# Pricing Behavior
# in the Indian Pharmaceutical Industry
# under the Threat of Entry

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**Abstract**

Medicines are expensive. A direct increase in competition can drive down prices, but can an indirect increase in competition have the same effect? In this study, the effect of an increase in the threat of entry (TOE) on prices is assessed. Although the relation between the TOE and prices is theoretically well-established, no clear empirical evidence is available on the effect of an increase in the TOE on prices. The effect of the TOE on prices is empirically hard to study, because the TOE is unobserved. This thesis aims to shed light on the relationship between the TOE and prices in two steps. First, a new measure for the TOE is constructed using multiple exogenous factors that influence the TOE. Second, the measure for the TOE is used to assess the influence on prices in the market of 84 combination medicines in India. The analysis indicates that an increase in the TOE is associated with a relative decrease of the price of a combination medicine.

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**Keywords:** Threat of entry, entry deterrence, limit pricing, pharmaceutical industry, medicine prices, combination medicines

## 1. Introduction[1]

Incumbents undertake strategic entry deterrence to deter potential entrants. According to Ellison & Ellison (2011), incumbents use advertising, investment in excess capacity, capital structure, contractual practices, learning-by-doing and long-run decision making as entry deterrents. Fundamentally, an incumbent provides itself an edge in strategic play if it makes a sunk investment (Dafny, 2005). On the other hand, economists described the concept of limit pricing, which means that the incumbent sets prices such that the net post-entry results for potential entrants is negative (Bain, 1956). No previous empirical work has yet been able to test this concept. Therefore, this thesis aims to test the relationship between the threat of entry (TOE) and pricing behavior of incumbents.

The social relevance relates to the fact that the Indian pharmaceutical industry accounts for approximately 65 percent of the production of medicines listed on the World Health Organisation (WHO) Prequalified List of Medicinal Products (World Health Organisation, 2015). However, retail prices in the pharmaceutical industry are high due to limited competition (Bhaskarabhatla, Chatterjee & Karreman, 2015). Moreover, a crucial challenge for the Indian government is to develop effective regulatory schemes for the pharmaceutical industry. A better understanding how the TOE affects the prices of medicines will, in turn, provide policy tools to develop a more effective regulatory framework, which can increase the accessibility of essential medicines in India (World Health Organisation, 2015).

So far, evidence of the effect of the TOE on prices is mainly theoretically established. Theory states that entry rates are positively correlated with industry profits. Industries with higher prices and profits face higher entry rates (Darius & Gaskins, 1970). Thus, a dominant firm with high current profits sacrifices on future profits. Consequently, incumbents can use price as an entry deterrent to protect future profits. The underlying mechanism is also known as limit pricing: incumbents set prices at such a level that potential entrants are deterred, and long-run profits maximized (Bain, 1956). The difference between the limit price and the competitive market outcome is influenced by entry barriers, which among others include advertising, economies of scale, capital intensity, customer loyalty, and predatory pricing.

[1] This study builds further on the work of Georgiev, Hullegien & Quist (2016). Parts of the introduction, literature review and hypotheses development are re-used.

Consequently, the response of incumbents to an increase in the TOE may depend on the level of entry barriers as well.

Some empirical literature on strategic entry deterrence in the pharmaceutical industry focused on the response of incumbents when actual entry occurred (Morton, 1998; Morton, 1999). Other research has focused on the TOE instead of actual entry. These studies used patent expiration as a discrete shift in the TOE and examined the effect on incumbent behavior prior to patent expiration and after patent expiration (Caves, Whinston & Hurwitz, 1991; Bergman & Rudholm, 2003; Ellison & Ellison, 2011). However, patent expiration is an expected event which incumbents can prepare for. Moreover, patent expiration can only be used for fairly new drugs. By far most drug are out of patent. One study was able to detect a discrete shift in the TOE, but didn't assess the impact on prices, but instead focussed on strategic investment in capacity (Cookson, 2015). No previous research exploited an unexpected shift in the TOE to identify the effect on pricing behavior.

This thesis attempts to fill this gap by providing a new identification strategy for the TOE and thereby the understanding of these dynamics. In this thesis, a discrete shift in the TOE is identified in terms of selling components of combination medicines. A combination medicine consists of two components. Incumbents in the combination market experience a discrete shift in the TOE when potential entrants start selling an extra component, but not the combination of the components. As a result, they might adapt their strategic pricing behavior to deter entry.

The research question is the following: what is the effect of the threat of entry on prices in the Indian pharmaceutical industry between May 2008 and September 2013? The objective is twofold. First, this thesis aims to identify a discrete shift in the TOE. Second, the effect of such a discrete shift in the TOE on medicine prices is assessed.

The empirical setup of this thesis is a two-stage regression. In the first stage, a selection of combination medicines is made that meet the following two requirements. First, the combination medicine must consist of exactly two components. Second, the combination and the individual molecules of the combination must be sold as independent medicines at some point in the observed time period. These requirements simplify the analysis, without losing generalizability. A dataset is constructed with all the firms that sell at least one independent medicine of any of these combinations and components. This dataset, with some additional control variables, is used to estimate the probability of a firm selling a

combination medicine in a given month. The sum of the predicted probabilities over all firms by combination medicine and month is used as one of the proxies of the TOE for a given combination in a given month. An earlier exploited proxy for the TOE is just the number of firms that sell both components of a given combination in a given month (Georgiev, Hullegien & Quist, 2016). An alternative proxy for the TOE is used in this thesis for a robustness check, which will be discussed in chapter 4 and 5. These three proxies of the TOE are used in the second stage of the instrumental variable regression.

In the second stage, the dataset contains information on all doses of each combination in all months sold by all companies in India between May 2008 and September 2013. The dependent variable of the second stage is the markup ratio of the combination over the components. This markup ratio is calculated as the price per dose divided by the weighted sum of the prices of the components. An increase in the markup ratio indicates that the combination medicine becomes relatively more expensive.

The relevance of studying such combination medicines clearly arises from a brief case study of human immunodeficiency virus (HIV) medicines. HIV is a virus that causes HIV infection: a disease that weakens the immune system. In a later stage of an HIV infection, patients are more likely to incur common infections like tuberculosis. This stage is also referred to as acquired immunodeficiency syndrome (AIDS). HIV/AIDS has an impact on a macroeconomic level in terms of economic growth, productivity and tax income (Greener, 2002). In 2013, an estimated 2.1 million people are currently living with HIV in India with a total of 130 thousand deaths estimated (Central Intelligence Agency, 2015).

Treatment of HIV infections primarily aims to prevent the infection from progressing to AIDS, because there is no cure for the disease. As a result, patients have to use medicines for the rest of their live when HIV is diagnosed. Therefore, medicine adherence is a crucial factor in HIV treatment. Effective HIV management medicines are approved by the FDA since 1987. The first class of medicines were nucleoside reverse transcriptase inhibitors (NRTI) antiretroviral (ARV) drugs, however patients still inevitably died from these therapies. Examples of these medicines are zidovudine, didanosine, zalcitabine, stavudine, lamivudine, and emtricitabine. These medicines reduce the replication of the virus in the patient's cells, but they don't fully suppress viral replication. Therefore, drug resistant strains can emerge. Zidovudine and emtricitabine are very similar, and therefore strains resistant to zidovudine are almost always resistant to emtricitabine as well. Lamivudine however is

known to reduce drug resistance when combined with zidovudine. Therefore, treatment with zidovudine is often combined with lamivudine.

HIV combination medicines are a more effective treatment for HIV. Especially since 1996, when proof was found that treatment with a combined medicine with indinavir, zidovudine, and lamivudine as compared to zidovudine and lamivudine alone significantly slows the progression of HIV-1 disease (Scott, Hammer, Squires et al, 1997). The three-drug therapy (also known as AIDS cocktails) rapidly showed a decline rate of 60% to 80% in terms of AIDS, death and hospitalization (Moore, Chaisson, 1999). All treatments of HIV are currently based on the combination medicine therapies. Six AIDS cocktails are being sold in the studied period in India, which are summarized in table 1. As the table shows, the vast majority of the monthly sales of HIV medicines comes from four combinations.

If a firm starts selling an extra component of a HIV combination medicine, the incumbents might respond by decreasing the price of a combination medicine to deter entry. In the available data, which contains information on all medicines sold in India between March 2007 and September 2013, 68 increases in the TOE are identified where a potential competitor starts selling an extra component of a combination medicine. Most of the incumbents don't change their price, on average the price increases 0.1% to 0.7%. This observation is unexpected. A possible explanation could be that other factors are driving the increase in prices, i.e. endogeneity problems exist. More precisely, pricing behavior of incumbents in the combination market may depend on pricing behavior in the components market, which in turn is influenced by the fact that entry occurred. Figure 1 graphically illustrates this type of endogeneity.

A more general approach in terms of sample selection, identification of the TOE and pricing behaviour of incumbents is required to identify what exactly is the relationship between incumbents prices and the TOE. Since only six three-drug HIV combination medicines are being sold in India in the observed period, a more general look at combination medicines in the Indian pharmaceutical industry is required. Selection of all combination medicines with exactly two components which are also sold as independent medicines enables to make a strong statistical claim about the effect of a discrete shift in the TOE on prices. The identification of the TOE is generalized such that also characteristics of the combination market are taken into account, i.e. whether the combination medicine market is a monopoly and how many varieties are available in the combination medicine market. Lastly,

the pricing behavior of incumbents in the combination market is generalized to also control for the price of components.

The contribution of this thesis is mainly academically. With regards to the effect of the TOE on prices, academic opinions mainly go in two directions. First, some say that incumbents do not respond to an increase in the TOE until they have to, i.e. until actual entry occurs. The opinion of the second group of academics is discussed more extensively in chapter two as well. They argue that incumbents respond to an increase in the TOE because it maximizes long-run profits. Empirical evidence so far has detected mainly evidence for the latter, although no evidence on the effect of an increase in the TOE on prices is provided. This thesis contributes in doing exactly that, thus finally resolving this debate.

The main result of the first stage of the analysis is that selling components of a combination significantly increases the probability of selling a combination. The second stage of the analysis shows mixed results. On the one hand, evidence is found that an increase in the TOE is associated with an increase in the price markup ratio. However, this result is not robust to a sample excluding the largest combination market, nor is it robust to alternative definitions of the TOE.

The remainder of this thesis is organized as follows: Chapter 2 provides an overview of the existing literature regarding strategic entry deterrence. Chapter 3 presents the hypotheses development. In chapter 4, the data and methodology are illustrated. Chapter 5 encompasses the main results of the empirical analysis, and robustness checks are given. Chapter 6 provides conclusions, discussion, limitations and suggestions for further research.

## 2. Literature Review

This chapter builds the theoretical foundation of this study. First, a general model of entry will be discussed, which defines entry to be depending on the cost of entry. The cost of entry can be influenced by strategic entry deterrence. Second, studies of strategic entry deterrence have also focussed on the pharmaceutical industry, which will be discussed as well. Lastly, the theoretical background of entry deterrence in monopoly markets will be discussed.

The theoretical and empirical foundation of entry is well-documented, and summarized by Geroski (1995). The relevant observations in his study will be summarized in the following sections. Empirical observations show that entry rates are highly correlated to exit rates, and the average survival rates of entrants is very low. On top of that, it takes

successful entrants a long time to reach the size of the average incumbent. In contrast to new entrants, diversification entry is more successful, but less common. A typical theoretical model of entry assumes that entry will be proportionally increasing with post-entry profit, which is defined as the net profit of entry. An example of such a model is

$$E = \beta\{\pi^e - F\} + \mu, \quad (1)$$

where $E$ is entry, $\pi^e$ is expected post-entry profits, $F$ is the cost of entry, and $\beta$ is an unknown parameter which measures the speed of entry in response to profitable opportunities. $F$ is the level of profits at which entry is cut off, also referred to as 'limit profits', which makes the model of equation 1 useful to estimate the height of entry barriers. $\mu$ stands for the error term. Profitability varies mostly between industries, and little over time, in contrast to variation in entry, which is mostly varying within industries, and hardly over time. As a consequence, to explain entry one needs time-varying features of markets that do not necessarily differ across industries. However, the time-variation of the usual proxies for $\pi^e$ and $F$ is low, rendering results that don't predict entry very well. While predicting entry requires time-varying features of markets, predicting profitability requires cross-sectional features of markets. The empirical results so far suggest only a modest effect of entry on prices-cost margins. In line with this, prices are not usually used by incumbents to deter entry. A more elaborate discussing about the response of incumbents in monopoly markets on entry will be provided in section 2.3. Before that, a more extensive discussion of entry deterrence will be provided in section 2.1 and section 2.2.

### *2.1 Strategic Entry Deterrence*

Several channels through which firms possibly can deter entry are assessed in previous literature. These channels consist of excess capacity, capital structure, advertising, contractual practices, learning-by-doing and long-run decision making (Ellison & Ellison, 2011). Dixit (1979; 1980) shows that investing in excess capacity can serve as an instrument for strategic entry deterrence for incumbents. It can increase the range where entry is effectively deterred at the expense of the range where entry is possible. Spence (1981) focuses on the aspect of learning by doing, and concludes that learning by doing can create barriers to entry, because it gives incumbents a cost advantage relative to potential entrants. Schmalensee (1983) provides evidence that incumbents increase advertising investment in response to entry. The underlying explanation is that by raising advertising expenditures, the incumbent prevents entrants raising awareness of customers. The fundamental insight from

the theory on strategic entry deterrence is that once an incumbent in a certain market makes a sunk investment, it credibly commits itself and, therefore, provides itself with an edge in strategic play (Dafny, 2005).

While the theoretical body of strategic entry deterrence motives is well-developed, the empirical evidence of strategic entry deterrence is rather sparse. The majority of previous literature focuses on market behavior after actual entry occurs rather than the threat of entry (TOE). Instead of identifying strategic motives for investments, most studies documented competitive responses to investment decisions. Lieberman (1987) presents evidence that incumbents in the chemical processing sector engage in pre-emptive action to deter entry. On the contrary, incumbents tend to lower their investments as a response to expansion by entrants. Furthermore, Chevalier (1995) conducts a study on local supermarket competition in terms of capital structure and product-market competition. The results show that product-market competition softens after the announcement of a leverage buyout, because it increases the expected future profits of potential entrants and it encourages entry. More recently, Cookson (2013) studies the effect of an increase in the TOE by looking at publicly announced plans of entry in the casino industry. As a response to this increase in the TOE, some incumbents invested in expanding capacity. The author concludes that these investments influence the entry decision: in some cases, entry is successfully deterred through strategic investments. The inferred mechanism is an increase in customer loyalty, which serves as a barrier to entry.

One example of entry deterrence through contractual practices is long-term price contracts between incumbents and customers (Aghion & Bolton, 1987). When a potential entrant shows up, the incumbent signs an exclusive contract with the customer(s), which forces the customer to pay a fee to the incumbent if the customer starts buying from the entrant. This results in market power for the incumbent, such that the incumbent can charge a price higher than the entrant, determined by the height of the fee. If the probability of entry is dependent on market size, and there is more than one customer in the market, incumbents can offer a contract to one customer, which, if accepted, poses a negative externality on other buyers, because the potential market share of the entrant is reduced, thus the probability of entry is lower. To clarify this mechanism, suppose that the monopolistic incumbent currently charges a price of 100, which extracts all the surplus out of every customer. Then, a potential entrant appears which could profitably charge 90. The incumbent writes a contract with at

least one incumbent to fix the price at 95, which also locks out the potential entrant by imposing a fee of 10 on switching. Therefore, the potential entrant faces a smaller market, which makes entry less profitable and less likely. Consequently, the incumbent can charge more to other customers as well to extract more (or even all) surplus out of every customer. The authors argue that this is an optimal strategy for both incumbents and customers. Effectively, long-term contracts can therefore serve as an entry deterrent.

### *2.2 Entry Deterrence in The Pharmaceutical Industry*

There are several papers which focus on strategic entry deterrence in the pharmaceutical industry in particular. These papers, however, focus on the TOE and the strategic response of incumbents in terms of patent expiration. Caves et al. (1991) conduct an exploratory analysis of competition patterns close to patent expiration for thirty medicines which lost their patent in the period of 1976 - 1987. They identify general patterns of competitive behavior in terms of prices, advertising expenditures and quantities sold. The authors present evidence that the price of branded medicines tend to increase when facing generic competition after patent expiration. On the contrary, the prices of generic medicines tend to fall in these circumstances. Furthermore, patent expiration tends to decrease the advertising expenditures for branded medicines significantly after entry. This effect tends to become stronger after more firms have entered the market. Lastly, the effect on the total quantity sold of branded medicines also declines just before a patent expires (Caves et al., 1991). Frank and Salkever (1997) provide similar results with respect to the prices of generic medicines and brand name medicines. Their results also suggest that after generic entry the price of brand name medicines rise, while on the other hand, the prices of generic medicines decline. Morton (1998) finds evidence that advertising expenditure does not serve as a method to deter generic entry after patent expiration. Moreover, Dafny (2005) finds evidence for strategic entry deterrence using hospital data. The author presents evidence that hospitals facing an increase in the TOE in an intermediate market increases their procedure volumes the most as compared to small and large markets. The evidence suggests that monopolist incumbents are most likely to engage in strategic entry deterrence.

More recently, Ellison and Ellison (2011) provide a new approach to test for strategic entry deterrence of pharmaceutical incumbents before patent expiration. They examine how firms set their prices and advertising expenditures, and how they change their presentation-level product mix in response to the direct TOE caused by patent expiration.

Evidence is found that incumbent firms in medium-sized markets behave strategically to deter entry. Their attempts to deter entry work through two mechanisms. The first is a decrease in advertising expenditures in medium-sized markets and the second is the increase in product presentation variety by incumbent firms prior to patent expiration. When a medicine is presented in multiple ways it is more expensive for an entrant to replicate the complete product line of the incumbent firm. As a consequence, the expected profits of entrants are reduced (Ellison & Ellison, 2011).

### *2.3 Entry deterrence in monopoly markets*

Studies of industrial organization extensively discuss the effect of entry and the TOE on pricing in monopoly and oligopoly markets. In monopoly or collusive oligopolistic markets, the optimal pricing strategy for incumbents is to set price such that it maximizes long-run profit.

In monopoly markets, pricing strategy is built upon the creation of artificial scarcity: output is restricted by the monopolist and buyers bid up prices. To block entry, the monopolist has to apply the concept of limit pricing: set prices such that the net post-entry results for potential entrants is negative. If barriers to entry are high, monopolists will not have to set a limit price much below monopoly equilibrium price. If barriers to entry are low, the market is contestable and effectively competitive, forcing the monopolist to set limit price such that it approaches the competitive outcome. This theory makes sense if potential entrants believe that incumbents will not change their pre-entry output levels post-entry, which also referred to as the Sylos Postulate (Geroski, 1995). In this theory, the monopolist decreases prices to deter entry when the TOE increases, and keeps all profits for itself, at the cost of profit margin. However, this assumes that potential entrants look at prices of incumbents to decide on entry. This assumption is contestable. The relevant price for potential entrants is the price they set or take after entry. The current price or profit in the industry need play no *direct* role in the entry decision. Indirectly, the current price or profit may indicate the character of the industry demand and the probable character of rival policy after entry. A lower price or moderate profit indicates more uncertainty about price elasticity of demand, and thus may influence the entry decision, deterring entry (Bain, 1949). This application of limit pricing is effective if the potential entrant believes the signal, which may be the case if the potential entrant has limited information (Seamans, 2010).

Empirical studies suggest similar results. Hurdle, Johnson, Joskow, Werden and Williams (1989) determine that market structure matters for entry deterrence in the airline industry. They impose that the effect of the TOE depends on individual characteristics of firms. In turn, these individual characteristics define the extent to which economies of scale and scope serve as an entry deterring factor. Moreover, evidence is found that entry is less likely when market concentration is high compared to less concentrated markets. The reason is that highly concentrated markets pose a greater effect on barriers on profit while in lower concentrated markets these barriers on profit are lower (Bain, 1956; Bain, 1968). Furthermore, evidence is found that firms in more concentrated markets earn more profits as compared to firms in less concentrated markets regardless of their efficiency (Molyneux & Forbes, 1995).

## 3. Hypotheses Development

This chapter links the theoretical framework to the research question, and in doing so, it structures the research as well as the empirical analysis. The first and second hypotheses will relate to the first stage of the empirical analysis, which aims to identify a discrete shift in the threat of entry (TOE). The other hypotheses relate to the second stage of the empirical analysis, which aim is to measure to the effect of a discrete shift in the TOE on prices.

As illustrated in Figure 1, this study exploit entry in the market of a component of a combination as a proxy for a discrete shift in the TOE. In the preceding research of Georgiev, Hullegien & Quist (2016) a similar approach to a change in the TOE has been applied to the Indian pharmaceutical industry. The probability of entry in a two-component combination market increases when a firm starts selling both components of the combination. This result was obtained from a survival analysis, which assesses entry rates.

A somewhat similar approach has been taken by Goolsbee and Syverson (2008), who study how the behavior of incumbents in the airline industry changes as a response to changes in the TOE. When the competitor starts serving a new airport it increases the threat of connecting that specific airport with other airports in its own network. They present evidence that the probability of entry rises when the airline starts operating in either one endpoint or both endpoint airports. Therefore it raises the TOE on all routes from this new airport, specifically on those routes where it serves both endpoints. The rationale behind the findings of Goolsbee and GHQ is the concept of minimum efficient scale as determinant c.q. deterrent of entry.

In the Indian pharmaceutical industry, firms can reach the minimum efficient scale by building an efficient distribution network, build customer loyalty and brand name, and establish close ties with regulatory authorities. These factors are not fully medicine-specific. Positive spillovers may arise from investments in one medicine to other medicines; for example Abbot brands Ibuprofen with the name BRUFEN, and Ibuprofen + Tizanidine with the name BRUFEN-MR. Clearly, the investments in brand name for BRUFEN also benefit BRUFEN-MR. Thus, if a firm starts selling and producing a component of a combination, the cost of entry for the combination medicine are reduced.

A considerable amount of molecules for medicines are patented. Patent holders sign licensing deals with Indian drug makers to speed delivery at low cost in greater volume (India Brand Equity Foundation, 2016). The Indian drug maker pays royalties to the patent holder. In 2012, the first compulsory license was granted with a six percent royalties rate of net sales (International Centre for Trade and Sustainable Development, 2012). Once a firm has signed a licensing agreement with a patent holder for a component of a combination, it is arguably easier to negotiate a license for a combination medicine. Thus, if a firm starts selling a component of a combination, the cost of entry for the combination medicine are reduced through brand name investment spillovers and potentially through easier and cheaper licensing. Therefore, the first hypothesis is:

*Hypothesis 1: The probability of selling a combination medicine is larger for firms that sell at least one component of a combination*

Similarly, all investments in a distribution network benefit all medicines to some extend, and thus reduces the cost of entry for a new medicine (Investopedia, 2015). Firms with a larger market share likely have a stronger developed distribution network. On top of that, firms with a larger market share likely have a more powerful lobby position with the regulatory authorities, and more capital to their disposal, which all reduces the cost of entry in a combination medicine. Therefore, firms with a larger market share in the Indian pharmaceutical industry have a greater probability of selling a combination medicine. The probability of selling a combination medicine is expected to be larger when a firm with a large market share sells at least one component of a combination medicine. In this context, market share means the firm's share of the total sales in the pharmaceutical industry. Therefore, the second hypotheses are:

*Hypothesis 2a: The probability of selling a combination medicine increases with a firm's market share*

*Hypothesis 2b: The probability of selling a combination medicine increases more with a firm's market share for firms that sell at least one component of a combination*

The increase in the TOE may affect the behaviour of the incumbents in the market of the combination. Incumbents may lower prices to reduce expected profits and deter potential entrants from actual entry (Bergman & Rudholm, 2003). In the airline industry there is evidence that incumbent firms drop fare prices when the TOE increases. On routes where an airline only threatens, incumbents drop fair prices by a significant amount. After actual entry, the prices fall even more. The results suggests that the TOE is an important determinant of price cuts in the industry. Most of the price effect of an entrant already takes place before actual entry occurs (Goolsbee & Syverson, 2008).

Such evidence is also presented for the pharmaceutical industry. In their study, Bergman and Rudholm (2003), examine what effect potential competition through patent expiration as well as actual competition have on the prices of medicines in the Swedish pharmaceutical industry. Their results suggest that potential entry causes the prices of medicines to fall. Moreover, the effect of actual entry accelerates this effect even more. These results are aligned with the results Ellison and Ellison (2011) have found. They show that price fall in markets where the probability of entry is the highest. Following the previous literature, the second hypothesis of this study is derived:

*Hypothesis 3: A discrete shift in the threat of entry is associated with a decrease in prices.*

Structural changes in the pharmaceutical industry have increased R&D investments, advertising expenditures, toughened price competition and increased industry concentration (Matraves, 1999; Malerba & Orsenigo, 2015). As discussed in section 2.3, incumbents in a monopoly market respond to an increase in the TOE. This suggests that even though the probability of entry is lower in monopoly markets, an increase in the TOE has a more negative effect on prices in more concentrated markets because the implications on profits are higher. In line with these observations the following hypothesis is developed:

*Hypothesis 4: A discrete shift in the threat of entry is associated with an additional negative effect on prices in a monopoly market, relative to less concentrated markets.*

## 4. Data & Methodology

The aim of this chapter is to describe the data and the plausibility of the research approach, analysis techniques, and identification strategy. First, it briefly describes the data, the data collection method and the identification strategy of the threat of entry (TOE). After that, a sample and variable description of the two stages of the analysis are provided. Lastly, the statistical methods and techniques are discussed.

### *4.1 Data description; Data collection method*

The Indian pharmaceutical market offers a very useful environment for studying the effect of the TOE. The available data gives information about many markets, including the markets of medicines that are combinations of two separately sold molecules. The data were collected by the All-India Organisation of Chemists and Druggists (AIOCD)'s own subsidiary marketing research firm, AIOCD Awacs Pvt. Ltd. The data were collected by monthly sample surveys of its members, the stockists and the retailers aligned with its association. This entails approximately 95 percent of all traders in India. The AIOCD data are disaggregated at the regional level. The primary sample consists of monthly sales and prices for more than 2.500 homogeneous medicine markets sold across the 23 Indian geographic regions from March 2007 until September 2013 (Bhaskarabhatla et al., 2015).

### *4.2 Identification strategy*

As discussed in the introduction, the TOE is an unobserved factor in the pricing decision of incumbents. In this study, three alternative proxies for the TOE are exploited. To simplify the explanation of these proxies, an analogy is made with the market for sticky notes. Suppose that the production of sticky notes requires two ingredients, glue and paper. Therefore, sticky notes can be called a combination product, consisting of two components: glue and paper. The combination-specific investment required to enter in the combination market is lower for firms that sell glue and paper independently, relative to firms that don't sell these components.

Now let's assume there are three firms in a market for office materials where only glue, paper and sticky notes are produced and sold in two periods. Firm A produces and sells sticky notes in both periods, and is therefore the incumbent in the combination market of

sticky notes. Firm B produces and sells in the first period both glue and paper, whilst in the second he starts to sell also sticky notes. Firm C produces and sells only glue in the first period, and in the second period it sells glue and paper. The TOE in this example arises from firm B and C. The threatened market is the combination market of sticky notes. Since firm B already sells both components, it is a small investment to also start selling the combination. Therefore, firm B threatens to enter the market of sticky notes. Firm C produces and sells only glue in the first period. This means that firm C's threat of entering the combination market is lower compared to firm B's threat. When firm C in period two starts producing and selling paper, there is a discrete shift in the TOE in the combination market.

The analogy can be translated back to the medicine market in India. The combination market is the market of medicines that consist of two molecules, which are also sold as independent drugs. The office materials market translates to the medicine market in India. The marginal combination-specific investments can be seen as sunk costs. Sunk costs influence the entry decision: higher sunk costs makes entry less profitable (Geroski, 1995). Several factors influence the sunk costs, including marketing and advertising, capital intensity, and minimum efficient scale.

As discussed in the argumentation of the first hypothesis, firms in the Indian pharmaceutical industry can reach the minimum efficient scale by building an efficient distribution network, build customer loyalty and brand name, and establish close ties with regulatory authorities. These factors are not fully medicine-specific. Positive spillovers may arise from investments in one medicine to other medicines. As argued in the building of the first hypothesis, if a firm starts selling and producing a component of a combination, the cost of entry for the combination medicine are reduced through brand name investment spillovers and potentially through easier and cheaper licensing.

Since the objective of this study is to assess the effect of the TOE on prices, no attempts will be made to estimate the level of the TOE in a certain market. This study will analyse changes in the TOE, and thus aims to produce a proxy for the TOE which is based on exogenous factors influencing the TOE. This approach is inspired by, but not the same as instrumental variable (IV) analysis. In IV, the instruments are required to be relevant and valid. A relevant instrument means that the instrument significantly influences the endogenous variable, conditional on the other covariates. Validity means that the instrument is uncorrelated with any other (unobserved) determinants of the dependent variable. In this

study, changes in the TOE are identified with an approach similar to IV. In the first stage, the probability of selling a combination is estimated based on two relevant and exogenous variables: whether a firm sells at least one component of the combination (D_COMP), and the logarithm of the market share (ln_MSHARE) of the firm in the Indian pharmaceutical industry. Just like in IV, the covariates of the second stage are included in the first stage model: whether the market is a monopoly market (D_MONOPOLY), and the number of varieties sold in the market (N_VARIETY). Including these covariates is important, because they influence both the entry decision and the pricing behavior of firms. By including them in both stages, the effect of these market characteristics on prices is extracted from the observed changes in the TOE.

The difference between IV and this study's approach needs further discussion. The main difference between IV and this study's approach is what happens with the results of the first stage. In IV, the predicted values of the first stage are used in the second stage. In this study, the predicted values are transformed to a proxy for the TOE. Recall that the first stage predicts one firm's probability of selling a combination. The TOE is a market characteristic, rather than a firm characteristic. Therefore, the predicted probabilities of entry for all firms by market are summed. The resulting proxy for the TOE can be defined as the sum of the predicted probabilities of entry, depending on two relevant and exogenous 'instruments' and the market characteristics that influence the entry decision and the pricing behavior.

The exogeneity of the two 'instruments' needs further discussion as well. Probably the most complex statement of this study is that the relevant exogenous variables are not instruments in the same definition as in IV, because they are not directly correlated with the actual unobserved TOE. A more intuitive example could clarify this. Suppose that an airline company is concerned about the fuel usage of their airplanes. They know that fuel consumption is correlated with the weight of the airplane. Therefore, the airline company wants to measure the total weight of the passengers of each plane. However, for some reason this data is not available, only the body mass index (BMI) and the height of each person is known. Therefore, the airline company tries to proxy the weight of each person with the instruments (height and BMI). Next, the estimated weights are summed to obtain the total weight of the airplane's passengers. The airline company can now identify the sign and significance of the effect of passenger weight on fuel consumption. However, the individual's height and BMI are not directly correlated to the aggregated weight of passengers in a plane.

The total weight of passengers in a plane is correlated with the country of origin, which is also correlated to fuel consumption. People from USA are in general more obese compared to people from Germany, and the USA airplane might also fly at higher average speed, thus consume more fuel. Therefore, in both stages of the analysis, the variable 'country of origin' needs to be included for a clear identification of the effect of passenger weight on fuel consumption.

The example can be translated to the Indian pharmaceutical industry and the TOE. Planes translate to combination markets, total passenger weight to TOE, BMI and person height to the 'instruments' whether a firm sells at least one component of a combination (D_COMP) and the logarithm of the market share (ln_MSHARE) of the firm in the total sales in the pharmaceutical industry, not just of the combination medicines, but also of all other medicines. Fuel consumption translates to pricing behavior of combination medicines, and country of origin is a plane characteristic that translates to combination market characteristics: the number of varieties offered in a market (ln_VARI), and whether the combination market is a monopoly (D_MONO). The exogeneity of D_COMP (or BMI in the airline example) is clear: no direct or indirect correlation exists between D_COMP and pricing behavior. ln_MSHARE is assumed to be sufficiently exogenous - no structural relation exists between the market share of an individual firm in the total Indian pharmaceutical industry, and the pricing behavior in a single combination market.

The exogeneity of ln_MSHARE is less obvious, but becomes clearer when looking at some scenarios. If a firm with a large market share is not selling a combination, it is clear that the only relation between this firm's market share and pricing behavior of incumbents channels through the TOE. If a firm with a large market share is selling a combination, endogeneity problems arise if this market share is related with pricing behavior. Two reasons will be provided why this potential problem is assumed to be limited. First, firms with a larger market share in the total Indian pharmaceutical industry not always need to have a larger market share in a single combination market. Second, firms with a larger committed customer base are known to be less likely to cut prices, more likely to increase advertising and more likely to increase product variety (Simon, 1997). Since this study controls for the effect of product variety, only the effect of firms with a larger committed customer base on prices are relevant. Combined with the first argument leaves relatively little room for endogeneity concerns. If any bias would arise, this would be upward bias. The estimated

TOE is expected to be higher if the market share is higher, and firms with a larger market share ask higher prices. Since the expected effect of the TOE on prices is negative, any bias in this variable would enforce the results.

### *4.3 Sample description first stage*

The sample of the first stage is constructed as follows. First, a list is constructed of combination medicines with exactly two components which are also sold as independent medicines. 131 of these combination exist in India, of which 99 are being sold in Mumbai. Mumbai is selected as region for analytical simplification: it is the largest region in India, and international firms are most likely to enter India through it. The sample of the first stage of the regression consists of almost two million observations in 25146 groups with each 79 observed time periods. Each group has the same structure: it lists for all 254 firms all the 99 combinations. The dependent variable is a dummy indicating whether the firm sells the given combination in the given month and equals one in 0,5% (9631) of the observations. The average market share of all firms in the Mumbai pharmaceutical industry is 0,4%. The largest observed market share is 30.4% for Ranbaxy Laboratories Ltd in September 2007, which is the only firm that in any given month has had a market share of more than 7% in the total pharmaceutical industry in Mumbai. Since January 2009, its market share dropped below 10% for the remainder of the observed time period. The number of varieties ranges from zero to 81. 90% of the observations have 5 or less varieties. The combination medicine markets are in 20% of the observations monopoly markets. Summary statistics are provided in table 3. As was discussed in chapter 2, one needs time-varying features to explain entry. All variables do vary over time to some extent, providing sufficient variation to explain entry.

### *4.4 Variable description first stage*

The first stage of the IV regression aims to produce the predicted values of the threat of entry (TOE) for each combination for each month. The predicted values of the TOE are obtained from the sum of the predicted probabilities of a firm to be selling a combination in a given month. The first stage is estimated using a logit regression in a strongly balanced panel. A dummy for the combination medicine is the dependent variable and has a value of one if a firm in a given month sells a given combination, zero otherwise. Three sufficiently exogenous instruments are implemented in this first stage of the IV regression. First, a dummy has a value of one if a company in a given month for a given combination sells at least one component of the combination, zero otherwise (D_COMP). Second, a continuous

variable is the logarithm of the market share of a firm in a given month in the pharmaceutical industry in Mumbai, and as such measures market power of the firm (ln_MSHARE). Third, an interaction between D_COMP and ln_MSHARE is included.

The control variables aim to control for competition effects and market differentiation effects. First, a dummy equals one if the combination market is characterised by a monopoly (MONO). A market is defined as monopoly if exactly one firm sells the given combination in a given month. Second, a count variable for the number of varieties is included (VARI). The number of varieties is defined as the number of unique Stock Keeping Units (SKUs) available in a given month for a given combination. Variety could also be defined as the number of unique doses or the number of unique brands for a given combination. The variation in these alternative definitions would be smaller, and the interpretation depends on the definition. The definition of unique doses interprets as the broadness of medicine applicability and the coverage of niche markets. It fails to give information on the intensity of competition within a dose. In contrast, the definition of unique brands interprets as the intensity of competition within a combination medicine, but it fails to detect coverage of niche markets and broadness of medicine applicability. The definition of variety as the number of unique SKUs captures all of these factors.

### *4.5 Sample description second stage*

The second stage sample is obtained by collecting sales data on the same 99 combination medicines as in the first stage, but unlike the first stage, all regions in India are included in the sample. This means that the value of the TOE in a certain month for a certain combination medicine is estimated in Mumbai, and applied to all regions to estimate the effect of the TOE on prices. Thus, the TOE does not vary between states, only over time and between combination medicines. After cleaning the data, 84 combination medicines remain with complete information on all variables. 15 combination were lost because no information was available about dose or number of doses in a package. As can be observed in table 4, in total 220.650 observations across 9420 groups are available. Each group is a unique set of monthly observations for a given SKU of a given firm in a given combination medicine in a given state. For each group is at least one month, on average 23,4 months, and a maximum of 65 months observed. India has 23 states. The number of observations per state ranges between 8146 to 10939. The number of observations also varies over combinations. In fact, almost 20% of the observations is for a single combination: cefixime + ofloxacin. The

average markup ratio (which will be discussed in the next section: variable description second stage) for this combination is 0.6, which is slightly lower than the overall average of 0.7. The estimated TOE is 36.1 in this combination, while the overall average is 7.3. The average value of the TOE in a sample excluding cefixime + ofloxacin is 0.11. To account for possible nonlinear effects, the TOE is logarithmically transformed. As discussed in chapter 2, one needs variation across industries to explain profit margins and, consequently, prices. All variables do vary between industries, providing sufficient variation to explain pricing behavior of incumbents in the combination medicine market.

### *4.6 Variable description second stage*

The second stage of the IV regression aims to relate the TOE to pricing behavior of incumbents in the combination market. The dependent variable is the markup ratio. This variable is calculated as the price of a SKU of a combination divided by the expected price of the SKU. Each SKU can have a different dose per pill, and a different number of pills per package. The expected price of the SKU in a given month is calculated as the sum of the doses of the components in the combination, multiplied by the average price per mg of the component in a given month. A markup ratio under one means that combinations are sold with a price discount over the components. If the markup ratio is close to one, there is no price discount or markup over the components. If the markup ratio is over one, the combination is sold with a price markup over the components.

The average price of a component may depend on the dose of the component. For example Ibuprofen is available over the counter for packages with tablets containing less than 600 mg. Ibuprofen tablets containing 600 mg are only available on prescription. The market of Ibuprofen 200 mg is therefore of an entirely different nature than the market of Ibuprofen 600 mg, as is the case for many medicines with higher doses. Medicines with higher doses are more likely to be sold on prescription or controlled in hospital environment. Table 2 summarizes the pricing of Ibuprofen. Clearly, increasing return to scale apply, as the price per milligram of Ibuprofen decreases in package size and dose.

Two main explanatory variables both proxy the TOE. The first measure is the number of firms that sell all components of a given combination in a given month. The second proxy for the TOE is the sum of the predicted values of the first stage of the regression. A third, alternative proxy for the TOE is used as robustness check. The TOE is the same for all SKUs

in a given month for a given combination. All three proxies of the TOE have a similar interpretation: a higher value of the TOE indicates that entry is more likely.

The variables for the markup ratio, TOE, and variety are logarithmically transformed to allow non-linearity. The control variables in the second stage are the same as in the first stage. Additionally, time, combination, dose, and firm fixed effects are added.

***4.7 Research techniques***

The analysis is performed in two stages. The first stage is a probit regression. Exogenous variables identify changes in the probability of selling a combination medicine. The second stage of the analysis is estimated using panel ordinary least squares regression. In this study, the TOE is assumed to be equal for all firms and all doses of a combination.

The equation for the first stage of the regression is the following:

$$Pr(d\_combinationx = 1 \mid E_{xzt}) = \Phi(\beta_E E_{xzt}) \quad (2)$$

Where *Pr* denotes probability, $d\_combination_x$ is a dummy that takes value 1 if a firm sells combination *x,* Φ is the cumulative distribution function of the standard normal distribution, and $\beta_E$ is the vector of coefficients of variables $E_{xzt}$. $E_{xzt}$ is the value of the explanatory variable for combination *x* for firm *z* in time period *t*, where *E* is D_MONO, ln_VARI, D_COMP and ln_MSHARE.

The equation for the second stage of the regression is the following:

$$Markup_{xyzt} = \beta_0 + \sum_{j=2}^{N} \beta_j X_{j,xyzt} + \beta_1 TOE_{xt} + \varepsilon_{xyzt} \quad (3)$$

Where $\beta_0$ is the constant, $\beta_j$ is the vector of the coefficients of control variables $X_j$, $X_{j,xyzt}$ denotes the value of control variable $X_j$ for combination *x* in dose *y* in period *t*, and $\varepsilon_{xyzt}$ is the error term. *N* is the number of variables, $Markup_{xyzt}$ is the markup ratio of combination *x* in dose *y* for firm *z* in period *t*. The markup ratio is calculated as follows:

$$Markup_{xyzt} = \frac{P_{xyzt}}{dose_1 \overline{Pcomp1_{ct}} + dose_2 \overline{Pcomp2_{ct}}} \quad (4)$$

where $P_{xyzt}$ stands for the price of a single dose of combination *x* in dose *y* charged by firm *z* in month *t*. *Dose1* stands for the dose of the first component in the combination, $\overline{Pcomp1_{ct}}$ stands for the average price of component *c* in month *t*, dose2 stands for the dose of the second component in the combination, and $\overline{Pcomp2_{ct}}$ stand for the average price of component *c* in month *t.*

In the equation for the second stage of the regression (Equation 3) $\beta_1$ stands for the coefficient for the explanatory variable $TOE_{xt}$. $TOE_{xt}$ is the value of the threat of entry for combination *x* in period *t*, which is constructed in three ways. First, the number of potential competitors is proxied by the number of firms that sell both components of combination *x*. This operationalization of the TOE is labeled in the regression tables and the next chapters as *ln_TOE_old.*

The second operationalization of $TOE_{xt}$ is as follows:

$$TOE_{xt} = \sum_{z=1}^{264} \widehat{Pr}(d\_combination_{xzt} = 1 \mid E_{xzt}) \qquad (5)$$

Where $\widehat{Pr}(d\_combination_{xzt} = 1 \mid E_{xzt})$ denotes the predicted probability of firm *z* selling a given combination *x* in a given month *t*, obtained from equation 2. The predicted probabilities are summed for firm *z* =1 to 264, as there are 264 firms in the dataset of the first stage. This operationalization of the TOE is labeled in the regression tables and the next chapters as *ln_TOE*.

The third operationalization of the TOE is based on equation 5 as well. It differs from the second operationalization in that equation 2 is modified. In equation 2, *E* is changed to contain the explanatory variables *d_MONO* and *ln_VARI*. Additionally, the variable D_COMP is split into two variables, D_COMP1 and D_COMP2, which will be discussed in the next chapter. This operationalization of the TOE is labeled in the regression tables and the next chapters as *ln_TOE_alternative.*

**5. Results**

This chapter discusses the results of the two stages of analysis, with some additional robustness checks. Model 1 in table 5 summarizes the results of the first stage regression. The first hypothesis can be confirmed: the coefficient of D_COMP is positive and statistically significant at 1% significance level. This means that firms are more likely to sell a combination if they sell at least one component of the combination. Hypothesis two can be confirmed as well - the probability of selling a combination increases in firm size, which can be observed from the positive and significant coefficient of ln_MSHARE. However, the interaction between ln_MSHARE and D_COMP is insignificant, which means there is no evidence that the probability of selling a combination medicine increases even more for firms with a larger market share which are selling at least one component of a combination. The coefficient of D_MONO is insignificant as well, so there is no evidence that the probability

of selling a combination medicine is higher in more concentrated markets. The coefficient of VARI is positive and significant at 1% significance level. This means that the probability of selling a combination is larger in markets where many varieties are being sold.

Model 2 in table 6 summarizes the results of the second stage regressions. Three proxies for the TOE are exploited: ln_TOE is the resulting proxy of the first stage of the regression, ln_TOE_old is the number of firms selling both components of a combination in a given month, and ln_TOE_alternative is a results from a different estimation of the first stage of the analysis, discussed more extensively in chapter 4. The three proxies are centralized by subtracting the mean and dividing by the standard deviation. This makes comparing the coefficients more convenient. The coefficient of the new measure of the TOE in this study (ln_TOE) is positive and significant. Hypothesis three can therefore not be confirmed, since a negative sign of the coefficient was expected. The coefficient of D_MONO is negative and significant. This means that the markup ratio in monopoly markets is on average 0.5 percent lower, which is surprising. The coefficient of ln_VARI is negative and significant as well. In markets with a one percent higher variety, the markup ratio is 3.3 percent lower. The R-squared score within groups is 0.13, between groups 0.04, and overall 0.02.

In model 3, the coefficient of the first proxy of the TOE, which is the number of firms selling both components of a combination (*ln_TOE_old*) is negative and significant. The coefficient of D_MONO is negative and significant. This means that the markup ratio in monopoly markets is on average 0.41% lower. The coefficient of ln_VARI is negative and significant. This means that on average a one percent increase in the variety is associated with a 3.14% decrease in markup ratio. The R-squared score within groups is 0.13, between groups 0.01, and overall 0.00. This model seems to explain less variation, as compared to the model with the predicted TOE (model 2).

Model 4 tests the effect of an increase in the TOE on the markup ratio in monopoly markets. Estimating the coefficient of the interaction with the estimated TOE is not possible due to the inherent low values of the estimated TOE in monopoly markets. The estimated TOE is directly associated with the probability of entry, which is inherently low because there is only one incumbent out of 264 firms. Therefore, the number of firms that sell both components of a combination (*ln_TOE_old*) is used in the interaction with *D_MONO*. Model 4 shows that the coefficient of *ln_TOE_old* is negative and significant, while the coefficient of the interaction is positive and significant, and the coefficient of *D_MONO* is negative and

significant. This indicates that incumbents in monopoly markets are less likely to lower prices in response to an increase in the TOE, relative to incumbents in other markets. Hypothesis 4 can therefore be confirmed.

As discussed in the sample description, substantial differences exist between predicted TOE in the largest combination medicine cefixime + ofloxacin and all other combination medicines. These substantially different levels of predicted TOE call for a robustness check excluding cefixime + ofloxacin, as it will provide more information about the disturbing effect of this apparent skewness in the sample. The robustness check in model 5 shows that the coefficient of ln_TOE is negative and significant if cefixime + ofloxacin is excluded from the regression. In this sample, 176,591 observations in 7778 groups remain. In this situation, a one percent increase in the TOE is associated with a 14% decrease in markup ratio. The coefficients of D_MONO and ln_VARI are negative and significant, indicating that the markup ratio is lower in monopoly markets and decreases in variety. In this model, the R-squared score within groups is 0.27, between groups 0.07 and overall 0.04. Of all models discussed so far, are these scores the highest and therefore indicate that most variation is explained by the model. The same robustness check is performed with the old variable for the TOE. In model 6, the coefficient of ln_TOE_old is positive and significant. A one percent increase in this measure for the TOE is on average associated with a 1.97% increase in markup ratio. The coefficients of D_MONO and ln_VARI are negative and significant, indicating that the markup ratio is lower in monopoly markets and decreases in variety. The R-squared score within groups is 0.18, between groups 0.08, and overall 0.06.

So far, some market characteristics are assumed to affect both the entry decision and pricing behavior of incumbents in the combination medicine market. Therefore, they were included as control variables in the first stage of the analysis. However, as can be observed in the correlation table (table 7) the resulting predicted TOE is correlated with these market characteristics. This could be problematic, because high correlations between covariates may influence the coefficients of the correlated variables in the second stage, which complicates interpretation. If excluding the control variables in the first stage of the analysis renders the same results, the conclusions can be more robust to this criticism. Additionally, the variable D_COMP will be split into two variables: D_COMP1 and D_COMP2. Reflecting on the example of fuel consumption of an airplane, as discussed in the identification strategy (chapter 4.2), the impact of BMI on weight might systematically differ from the impact of

height on weight. Similarly, first-mentioned components of a combination could have a systematically different impact on the probability of selling a combination and on prices. An additional benefit of splitting D_COMP into D_COMP1 and D_COMP2 is the cumulative effect of the coefficients on the estimated probability of selling a combination medicine if a firm sells both components of a combination, i.e. splitting allows the probability of selling a combination medicine to depend on whether a firm sells both components of a combination.

Therefore, model 7 summarizes the results in the alternative model for estimating the probability of selling a combination medicine. The coefficient of ln_TOE_alternative is negative and significant.. Surprisingly, the coefficient of d_MONO is negative and significant. The coefficient of ln_VARI is negative and significant as well. The R-squared score within groups is 0.14, between groups 0.02, and overall 0.01.

## 6. Conclusion & Discussion

This chapter discusses the findings of the previous chapters, provides a conclusion, discusses the limitations and makes some suggestions for further research.

### *6.1 Conclusions*

This thesis identifies a change in the TOE when a firm starts selling at least one component of a combination medicine, and additionally if the market share of that firm is large. The analysis is performed in two stages, much like, but not the same as instrumental variable analysis. The first stage identifies changes in the TOE. The second stage estimates the effect of the identified changes in the TOE on prices. The main finding of the first stage is a confirmation that whether a firm sells at least one component of a combination is a strong and presumably sufficiently exogenous instrument for the TOE. This result is based on a sample of medicines sold in Mumbai. Dummies were generated for each firm whether it sells a the combination medicines and its components for every month, regardless of whether the firm in any month has sold the combination medicines. This is possible because the original data contained data for all firms in all months for all medicines. Obviously, of the 264 firms in the sample, only a few actually sell a specific combination medicine of the 99 analyzed combination medicines. As a result, the estimated probabilities of selling combination medicines are rather low. This will have consequences in the second stage of the analysis.

The analysis in the second stage aims to identify the sign and significance of the effect of an increase in the TOE on prices. As discussed in the introduction and illustrated in Figure 1, the price of a combination medicine may be depending on the prices of its

components as well, thus the dependent variable is the markup ratio: the ratio of the price per dose of combination over the sum of the average price of the doses of the components. Changes in the TOE are identified using two proxies. The first proxy is (log of) the number of firms that sell both components of a combination medicine in a given month. The second proxy is constructed as the sum of the predicted probabilities of selling a combination medicine in a given month obtained from the first stage regression. While the first proxy produces negative and significant results, the second proxy results are positive and significant. Surprisingly, the markup ratio in monopoly markets is found to be lower relative to other market structures, according to the regression results. The effect of an increase in the TOE on the markup ratio is less negative in monopoly markets. Interpretation of these results can only be done after discussing the robustness checks.

The first robustness checks excludes cefixime + ofloxacin because 20% of the observations fall in this group. As a result, the coefficient changes sign: an increase in the TOE is now associated with a decrease in markup ratio. The second robustness check changes the estimation of the TOE. Since the control variables ln_MSHARE and D_MONO are included in both stages of the analysis, high correlations between the estimated proxy for the TOE and the control variables may influence the sign of the proxy, and complicate interpretation. The alternative estimation of the TOE excludes the control variables, and D_AB is replaced with two dummies, D_COMP1 and D_COMP2 to accommodate for eventual systematic differences between the relative impact of the first- and second mentioned component of a combination medicine. D_AB is defined as a dummy equal to one if a firm sells at least one component (of the two components) of a given combination medicine in a certain month. D_COMP1 and D_COMP2 are defined as dummies equal to one if a firm sells the first mentioned component respectively the second mentioned component of a given combination in a certain month. In this setup, the effect of the TOE on the markup ratio is found to be negative, thus indicating that indeed collinearity was problematic in the initial estimation of the TOE.

A clear conclusion arises from these mixed findings. Indeed, identifying changes in the TOE by analyzing changes in whether firms sell components of a combination medicine is possible, could not be proven invalid, and produces relevant results. An increase in the TOE is associated with a decrease in markup ratio. A decrease in the markup ratio can be driven by a decrease in the price of the combination medicine, or an increase in the price of

(one or both of) the components of the combination medicine. Both changes effectively should be interpreted as a decrease in the relative price of the combination. Thus, the historic theoretical debate about the effect of an increase in the TOE on prices can now empirically be resolved. An increase in the TOE is associated with a decrease in relative prices. Reflecting on the discussion of AIDS cocktails, the empirical evidence found in this thesis contrasts the seemingly positive relation between an increase in the TOE and pricing behavior. Although the evidence is significant, the size of the effect seems to be rather small. Regulatory authorities can be assured that decreasing entry barriers is associated with a decrease in prices. This study also shows that increasing the entry rates in components markets does increase the TOE, but apparently not by much because the estimated probabilities of selling a combination medicine were very low.

### *6.2 Limitations*

This study finds evidence of a negative effect of the TOE on prices that is robust to alternative explanations, effectively exploiting exogenous factors that influence the TOE but not prices. It is important to consider that this result is not robust to a sample excluding the largest combination market, nor is it robust to alternative definitions of the TOE . However, several limitations need to be discussed. The major limitation is the operationalization of the markup ratio, which is defined as the price of a dose of the combination medicine, divided by its expected price, which in turn is defined as the sum of the expected prices of the components. The expected price of a component is defined as the strength in terms of milligrams, multiplied by the average price per milligram of the component. The limitation is that the average price per milligram of the component depends on the tablet or capsule it is sold in. Medicines with higher doses are more likely to be sold on prescription or controlled in hospital environment. The price per milligram of these medicines is most likely systematically lower compared over-the-counter drugs as well due to economies of scale, which introduces a systematic bias in the markup ratio.

A similar limitation applies to the estimation of the TOE. A firm is defined to produce a medicine if it produces any dose of the medicine. However, medicines with higher doses might be more expensive to produce as they are applied in more critique circumstances for the patients. Therefore, the accepted standard error in the production of high dose medicines might be lower. Therefore, the probability of entry is much lower for high-dose medicines relative to low-dose medicines. Combining this limitation with the one in the previous

paragraph results in a potential bias in the estimation. The probability of selling a high-dose medicine is lower, and prices are higher. No attempts have been made to control for this potential bias. A solution would be to estimate the probability of selling a combination medicine based on its dose. The bias most likely causes little problems for the inference made in this study, because in most cases a wide variety of doses is sold, averaging out the bias.

Related to these issues is the possibility that entrants in the components market systematically ask higher prices as compared to the incumbents in the components market. If this would be the case, entry in the components market would be associated with an increase in the components prices, thus a decrease in the markup ratio. Such an alternative explanation does not sound very plausible, because the entrants in the components market would most likely not be able to charge higher prices and reach the minimum efficient scale. However, the average price of a component is not weighted by market share. Obtaining the weighted average price of a component would improve the operationalization.

The value of the TOE is estimated in Mumbai. The effect of the TOE is estimated in all India. However, an increase in the TOE in Mumbai most likely doesn't influence prices in other regions to the same extent as in Mumbai. On top of that, the size of the change in the TOE is likely to be different across regions. Nonetheless, the assumption that the TOE in one region can be influenced by the TOE in another region seems legit. As a robustness check, one could estimate the TOE in every region independently, and compare results. Most likely little variation will be observed with regards to the effect of an increase in the TOE on prices, leaving the main result of this study unscratched.

### *6.3 Further research*

As this study managed to identify the sign and significance of the effect of an increase in the TOE, future research could aim to identify the size of the effect. The setup of this study is not appropriate for such a question, because a proxy that has relatively low correlation with the unobserved variable increases measurement error. This study only partly identified the level of the TOE in a market, and primarily identified changes in the TOE and their respective effect on prices. Future research could aim to obtain data about the perceived TOE. So: how do incumbents perceive the TOE in a certain market?

Future research with a similar type of dataset could use survival analysis to predict hazard rates, which interpret as entry rates. The benefit of such an approach is that it focus on entry, rather than the probability of selling a combination medicine. This would especially be

beneficial in unbalanced datasets as the one used in this study, where 20% of the observations are clustered in a single combination medicine. Only new potential entrants are contributing to the estimated TOE in survival analysis.

Further specification of the effect of the TOE on prices in the pharmaceutical industry could focus on the difference between generic and branded medicines, as these are known to behave completely different, as discussed in the introduction and literature review. In branded medicines, a similar study most likely finds the used instruments a stronger predictor of the probability of selling a combination medicine, as was identified in the first stage of the analysis. The reason for this hypothesis is that entry barriers are higher in branded medicine markets. For generic medicines, the effect of an increase in the TOE is likely smaller, because competition is more intense in these markets.

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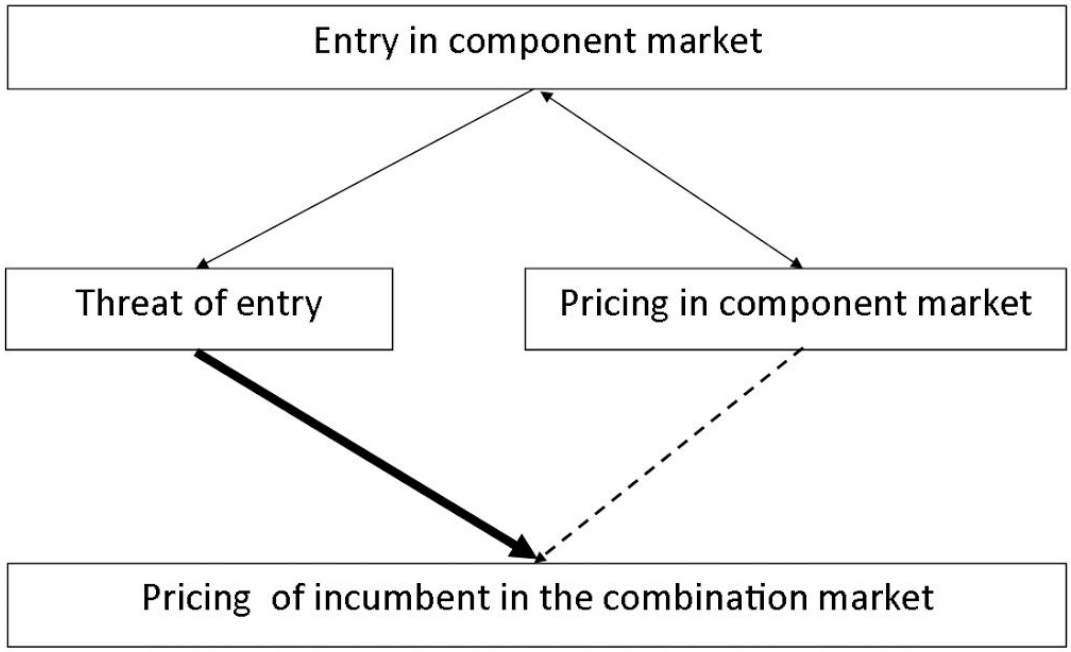
## Appendix 1: Tables and Figures

**Table 1:** Summary of the AIDS cocktails and the average sales value per month in million rupee sold in India.

| Combination name | Average sales per month |
|---|---|
| EMTRICITABINE + TENOFOVIR + EFAVIRENZ | 5,50 mln rupee |
| LAMIVUDINE + STAVUDINE + NEVIRAPINE | 3,24 mln rupee |
| LAMIVUDINE + TENOFOVIR + EFAVIRENZ | 2,18 mln rupee |
| LAMIVUDINE + ZIDAVUDINE + EFAVIRENZ | 0,07 mln rupee |
| LAMIVUDINE + ZIDAVUDINE + NEVIRAPINE | 2,30 mln rupee |
| STAVUDINE + LAMIVUDINE + EFAVIRENZ | 0,35 mln rupee |

**Figure 1:** Illustration of the effect of entry on pricing behavior




Note: This figure illustrates the effect of entry in the market for a component of a combination on pricing behavior of the incumbent in the combination market. This thesis aims to identify the effect of the threat of entry (TOE) on pricing behavior of incumbents in the combination market, illustrated in the figure by the bold arrow. As the TOE is unobserved, entry in component markets is used as a proxy for the TOE. However, entry in component markets may influence pricing behavior of incumbents in the combination market also trough pricing in the market which the entrant entered, illustrated in the figure by the dashed arrow.

**Table 2:** The price of Ibuprofen in rupee per Stock Keeping Unit (SKU), per tablet, and normalized per 1000 MG for all doses and packages for sale in India.

| Number of tablets in SKU | MG per tablet 200 | 400 | 600 |
|---|---|---|---|
| | **Price per SKU** | | |
| 10 | 3.5 | 6.9 | 7.6 |
| 15 | 4.6 | 7.5 | 10.8 |
| 100 | 18.1 | 31.0 | n.a. |
| | **Price per Tablet** | | |
| 10 | 0.35 | 0.69 | 0.76 |
| 15 | 0.31 | 0.50 | 0.72 |
| 100 | 0.18 | 0.31 | n.a. |
| | **Price per 1000 MG** | | |
| 10 | 1.76 | 1.73 | 1.27 |
| 15 | 1.53 | 1.24 | 1.20 |
| 100 | 0.91 | 0.78 | n.a. |

**Table 3:** Summary statistics for the sample of the first stage of the analysis

| Variable | category | mean | sd | min | max | obs | |
|---|---|---|---|---|---|---|---|
| d_COMBI | overall | 0,00 | 0,07 | 0 | 1 | N = | 2.335.872 |
| | between | | 0,05 | 0 | 0,96 | n = | 29.568 |
| | within | | 0,05 | -0,96 | 0,99 | T-bar = | 79 |
| ln_MSHARE | overall | 0,00 | 0,01 | 0 | 0,30 | N = | 2.335.872 |
| | between | | 0,01 | 0 | 0,08 | n = | 29.568 |
| | within | | 0,00 | -0,04 | 0,23 | T-bar = | 79 |
| Interaction | overall | 0,00 | 0,01 | 0 | 0,30 | N = | 2.335.872 |
| | between | | 0,01 | 0 | 0,08 | n = | 29.568 |
| | within | | 0,00 | -0,08 | 0,28 | T-bar = | 79 |
| d_COMP | overall | 0,12 | 0,32 | 0 | 1 | N = | 2.335.872 |
| | between | | 0,29 | 0 | 1 | n = | 29.568 |
| | within | | 0,14 | -0,87 | 1,11 | T-bar = | 79 |
| d_MONO | overall | 0,22 | 0,41 | 0 | 1 | N = | 2.335.872 |
| | between | | 0,20 | 0 | 0,91 | n = | 29.568 |
| | within | | 0,36 | -0,69 | 1,21 | T-bar = | 79 |
| ln_VARI | overall | 0,59 | 0,79 | 0 | 4,41 | N = | 2.335.872 |
| | between | | 0,45 | 0,01 | 2,29 | n = | 29.568 |
| | within | | 0,65 | -1,70 | 3,62 | T-bar = | 79 |
| d_COMP1 | overall | 0,07 | 0,25 | 0 | 1 | N = | 2.335.872 |
| | between | | 0,23 | 0 | 1 | n = | 29.568 |
| | within | | 0,11 | -0,92 | 1,05 | T-bar = | 79 |
| d_COMP2 | overall | 0,07 | 0,25 | 0 | 1 | N = | 2.335.872 |
| | between | | 0,23 | 0 | 1 | n = | 29.568 |
| | within | | 0,11 | -0,92 | 1,06 | T-bar = | 79 |

Note: This table reports summary statistics for the variables of the first stage of the analysis.

**Table 4:** Summary statistics for the sample of the second stage of the analysis

| Variable | category | mean | sd | min | max | obs | |
|---|---|---|---|---|---|---|---|
| ln_markup | overall | 0,52 | 0,16 | 0 | 2,22 | N = | 220650 |
| | between | | 0,16 | 0,012 | 2,21 | n = | 9420 |
| | within | | 0,05 | 0,162 | 1,57 | T-bar = | 23,42 |
| ln_TOE | overall | 0,68 | 1,41 | 0 | 3,95 | N = | 220650 |
| | between | | 1,29 | 0 | 3,93 | n = | 9420 |
| | within | | 0,55 | -3,01 | 4,36 | T-bar = | 23,42 |
| ln_TOE_old | overall | 3,35 | 0,61 | 0,69 | 4,47 | N = | 220650 |
| | between | | 0,52 | 0,69 | 4,44 | n = | 9420 |
| | within | | 0,15 | 2,62 | 4,26 | T-bar = | 23,42 |
| ln_TOE_alternative | overall | 1.90e-08 | 1.71e-08 | 4.92e-13 | 5.64e-08 | N = | 220650 |
| | between | | 1.67e-08 | 6.11e-13 | 5.63e-08 | n = | 9420 |
| | within | | 1.90e-09 | 5.73e-09 | 3.39e-08 | T-bar = | 23,42 |
| d_MONO | overall | 0,12 | 0,33 | 0 | 1 | N = | 220650 |
| | between | | 0,25 | 0 | 1 | n = | 9420 |
| | within | | 0,19 | -0,85 | 1,11 | T-bar = | 23,42 |
| ln_VARI | overall | 2,49 | 1,16 | 0 | 4,41 | N = | 220650 |
| | between | | 1,11 | 0 | 4,41 | n = | 9420 |
| | within | | 0,35 | -0,92 | 4,59 | T-bar = | 23,42 |

Note: This table reports the summary statistics for the variables of the second stage of the analysis.

**Table 5:** Regression results for the first stage of the analysis

| | (1) |
|---|---|
| **ln_MSHARE** | **58.83*** |
| | (19.79) |
| **D_COMP** | **3.43*** |
| | (1.31) |
| **Interaction** | **-44.43** |
| | (36.28) |
| D_MONO | 1.09 |
| | (0.97) |
| ln_VARI | 3.73* |
| | (0.30) |
| Constant | -19.36* |
| | (1.55) |
| Observations | 2,335,872 |
| Number of groups | 25146 |

Note: This table reports the results of the Probit regression for 99 combination medicines in India. The dependent variable is a dummy equal to one for firms that sell a combination medicine in a given month. Model 1 tests the effect of three (sufficiently exogenous) variables on the probability of entry. Robust standard errors in parentheses. * $p<0.01$, ¥ $p<0.05$, + $p<0.1$

**Table 6:** Regression results for the second stage of the analysis

| | (2) | (3) | (4) | (5) | (6) | (7) |
|---|---|---|---|---|---|---|
| **ln_TOE** | **0.01*** | | | **-0.14*** | | |
| | (0.00) | | | (0.00) | | |
| d_MONO | -0.01* | -0.00* | -0.03* | -0.01* | -0.01* | -0.00* |
| | (0.00) | (0.00) | (0.00) | (0.00) | (0.00) | (0.00) |
| ln_VARI | -0.03* | -0.03* | -0.03* | -0.03* | -0.04* | -0.02* |
| | (0.00) | (0.00) | (0.00) | (0.00) | (0.00) | (0.00) |
| **ln_TOE_old** | | **-0.02*** | **-0.02*** | | **0.02*** | |
| | | (0.00) | (0.00) | | (0.00) | |
| **Interaction** | | | **0.01*** | | | |
| | | | (0.00) | | | |
| **ln_TOE_alternative** | | | | | | **-0.03*** |
| | | | | | | (0.00) |
| Constant | 0.55* | 0.55* | 0.55* | 0.48* | 0.55* | 0.52* |
| | (0.01) | (0.01) | (0.01) | (0.01) | (0.02) | (0.01) |
| Observations | 220,650 | 220,650 | 220,650 | 176,591 | 176,591 | 220,650 |
| R-squared | 0.13 | 0.13 | 0.13 | 0.27 | 0.19 | 0.13 |
| Number of groups | 9,420 | 9,420 | 9,420 | 7,778 | 7,778 | 9,420 |
| Month FE | YES | YES | YES | YES | YES | YES |
| Firm FE | YES | YES | YES | YES | YES | YES |
| Combination FE | YES | YES | YES | YES | YES | YES |
| Dose FE | YES | YES | YES | YES | YES | YES |

Note: This table reports the results of the OLS regression analysis for 84 combination medicines in India. The dependent variable is the natural logarithm of the markup ratio, defined as the price of a combination medicine over the expected price, which in turn is defined as the sum of the average price per component multiplied by the dose of the components. Model 2 tests the effect of the TOE, measured as the sum of the predicted probabilities of entry in the first stage of the analysis presented in table 5. Model 3 tests the effect of the TOE exploiting the old measure of the TOE, defined as the number of firms selling both components of a combination medicine. Model 4 tests the effect of the TOE in monopoly markets, where the interaction is defined as ln_TOE_old interacted with d_MONO. Model 5 and 6 exclude the combination medicine cefixime + ofloxacin, and replicates model 2 and 3 in this smaller sample. Model 7 tests the effect of the TOE when defined only with exogenous 'instruments'. Robust standard errors in parentheses. * $p<0.01$, ¥ $p<0.05$, + $p<0.1$

**Table 7:** Correlation matrix for the second stage of the analysis

| | 1 | 2 | 3 | 4 | 5 | 6 |
|---|---|---|---|---|---|---|
| 1. ln_markup | 1.00 | | | | | |
| 2. ln_TOE | -0.13 | 1.00 | | | | |
| 3. ln_TOE_old | 0.23 | 0.13 | 1.00 | | | |
| 4. ln_TOE_alternative | -0.04 | 0.54 | 0.43 | 1.00 | | |
| 5. d_MONO | -0.01 | -0.18 | -0.04 | -0.27 | 1.00 | |
| 6. ln_VARI | -0.11 | 0.75 | 0.17 | 0.60 | -0.53 | 1.00 |

Note: Only the lower half of the symmetric matrix is reported.