduced competition, higher prices for consumers, and decreased innovation.

In its assessment, the CCI considered various factors, including market shares, product portfolios, geographic presence, and the likelihood of coordinated effects or unilateral conduct post-merger. Additionally, the CCI examined potential efficiencies that could arise from the merger, such as economies of scale and scope, improved research and development capabilities, and enhanced distribution networks.

After a thorough investigation and review process, the CCI approved the Sun-Ranbaxy merger, subject to certain conditions aimed at preserving competition in the pharmaceutical market. These conditions may include divestiture of overlapping businesses or product lines, licensing agreements, or other measures to mitigate anticompetitive concerns.

Overall, the CCI's assessment of the Sun-Ranbaxy merger case highlights the importance of competition authorities in safeguarding market competition and protecting consumer welfare in the pharmaceutical industry. By carefully analyzing merger and acquisition activities, the

CCI aims to balance the benefits of consolidation, such as efficiency and innovation, with the need to maintain a competitive marketplace.

Other places that the CCI should examine more closely.

We believe that although CCI has concentrated its efforts on investigating horizontal agreements (acquisitions and mergers, collusive practices under a trade body for margin fixation, and bid-rigging in public procurement cases), it has either not examined vertical agreements (agreements between trade associations at the wholesale and retail levels) or has not discovered any examples of such agreements. We believe that the CCI should take a closer look at these topics. It was particularly odd because, in the majority opinion of the CCI in the numerous AIOCD-related proceedings, OPPI and IDMA were the victims of anticompetitive behavior committed by AIOCD and its subsidiaries. It is interesting that, while being very strong lobbying groups on their own, the pharmaceutical companies never brought this up to the CCI or its predecessor during the long time that it had a Memorandum of Agreement, until they were officially included in the proceedings. Even if some of these have been mentioned in distinct orders by different CCI members, it doesn't seem like there is a suitable framework to handle such situations.

More significantly, the CCI (or any other regulatory agency, for that matter) has not sufficiently addressed the issue of the interaction between physicians and pharmaceutical firms that undermines competition to the disadvantage of consumers. (Bhattacharjea & Sindhwani, 2014) examine this matter in detail and conclude that this specific matter can be considered under either Section 4(1)(c) which relates to abuse of a dominant position by a person (i.e., the physician in this case) or Section 3(4)(a) of the Competition Act which deals with "tie-in" agreements. However, the pharmaceutical corporation may also be the main emphasis of these agreements rather than the doctor. According to the allegations, doctors write prescriptions that don't result in the least expensive option accessible because they are being pressured by pharmaceutical corporations to do so.

Competition Law and Intellectual Property

A patent is defined as "a set of exclusive rights granted to an inventor or assignee for a restricted amount of time by a sovereign state in exchange for detailed disclosure of an

invention." An innovation is a product or a method that addresses a particular technical issue.[15]

While copying an idea might be a relatively cheap endeavor, research & development is a dangerous endeavor with significant sunk costs. When competitors enter the market, prices must drop, which makes it harder to recoup sunk costs. It also suggests that invention does not have a "monetary reward." As a result, a patent is issued temporarily to allow an inventor to make a respectable profit; after that, competition is allowed to enter, resulting in profits for surplus consumers. As was previously said, India was forced to enact more lax intellectual property regulations after signing the Trade Related Intellectual Property Rights (TRIPS) agreement with the World Trade Organization (WTO) in 1995. Ten years later, in 2005, these laws went into effect since product patents, not simply process patents, were now permitted. There are, nevertheless, several assertions that Indian patent regulations are not as strict as those in the West.

In Hughes, Moore, and Snyder (2002), the trade-off between the two goals of enhancing innovation and raising consumer surplus is described. A fictitious situation helps clarify their point of view. Assume that a medication is created in Period 1 and is granted patent protection within that time. During such times, the company uses monopolistic pricing and earns a profit. The price drops to near marginal cost in Period 2 when the patent expires, and competition arises. This leads to a rise in consumer surplus and overall wellbeing. The inventor is sufficiently motivated to invest in research and development by the earnings from the first phase, increasing the likelihood of discovering additional medications within the same cycle. repeating oneself. In contrast, if Period 1 is defined by lenient patent regulations, price will be more in line with marginal cost during that period. This increases the excess of consumers in Period 1 alone.

But businesses won't spend money on R&D because there isn't any motivation for it. As a result, there are no new drugs coming onto the market starting in Period 2, which could negatively impact long-term surplus overall as well as future consumer surplus.[16]

[15] https://en.wikipedia.org/wiki/Patent

[16] For a comprehensive review of theoretical connection between innovation and intellectual property protection, see Rockett (2010).

CONCLUSION

In terms of production value and volume of consumption, the pharmaceutical sector in India is among the largest in the world. Furthermore, this business has garnered a lot of policy attention due to its crucial role. It is reasonable to infer that, in light of the constantly shifting legislative landscape, the enterprises modify their tactics, accordingly, affecting the very dynamics of the industry. For instance, the 1970s Indian Patent Act, which prohibited product patenting and only permitted process patenting, sparked the rise of the generic pharmaceutical sector, which today dominates the Indian market as well as global markets. Many studies on pharmaceutical markets have been published, although most of them are focused on the industrialized world. Even though India is a sizable pharmaceutical industry with untapped potential, very little study has been done to date to understand the characteristics of this market. As we wrap up this chapter, we go over some of the key issues that need to be addressed in this sector from the perspectives of public policy and research, with a focus on emerging countries like India.

The first problem that must be overcome is the trade-off between the availability of contemporary, innovative medicine and medication at a lower cost. The solution might be negotiated or differentiated price between the government and the inventor. Moreover, encouraging pharmaceutical firms to develop medications intended to address issues unique to India (by extending patents, providing funding for research and development, etc.) may be a step in the right direction. It may also be possible to reduce the cost of novel medications by incentivizing innovators to spend money on R&D and local production for Indian consumers in India.[17]

The price-quality conundrum is an additional matter that requires consideration. Large expenditures are necessary to provide the greatest quality, and this is frequently reflected in the cost. Prescription insurance is not available to most people in India; therefore this expensive item makes prescription drugs much less affordable. However, the absence of high-quality medications might result in additional, often confusing side effects from fake medications. Thus, is there a general solution to this dispute, or is it therapeutic domain- specific, it becomes an important query to address. This question becomes much more

[17] An interesting point to note is that India has several high-quality manufacturing units within the country. In fact, India has the largest number of Food and Drug Administration (FDA of the US Government) approved manufacturing units outside the US.`(http://www.business-standard.com/article/companies/drug-makers- should-learn-to-appreciate-fda-needs-better-say-experts114112000926_1.html)

relevant when considering costly and complex medications, such as biological pharmaceuticals.

These questions are not just important from the Indian standpoint alone; any developing country that aims at a robust pharmaceutical industry that aims at fostering competition, innovation and welfare needs to contemplate on these issues. Therefore, the policies adopted by the Indian authorities are being keenly watched in the international arena; this may provide India with an opportunity to exhibit thought leadership to countries like China, Russia, Brazil, etc. Competition Commission of India, the Indian Patent Office, Department of Health, and Department of Chemicals should work in addressing these questions and provide a roadmap for these issues.