Profiting from innovation through cross-border market co-creation and co-opetition: the case of global pharmaceuticals *

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Abstract

We study the impact of the new intellectual property (IP) regime, as shaped by international agreements such as the Trade-Related-Aspects-of-IP-Rights (TRIPS), on the competitive positions of emerging country firms and advanced country multinational enterprises (AMNEs). Drawing on ideas from the IP, international business, and strategic management literatures, we formalize the market co-creation perspective and extend it to the emerging country - AMNE context. Using the pharmaceutical industry as our focus, we show that market co-creation-based co-opetition is preferable to both emerging and advanced country firms when the former can leverage their firm- and country-specific advantages and complementary assets to co-create new market space, even as they compete for value capture. We further show that co-opetition is fostered when the bargaining power of the AMNE (afforded through trade agreements) is counterbalanced by actions of emerging country firms and a robust IP law interpretation and enforcement by the host country’s courts.

Keywords: cross-border co-opetition, market co-creation, complementary assets, intellectual property rights, MNEs, pharmaceuticals.
Introduction

In its August 8th 2015 leader, the Economist magazine questioned the widely held view that strong intellectual property (IP) protection fosters innovation and trade opportunities across the world and facilitates technology transfer from advanced to emerging countries. This is a controversial conclusion, given that a series of international trade agreements over the last two decades has strengthened the IP regime worldwide. Such agreements include the Trade-Related Aspects of Intellectual Property Rights (TRIPS), the subsequent Anti-Counterfeiting Trade Agreement (ACTA), and the more recent Trans-Pacific Partnership (TPP) one.

The resultant IP regime impacts on competitive dynamics, particularly in the pharmaceutical industry, where patents confer robust protection and are seen as essential for the commercialization of innovations (James et al., 2013). In the past, “emerging” country pharmaceutical firms (EPFs) relied extensively on reverse engineering of patented compounds to produce copycat, “generic” versions of branded drugs at a fraction of the costs faced by the original innovators (McKinsey Report, 2013). However, the TRIPS (and subsequent trade agreements) have placed restrictions on the space for the production of generic drugs (Shaffer and Brenner, 2009). As a result, EPFs have to fundamentally rethink their (in-house reverse engineering and low-cost manufacturing-based) business model (Angeli, 2013).

In this paper, we propose that under the new IP regime, direct competition between EPFs and advanced country multinational enterprises (AMNEs) may not be the most desirable outcome for either group of firms. Because emerging and advanced country firms tend to possess dissimilar strategic assets, some form of cooperation that leverages both sets of assets can prove preferable to both parties. There are various types of cooperation, ranging from price collusion through strategic alliances and joint ventures to ‘clusters’ (Pitelis, 2012). For instance, in 2009, Dr. Reddy’s Labs, an Indian EPF, established a
partnership with GlaxoSmithKline to develop and market drugs in fast growing therapeutic segments (e.g. cardiovascular, diabetes, oncology, gastroenterology) across several emerging markets, in which it possessed better knowledge. Products were manufactured by Dr. Reddy’s and were licensed and supplied to GlaxoSmithKline in various emerging markets, while revenues shared between the two partners. Despite their cooperation, in other products and markets the two firms continued to compete.

With this study, we explore the theoretical logic and arguments behind such arrangements, by focusing on how EPFs and AMNEs can benefit from combining cooperation with competition to create new market space, instead of engaging in purely rivalrous behavior, or in types of cooperative behavior that aim to take advantage of extant market space (like pay to go away\(^1\)). We first draw on developments in strategic management scholarship, centred on the coincidence of competition and cooperation (i.e. co-opetition) (Brandenburger and Stuart, 1996; Lado et al., 1997), as well as the role of hard to transfer complementary assets in the IP and international business (IB) scholarship (Hennart, 2009; Teece, 1986, 2006). We then draw on the idea of market co-creation developed by Pitelis and Teece (2009). This states that markets are co-created by entrepreneurial actions that involve and leverage the comparative advantages and actions of a number of actors in business ecosystems, including customers, suppliers and sometimes competitors too, and hence that market space in existing markets or totally new markets are the outcome of joint actions, that help foster value creation. Each party then tries to appropriate the value created through competitive value capture strategies.

In the above context, we propose that AMNEs and EPFs can benefit by co-creating new market space by developing and leveraging their respective comparative advantages. We suggest that in so doing, both types of firms can benefit, while providing - at the same

\(^1\) This is a non-market extending cooperative arrangement, whereby an AMNE pays an aspiring producer of generics to prevent the introduction of a cheaper generic version of a drug (Kessel, 2014).
time - access to key drugs to the consumers of emerging economies, hence also fostering wider social benefits.

Method-wise, acknowledging the central role of strategic interdependence between EPFs and AMNEs, and in line with an established stream of strategic management scholarship (e.g. Casadesus-Masanell and Zhu, 2013; MacDonald and Ryall, 2004), we adopt a cooperative game theoretic approach and model to derive formally the conditions under which market co-creation and co-opetition can ensue. Formalization adds value in that it helps generalize empirical observations which may be otherwise interesting but potentially non-applicable in different contexts. In addition, it helps highlight the (sometimes restrictive) assumptions under which a particular verbal statement has more general applicability. While less common in some management areas, formalization is seen as *sine qua non* in the IP and management science literature. In this sense, we cross-fertilize management and IP scholarship and add value by being first to formalize the idea of market co-creation. The model itself, frames the IP conflict between “typical” AMNEs and EPFs, by considering a case where an AMNE introduces a new patent-protected drug. The EPF can either attempt to capture the value created by the AMNE by producing a “generic” version of this drug, or it can invest in developing complementary assets and capabilities that would allow it to create new market space and add value to the AMNE’s drug. In turn, the AMNE can either cooperate with the EPF or engage in a legal conflict that can be resolved by a court within the parameters imposed by TRIPS.

Our model shows that the advantage of market co-creation-based co-opetition depends on the ability of EPFs to create new market space for the drug in question. The resultant additional value created can provide a bargaining space, within which both parties can find a cooperative solution. The model also shows that the possibility of a cooperative outcome can be fostered when the bargaining power of the AMNE (afforded through TRIPS-
type agreements) can be counterbalanced by actions of emerging country firms and a robust IP law interpretation and enforcement by the host country’s courts. For instance, when an emerging country’s courts can credibly threaten to block an AMNE’s attempt to adopt aggressive “strategic” patenting (e.g. overly extending the scope and duration of otherwise legitimate IP rights) (see Hall et al., 2012), the bargaining power of value-adding EPFs is strengthened and cooperation becomes preferable to both parties compared to rivalry.

Our study contributes to the IP, IB, and strategic management (in particular co-opetition and market-co-creation) literatures by formalizing through game theoretic modelling the market co-creation perspective (Pitelis and Teece, 2009), first published in this journal, and by extending it to the emerging country - multinational enterprise context. In this way, we challenge the conventional wisdom vis a vis the terms of engagement of emerging country firms and MNEs in the important global pharmaceutical sector. We show that market co-creation-based co-opetition is preferable to both parties when the former can leverage their firm- and country-specific advantages and complementary assets to co-create new market space, even if they then still compete for value capture of the enhanced co-created market space and value. Second, we identify what emerging country firms and courts of law can do to make a co-opetitive outcome the preferred solution for all the parties involved.

Contextual Background

The Emergence of a New IP Regime

Until the 1990s, drug innovation and the global trade of pharmaceutical innovation were mostly concentrated in advanced economies that provided IP protection. Emerging countries, which lacked strong IP protection, did not engage as much in innovation or trade. Besides potential resource constraints, this is in part because in weak IP regimes, drug firms may not have strong incentives to carry out necessary clinical trials to meet local
requirements, obtain regulatory approval, educate healthcare providers, or even to build marketing and distribution infrastructure to sell their drugs (Cockburn et al., 2014).

Operating in a weak IP regime, EPFs had become the main producers of “generic” drugs. Generic drugs are meant to contain the same active ingredients as the original drug and are normally introduced when the statutory period of patent protection expires. However, a number of EPFs copied and rebranded medicines before patent expiration. Their business model involved capitalizing on opportunities to reverse engineer patented compounds by AMNEs and produce them at lower cost through low input cost and process innovation (Angeli, 2013).

The regulatory environment changed considerably with the introduction of the TRIPS agreement, which is administered by the World Trade Organization (WTO) and was negotiated in 1994. The agreement’s main aim was to standardize IP regulation among signatory members, by specifying minimum standards for IP protection. The reason behind such an international harmonization was the belief that by lifting country restrictions on IP, all innovators would face similar standards of protection across countries. Under TRIPS, copying and rebranding products that are under patent protection is an illegal practice that constitutes infringement. This new IP regime’s purported aim was to foster trade of advanced technological products, encourage R&D investment, and allow emerging countries to benefit from advances made by advanced economy firms (Dinopoulos and Segerstrom, 2010; Diwan and Rodrik, 1991; Meschi, 2005).

After a ten-year transition period to enable IP law convergence, the TRIPS agreement came into force in emerging countries around the mid-2000s. Exception for medical emergencies, where emerging country governments could be allowed to circumvent IP rights for better access to essential medicines (see the Doha Declaration on the TRIPS Agreement and Public Health in 2001), TRIPS gave rise to a new stronger IP regime for emerging
country firms. However, the anticipated benefits from TRIPS have not always materialized. For instance, Kyle and McGahan (2009) found that the introduction of patents in emerging countries has not been followed by an increase in R&D efforts on diseases that primarily affect the world’s poor. This is a serious issue that goes well beyond corporate profitability, to which our paper aims to contribute.

Even though several emerging countries have adopted TRIPS-compatible laws, the de facto drug-related IP protection varies as a result of serious domestic health concerns, business interests and pressure groups, such as local NGOs (Jandhyala, 2015). The ACTA, originally signed by eight countries in 2011, came as an addition to the fight against infringed and pirated products. Even though ACTA was met with considerable opposition, and its implementation remains under doubt, its relevant provisions are often reincarnated as parts of “TRIPS-plus” bilateral agreements. The view of ACTA is that the calculation of damages should be based upon the assumption that each copyright infringement equates to a lost sale\(^2\). The more recent TPP agreement - as leaked versions of preliminary drafts indicate - borrows heavily from ACTA (DePillis, 2013).

The IP harmonization (pursuant the TRIPS-type agreements) has constituted a major institutional change in most emerging country economies (Battilana et al., 2009; Scott, 2001) and has impacted upon on the competitive dynamics between AMNEs and EPFs. This is particularly the case with the pharmaceutical industry, where patents confer robust protection and are seen as essential for the commercialization of innovations (James et al., 2013). We, thus, focus on the key emergent change of cooperative agreements between AMNEs and EPFs below.

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\(^2\) Of notable concern is ACTA’s article 9.1 that focuses on damages. It requires courts to consider any legitimate measure of value the product’s producer submits. This may include, inter alia, lost profits, the value of the infringed goods, or services measured by the market price, or the suggested retail price. Furthermore, ACTA’s article 9.2 requires that compensation should at a minimum reflect the profits derived from infringement.
Cross-border Cooperation in the Indian Pharmaceutical Industry

The new IP regime has engendered considerable scope for cooperative arrangements. Indeed, in the global pharmaceutical sector, in particular, we are already witnessing numerous agreements between AMNEs and EPFs.

Using the Indian pharmaceutical industry as an indicative group of EPFs and an important international player\(^3\), data from Thomson’s SDC database of strategic alliances (a key form of cooperation) show that such deals have increased dramatically. We were able to identify a total of 317 deals during the period 1995-2012, of which 275 (87\%) involved at least one foreign partner, having increased from 8 in 1995 to 21 in 2012.\(^4\) Foreign partners involve leading AMNEs, such as Pfizer Inc, GlaxoSmithKline PLC, Bayer AG, Merck & Co Inc, Boots Healthcare International, Novartis AG, and Bristol-Myers Squibb Co. Cross-border alliances cover primarily manufacturing (40\%) and marketing (34\%) agreements, but they also involve joint R&D (28\%) or licensing agreements (9\%). The bulk of this alliance activity by Indian firms is concentrated on a handful of large and publicly-traded companies, with firm size ranging from 2,800 to 16,617 employees. The list of the seven companies with the highest alliance activity (more than ten alliances during the period 1995-2012) is presented in Table 1. However, about 99.9\% of the 25,471 Indian pharmaceutical firms are small (with less than 100 employees according to Euromonitor (2015)), and they do not appear to be active in cross-border alliances with AMNEs. Such alliances are one way for market space to be extended through the combined efforts of the alliance partners each leveraging their comparative advantages and capabilities. A more general case, however, is

\(^3\) In recent years, the Indian pharmaceutical market has grown with an annual compound rate of 13.2\% reaching a total market value of $11.9 billion in 2013 (MarketLine, 2014). In 2014, India was amongst the five largest producers of active pharmaceutical ingredients in the world (Euromonitor, 2015).

\(^4\) Thomson SDC Platinum provides information on strategic alliances using SEC filings and their international counterparts, trade publications, wires and news sources. The information collected is thus bound to be biased in favour of larger and international deals that have attracted more extensive business press coverage.
an arms-length, market-co-creation approach that does not require formal agreements and hierarchical structures and leverages the combined benefits of cooperation and competition (i.e. co-opetition).

Next, we explore further the concepts of market co-creation and co-opetition in the context of the pharmaceutical sector.

[Insert Table 1 about here]

**Co-opetition Through Market Co-creation**

In most global industries, like the pharmaceutical one, firms across the world possess highly asymmetrical capabilities. On the one hand, AMNEs tend to possess formally protected drugs primarily developed for their home markets. On the other hand, emerging countries tend to be dominated by relatively smaller pharmaceutical firms that have (or had at least until recently) limited research and development (R&D), technological and other capabilities (Lanjouw and Schankerman, 2004). In such an arena, one typically observed AMNEs adopting go-alone strategies to capture value from consumers in emerging markets.

However, this approach underplayed the possibility for EPFs to develop and leverage firm- and country-specific advantages to create additional market space for AMNEs’ drugs (Barney, 1991; Cantwell, 1995). This can be done in three main ways. First, EPFs can leverage their comparative cost advantages to reduce input and labour costs and improve cost efficiency (Anand and Kale, 2006; Porter, 1980, 1985). For instance, they can benefit from their low-cost manufacturing, carry out standardized R&D activities (such as clinical trials), or leverage so called frugal (cost-efficient), innovation in order to reach ‘bottom of the pyramid’-based consumers (the poorer consumers who are often outside the radar of AMNEs as they are typically not in a position to pay for full price branded drugs). Second, they can direct their R&D efforts to differentiate AMNEs’ existing drugs in order to tailor them to local needs. For example, “incremental” product innovation by EPFs can
differentiate existing drugs in a way that renders them more efficacious for indigenous patients or help cure local diseases (see, for example, Kyle and McGahan, 2009). Alternatively, EPFs can direct their R&D to make drugs resistant to local climate conditions. This is particularly important as several drugs are inappropriate for emerging country climates, as they lose their potency if left out of the refrigerator (this is frequently the case in many emerging country pharmacies). Third, EPFs can offer AMNEs access to various specialized complementary assets which are needed for the successful commercialization of drugs (Li and Xie, 2011; Manning, 2008; Manning et al., 2008; Teece 1986, 2006). Such complementary assets may involve EPF’s scientific human capital, control over local distribution systems, deeper market knowledge, relationships with local hospitals and doctors, and, more generally, their key ecosystem partners.

Market co-creation is closely linked to that of market extension discussed in marketing (Kim and Mauborgne, 2005) and industrial organization (Tirole, 1988) literatures, through, for example, advertising and other promotion activities. It goes further, however, in that - while market extension is normally limited to existing products and markets - market co-creation also includes the creation of entirely new markets through the complementary efforts of business ecosystem participants such as suppliers, customers and even competitors, as opposed to the actions of individual firms. Pitelis and Teece (2010) for example charter the co-creation of the fast food market in Russia, first through the efforts and strategies of a company (McDonald’s) and then through the emerging and largely created and co-created participating ecosystem, the new competitors and the local government. In the context of our paper, while the two terms can be synonymous, they differ in cases where the efforts of EPFs lead to novel drugs that can be applied to entirely new markets. These new markets might emerge by accessing new consumer segments (such as bottom-of-the-pyramid) or establishing and exploiting new uses of existing chemical entities (a common phenomenon
in the drug industry where findings of accidental benefits and applications of drugs originally aimed for a different use).

An example of market co-creation through market extension is Ranbaxy’s improved version of an antibiotic (Ciprofloxacin) that was originally developed by Bayer. Bayer, a German multinational chemical and pharmaceutical company, introduced Ciprofloxacin, an antibiotic used to treat a number of bacterial infections, in 1991. Ciprofloxacin sales reached a peak of about 2 billion euros in 2001. Ranbaxy is the branded drugs business of the Indian firm Sun Pharma. It is best known for using its product development expertise (using its Novel Drug Delivery Systems (NDDS)) to generate new and improved formulations to previously available chemical entities (Sun Pharma website). In 1999, Ranbaxy managed to enhance the capacity of Bayer’s ciprofloxacin, reducing the two daily doses down to one. Ranbaxy’s innovation - which improved patient convenience, enhanced compliance and lowered treatment costs - was translated to additional patients choosing ciprofloxacin. Instead of a conflict, this led Bayer to pay Ranbaxy $65 million to use this improved product globally.

Under a market-co-creation perspective, EPFs may find it beneficial to change their typical business models which are centred on reverse engineering, towards business models that involve developing and leveraging a broader set of skills and capabilities. By leveraging their comparative firm- and country-specific advantages in a way that enables them to help co-create new market space, EPFs can render themselves attractive partners for AMNEs. When successfully implemented, the coexistence of cooperation (to increase the market space) and competition (to capture part of the additional value co-created), can help benefit both parties (Brandenburger and Stuart, 1996; Lado et al., 1997), while affording access to the drugs to more emerging market consumers.

The Model
We adopt a cooperative game theoretic model in the tradition of strategy and IP/industrial organization literatures which acknowledges the central role of strategic interdependence between industry rivals (Brandenburger and Nalebuff, 1997; Tirole, 1988) and we build on an established approach in management scholarship (Adner and Zemsky, 2006; Brandenburger and Stuart, 1996; Camerer, 1991; Casadesus-Masanell and Zhu, 2013; MacDonald and Ryall, 2004) that employs cooperative game theory.

Our game theoretic approach enables us to study the impact of a major institutional change on individual firm actions and industry responses. Institutional shocks break the status quo and can sometimes be met by organizational inertia that can lead to slow evolutionary changes by the various players affected (Battilana et al., 2009; Scott, 2001). This is particularly true in the case of the pharmaceutical industry, where there have been several changes in the IP regime over the last two decades, the implications of which have not been fully factored in competitive dynamics. Thus, one cannot easily track empirically the impact of gradual IP regime changes on EPFs strategies (like when measuring the causal effect of a discrete treatment event). Our game theoretic modelling allows us to overcome the empirical limitations imposed by limited data availability and poor data quality when weak proxies are used. By simplifying reality and focusing on the key parameters of interest, we explore the impact of IP regime change on individual firm competitive actions and responses by foreign industry rivals under different plausible scenarios.

**The Companies’ Dilemma**

We develop a game to study the strategic interaction between an innovating and an imitating pharmaceutical firm that are headquartered in different countries. By studying the equilibrium outcomes of the game, we try to identify the conditions under which the two firms will choose to compete against each other, or to cooperate. We focus on two types of firms, an AMNE (for example Bayer), which is the original drug developer, and an EPF (e.g.
Cipla), which is assumed to be an imitator. The AMNE holds a patent protected drug (e.g. Bayer’s Nexavar), which is initially marketed and sold in its domestic market, and wants to start selling its drug to EPF’s host country market. However, the EPF has started offering its own drug version to its home market. In this context, we explore conditions under which the two players may be inclined to choose cooperation, over conflict through litigation.\footnote{\textit{Conflict} is the outcome when the EPF and the AMNE fail to reach some form of cooperative agreement and the AMNE pursues litigation for patent infringement by the EPF, where litigation takes place in the EPF’s home country.}

We first employ a “prisoner’s dilemma” type strategy matrix that models the prospective benefits from cooperation \textit{vis a vis} conflict (see Figure 1). In this matrix both parties choose their actions (we will henceforth refer to their actions within the game as “strategies”) simultaneously, offering a static version of the interaction between the two companies. This static environment helps clarify the main idea by illustrating the necessary conditions for a solution, and allows for comparisons, paving the way for the dynamic analysis that we undertake later.

[Insert Figure 1 about here]

The AMNE faces two possible strategies: (a) It can compete directly with the EPF and litigate (filing the case in a local court) in order to try to claim back what it considers as being the proceeds from its IP (the legal battles fought by Bayer for ownership of Nexavar respectively fall in this type of strategy). (b) The AMNE can adopt some form of cooperation with the EPF and do not resort to litigation. The EPF is also faced with two strategies: (a) It can compete directly with the AMNE by copying the drug and infringing on the AMNE’s IP rights (Cipla’s generic version of Nexavar is a case example). (b) It can invest to expand the market size for AMNE’s drug by employing (a combination of) the three ways outlined above (pp.9-10). Accordingly, the strategy matrix of Figure 1 is divided into four cells.
We describe the strategies that each cell captures and outline their payoffs of the two players. Starting with cell D, the EPF copies the branded drug and the AMNE responds by filing an infringement suit (typical case of legal conflict). Cell C differs from cell D inasmuch as the EPF invests in enhancing the drug’s market and value. However, the AMNE considers that the “new” drug does not significantly differ from the original drug and it files an infringement suit. Cell B, represents a situation, where infringement can lead to a cooperative solution if the AMNE agrees to forego some of its profits, which are correspondingly captured by the EPF. The AMNE may turn a blind eye if the corresponding forgone profits are too “small” to justify the costs of litigation. Otherwise, such an erosion of profits can lead to lower R&D incentives or delays in the launching of new drugs.

Compared with cells B, C and D, which capture a conflict or jointly suboptimal outcomes, cell A represents a situation where the EPF invests resources to create new market space, increasing the market value of the drug. In this context, the AMNE finds cooperation with the EPF as more profitable. We, thus, explore whether cell A is a viable outcome, and if so, what conditions will allow the two parties to jointly select cell A, rather than cells B, C and D.

While cell A provides a necessary condition for cooperation between the two parties, it is not always a sufficient one. We explore the factors that can forge cooperation that involves market extension. We claim that the likelihood of such a cooperative outcome is strengthened when the EPF’s investments lead to a new version of the AMNE’s drug which is “significantly” different from the original drug and when the emerging country’s courts can identify and reward “value adding” EPFs by restricting the potential payoffs of AMNEs in the case of litigation.

The above claim on its own is not enough to lead to a solution. If, for example, EPFs perceive the AMNEs IP rights as highly contestable in court, they may see no reason to seek
a cooperative solution. The TRIPS agreement precludes such a one-sided treatment of foreign patentees. Specifically, as long as the country is a TRIPS signatory, its courts must abide by the international standards set out by TRIPS in adjudicating such cases. As a result, the local court is bounded in the way it interprets the relevant patentability requirements, such as the requirement of “innovativeness” and “novelty”. Thereby, even though legal norms can vary across countries, there is a bounded space for overtly biased court decisions. Against this backdrop, we claim that, in equilibrium, EPFs will be more likely to make the necessary investments in enhancing an AMNE’s drug market value. If so, the AMNEs will also be less likely to have an incentive to litigate.

The Companies’ Dilemma in a More Dynamic Context

To assist verbal exposition, we now focus on identifying the requisite conditions for cooperation to prevail in the context of a sequential game theoretic model. This model is more dynamic in the sense that the players have the ability to examine their opponent’s strategy before deciding their preferred course of action. We first explain the order of moves for the two players. Working sequentially, after the AMNE has introduced a patented drug the initiative rests with the EPF that must decide if it wants to merely copy AMNE’s patented drug, or also add value to it. If no value is added then pure infringement leaves little choice to the AMNE but to pursue litigation, where litigation takes place in the EPF’s home country. If some value is added by the EPF, then the AMNE must decide to either collaborate with the EPF or to pursue litigation.

We, thus, try to identify the set of strategies that will lead to what is known as a “subgame perfect equilibrium” (the strategies that allow for an equilibrium in each and every stage of the game), and the sufficient conditions, in terms of parameter values, under which this equilibrium will lead to a cooperative solution. In short, we try to establish the actions the AMNE should follow in anticipation of possible infringement by the EPF, and
correspondingly the actions that the EPF should undertake to avoid a non-cooperative solution. The combination of these two strategies defines the subgame perfect equilibrium. In order to find a solution, we compare the payoffs from each combination of strategies.

The payoff from a non-cooperative solution depends critically on two parameters. The first one is the probability that the AMNE prevails in court; the second one is the damages that the AMNE is entitled to if it wins the case. Considering that the competitive interaction takes place within TRIPS, the probability that the AMNE will prevail must depend on the international legal standards set out by TRIPS. This means that the probability of winning the case is effectively semi-exogenous, and that neither the EPF nor its host country can change the rules of the game. The second parameter, however, is not exogenous. What constitutes damages awards under TRIPS relies on domestic norms. For example, if Indian courts do not permit “ever-greening” patent practices, or have tight views as to what can be claimed as a patentable invention, then the estimate of foregone AMNE’s profits on which these damages must be based on is relatively small. Subsequently, damages are a mostly endogenous parameter that can be shaped by the EPF’s host country policies and the EPF’s willingness to take action against AMNEs.

The payoff from cooperation, on the other hand, must depend on the investment the EPF makes in enhancing the drug’s market space and value, and on how the two parties divide the additional market value that this investment creates. We assume that the AMNE and the EPF will split the additional value through bargaining. In modelling bargaining, we assume that firms bargain in a Nash-bargaining fashion, which constitutes the standard way of modelling bargaining problems of this nature (see Binmore, 1992). In simple terms, Nash bargaining involves defining the “pie” that the two parties need to split in terms of their

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6 AMNEs with patents over drugs that are about to expire try to retain their monopoly position by taking out new patents over small modifications of old drugs (e.g. over associated delivery systems or new pharmaceutical mixtures) for longer periods of time than would normally be permissible under the law (Hall et al., 2012).
respective shares and their optimal course of action in case bargaining fails. Using Nash bargaining has advantages: it is a simple approach which requires no restrictive assumptions as to the way the two parties split the pie into two shares. That is, the division of the pie can incorporate a multitude of settlements that do not necessarily involve market co-creation such as, a pay to go away arrangement, joint ventures, or any other type or cooperation.

Below, we introduce the formal model which focuses on the role of the two critical parameters in achieving a cooperative solution: the investment that the EPF must make to increase a drug’s market value; and the estimated damages awarded to the AMNE in the case of infringement.

**The Players and Their Strategies**

As before, we consider two firms: Firm 1 (the AMNE) which holds a patent protected drug and Firm 2 (the EPF) which wishes to offer its own drug version to its home market. Firm 1 accuses Firm 2 that its drug infringes its IP rights. Firm 2 can adopt two strategies: (a) to compete with Firm 1 by copying Firm 1’s patented drug formula (strategy IN – for infringement); or (b) to invest in adding value to its drug (strategy VA – for value added). In both cases, the creation of the drug by Firm 2 will lead to profits for Firm 2. However, as Firm 2 is perceived by Firm 1 to be selling Firm 1’s patented drug formula, these profits represent foregone profits (i.e. losses) for Firm 1, which sees its share of the market being captured by Firm 2.

When Firm 2 chooses to follow strategy IN and copy Firm 1, Firm 1’s losses are $l_1$ and Firm 2’s gains are $l_2$. Copying implies that Firm 2’s gains are Firm 1’s loses ($l_1 = l_2$).

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7 For the sake of simplicity, we frame the model in an environment deliberately sterilized from the effects of firm size and size differences between EPFs and AMNEs. To check how sensitive our findings are when firm size (and hence market size) are accounted for, we enhanced our model with a firm size parameter. The follow on analysis showed that the main findings and their interpretation remained unchanged, apart from the fact that size differences - assuming AMNEs are the larger firms in the model - shift the balance of power in favor of AMNEs.
Consequently, infringement results in a redistribution of the pie, with Firm 2 appropriating a share of Firm 1’s anticipated market share in the emerging country. Under strategy VA, on the other hand, Firm 2 invests in order to add value, and by doing so the size of the pie increases. In particular, we expect that Firm 2’s gains must be greater than 1’s losses; within the context of the model it is straightforward to show that any other assumption cannot lead to a cooperative solution. To capture this, we assume that the inclusion of value added requires Firm 2 to invest $i$ into its new product, in which case Firm 2 can garner gains that are greater than otherwise by a factor equal to $il_1$. Consequently, Firm 2’s gains from strategy VA are $l_2 = l_1 + il_1$. To sum up, strategy VA increases the overall pie by $V = l_2 - l_1 = il_1$, while strategy IN does not increase the overall pie, and $V = 0$.

Shifting our attention to Firm 1, upon recognising that Firm 2 has infringed, Firm 1 has three strategies that it can follow: (i) it can enter into a conflict (strategy C for compete), (ii) it can seek a cooperative solution (strategy A for accommodate), or lastly, (iii) it can do nothing (strategy N for no action). Strategy N will not be modelled further because the game ends with Firm 1 conceding defeat. Nonetheless, it will prove helpful to use the payoffs stemming from this strategy as a benchmark that defines what would happen if Firm 1 just decides to turn a blind eye. Figure 2 presents the game tree, which lists the strategies that firms can follow and the payoffs that each strategy leads to. It should be noted that the depicted strategies are essentially similar to the ones of the prisoner’s dilemma matrix. The main difference in this setting is the sequential nature of the argument.

In order for the conflict to be avoided, Firm 2 must first follow strategy VA, and then Firm 1 must also pursue strategy A. We envision that, in such a case, the disagreement is resolved through an out-of-court settlement. By contrast, if Firm 2 chooses strategy IN, or Firm 1 strategy C, the two parties proceed with the conflict. Starting with a settlement, we
will model settlement as a bargaining agreement between the two parties. In this case, through bargaining, Firm 1 will: (a) try to reclaim what is legally its own property, and (b) split the additional pie that Firm 2’s investment led to.

If the two parties choose a conflict, the conflict must ultimately result in some form of adjudication, where one party prevails. To simplify things, we assume that this adjudication takes the form of litigation in an emerging country court which has signed TRIPS. Hence, the issue of infringement is considered as a legal issue that must be treated according to international regulations, and Firm 1 can win in court with probability $\mu$. If Firm 2 is found to be infringing, it will have to return the appropriated profits and pay damages. The yardstick used by courts in estimating damages is the foregone profits from the sale of the infringing good.\(^8\) Accordingly, we model damages in terms of the losses $l_1$ that the plaintiff has suffered via infringement, framing damages as $\zeta l_1$, where $\zeta > 0$ corresponds to domestic legal norms.

Even though $\zeta l_1$ must be positive its value can vary. One way to vary $\zeta l_1$ is by changing the patent breadth/length of patented drugs; within the limits afforded by the TRIPS agreement. Specifically, a reduction in the drug’s patent breadth/length must lower the drug’s monopoly profits thereby diminishing $l_1$. Thereby, keeping $l_1$ steady, such a reduction is tantamount to a drop in $\zeta$. In our model, $i$ acts like a “carrot” for AMNEs so that they choose strategy A, affecting the gains that they can garner by a factor equal to $il_1$, while $\zeta$, acts like a “stick” for AMNEs should they choose to choose strategy C, affects the damages that it incurs by $\zeta l_1$. Thus, we envisage that for certain values of $\zeta$ and $i$ the two forces will re-enforce each other leading to a competitive solution.

\(^8\) Sometimes courts derive damages through the accumulated royalties resulting from a hypothetical licensing agreement. In theory both methods should provide identical results.
Analysis

The Payoffs from Each Strategy

We denote the profits of each firm prior to the emergence of a conflict as $\pi_{1,NC}$ and $\pi_{2,NC}$ (NC stands for no conflict) respectively. Equally, when the conflict emerges, and prior to any solution, the firms’ profits are denoted as $\pi_{1,N}$ and $\pi_{2,N}$ respectively; these are the profits that the two firms garner if Firm 1 chooses to turn a blind eye to infringement.

If Firm 1 follows strategy A and the firms eventually settle, they need to reclaim lost profits and split up $V = \theta l_1$ into two shares of $\varepsilon_1$ and $\varepsilon_2$ respectively, i.e. $V = \varepsilon_1 + \varepsilon_2$. This implies that the profits that the two firms derive by following strategy A should be equal to the profits that they would have respectively captured in the absence of a solution ($\pi_{1,N}$, $\pi_{2,N}$), plus their bargaining shares ($\varepsilon_1$, $\varepsilon_2$). Subsequently, the firms’ profits from a settlement, respectively denoted as $\pi_{1,A}$ and $\pi_{2,A}$ are, $\pi_{1,A} = \pi_{1,N} + \varepsilon_1$ and $\pi_{2,A} = \pi_{2,N} + \varepsilon_2$.

Allowing the two firms to bargain in a cooperative fashion, we must first establish the threat points that each firm faces, i.e. their best course of action and its payoff if bargaining fails. In other words, we need to find how the two firms split $V$ when settlement fails and the case is decided by a court. In this case, if Firm 1 wins (with probability $\mu$), it must get back the $l_1$ profits that Firm 2 appropriated, plus the $\zeta l_1$ damages that it is entitled to; if it loses Firm 2 captures the entire $V$. This reasoning implies that Firm 1’s threat point is $\mu(1 + \zeta)l_1$.

Focusing on Firm 2, if the case goes to court and Firm 2 wins, it can legally appropriate its full share of its contribution to $V$, which is $l_2$, making Firm 2’s threat point equal to $(1 - \mu)l_2$; if it loses it gets naught. Accordingly, the firms maximize the following Nash product, $\max_{\varepsilon_1,\varepsilon_2}[(\varepsilon_1 - \mu(1 + \zeta)l_1)(\varepsilon_2 - (1 - \mu)l_2)]$ where $V = \varepsilon_1 + \varepsilon_2$. This, so
called, Nash product captures the joint bargaining space that the two parties share. By maximizing this product, they can independently choose their bargaining shares \( \varepsilon_1, \varepsilon_2 \).

Bearing in mind that \( l_2 = l_1 + il_1 \), the FOC of this maximization problem is \( \varepsilon_1 = \frac{1}{2}((2 + i + \zeta)\mu - 1)l_1 \), and \( \varepsilon_2 = V - \varepsilon_1 \). Note that both \( \mu \) and \( \zeta \) have a positive effect on the bargaining share of Firm 1 and a negative on Firm 2. Hence, increasing the damages awards, or the probability of prevailing in court, shifts the balance of power towards Firm 1.

On account of the above \( \pi_{1,A} = \pi_{1,N} + \varepsilon_1 \) and \( \pi_{2,A} = \pi_{2,N} + \varepsilon_2 \) become:

(1) \( \pi_{1,A} = \pi_{1,N} + \frac{1}{2}((2 + i + \zeta)\mu - 1)l_1 \),

(2) \( \pi_{2,A} = \pi_{2,N} + \frac{1}{2}((2 + \zeta)\mu - 1 - i(2 - \mu))l_1 \).

Shifting our attention to strategy C and litigation, if after filing the case Firm 1 wants to pursue litigation then the firms’ profits from litigation are:

(3) \( \pi_{1,C} = \mu(\pi_{1,N} + (1 + \zeta)l_1) + (1 - \mu)\pi_{1,N} \),

(4) \( \pi_{2,C} = \mu(\pi_{2,N} - (1 + \zeta)l_1) + (1 - \mu)\pi_{2,N} \).

In (3), \( \mu(\pi_{1,N} + (1 + \zeta)l_1) \) denotes the profits that Firm 1 attains by winning the court case with probability \( \mu \). These should be equal to the \( \pi_{1,N} \) profits that accrue to Firm 1 when infringement takes place, plus the \( l_1 \) profits that it foregoes due to infringement, to which one should add the \( \zeta l_1 \) damages that Firm 1 is entitled to. On the other hand, if Firm 1 loses its case, with probability \( 1 - \mu \), then it can only get \( \pi_{1,N} \). Equation (4) draws a similar picture for the infringer, who has to pay damages and return the profits it appropriated (i.e. \( (1 + \zeta)l_1 \)) if it loses the case, while if it wins it can legally get the profits from infringement, i.e. \( \pi_{2,N} \).

Comparing Profits from Each Strategy
Having obtained the payoffs for strategy A and C we can now compare the two. To simplify
the results we will assume that both firms have an equal chance of winning the case. This
assumption allows us to focus on how Firm 2 can employ the parameter values of \( i \) and \( \zeta \) so
as to achieve a more favourable outcome. As far as Firm 1 is concerned, the profits from
strategy A are greater than those from strategy C if \( 2 + \zeta < i \). For Firm 2 the profits from
strategy VA are greater than those from strategy IN if \( \frac{1}{3}\zeta < i \). As the first inequality is
always greater than the second, we focus on:

\[
(5) \quad 2 + \zeta < i.
\]

which suggests that cooperation becomes more beneficial as \( \zeta \) (i.e. the anticipated damages
awarded to AMNE for infringement) declines relative to \( i \) (i.e. investment in the drug made
by the EPF). Simply put, Firm 2 will tend to choose to cooperate with Firm 1 when \( \zeta \) is
small relative to \( i \). Our results can be summed up through the following proposition:
Collaboration between an EPF and an AMNE will be the equilibrium outcome when EPF’s
investment to enhance the drug’s market and value that can be then shared by the two
parties, is relatively large and the estimated damages awarded by courts to the AMNE due to
foregone profits from the sale of the infringing product are relatively small.

To visualize equation (5) and the resultant proposition, Figure 3 depicts graphically
the bargaining space leading to cooperation (or conflict) as a function of EPF’s investment
level, as well as, the damages awarded to AMNE for infringement. To allow for
comparisons with the static model, Figure 3 also maps the four strategic outcomes which
were identified in the prisoner’s dilemma matrix. The point of intersection between the
vertical axis and the upward sloping demarcating line reflects the fact that, when the EPF
makes no value creating investment, a conflict will emerge only when the damages awarded
are big enough to make legal conflict beneficial for the AMNE.

[Insert Figure 3 about here]
An example of a company that has actively tried to employ the principles captured by the above proposition is Ranbaxy. We revisit the example of Ranbaxy’s innovation of Bayer’s antibiotic ciprofloxacin. By developing a once-daily formulation, Ranbaxy’s innovation led to additional patients choosing ciprofloxacin. Instead of a conflict, Ranbaxy licensed the right to sell its improved drug version globally to Bayer, the original marketer of the drug. In this case, the necessary condition was satisfied because Ranbaxy invested and improved ciprofloxacin considerably. The sufficient condition was also satisfied because it would be hard for Bayer to contest the evidently value adding character of the improvement in a court of law. By contrast, the inability of Dr. Reddy’s Labs to persuade the US Court of Appeals that its hypertension and angina drug (called AmVaz) constituted a significant improvement over Pfizer’s patent protected Norvasc offers an example where, even though the necessary condition was satisfied, the sufficient condition turned out not to (Business Standard, 2004).\(^9\)

**Discussion and Implications**

The Economist’s article cited in our introduction echoes concerns over the spreading of a “flawed” patent protection system (through deals such as the planned TPP), which has resulted in a “parasitic ecology of trolls and defensive patent-holders, who aim to block innovation” (Economist, August 8, 2015). In this paper, we studied the impact of the new IP regime on the position of EPFs relative to AMNEs and we explored how cooperation can become preferable to competitive rivalry to both groups of firms.

Our theoretical model and analysis suggest that, in the face of competitive challenges from TRIPS-type agreements, EPFs need to adopt strategies that help make cooperation

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\(^9\) The model we outlined above does not discriminate as to the role of each party. For example, the situation can be reversed and the EPF may face competition from an AMNE that lobbies local authorities to restrict the scope of the EPFs patent and the corresponding damages awards. In any event, our results are not affected by such a reversal of roles.
between firms in the two sets of countries the preferred strategic outcome. Specifically, we show that market co-creation-based co-opetition is preferable to both parties when EPFs can leverage their firm- and country-specific advantages (Barney, 1991; Cantwell, 1995) and complementary assets (Teece, 1986, 2006) to co-create new market space and increase the drug’s market value. Each party then tries to appropriate the additional value created through competitive value capture strategies. In our framework, AMNEs choose to share the now enhanced drug’s market value, allowing EPFs to ‘infringe’ rather than battling in a court of law. If the EPFs producing generics fail to increase a drug’s market value, however, it is hard to avoid the problem of dynamic inefficiency, as the AMNE and the EPF enter into an IP conflict that is more likely to be resolved via litigation.

The main suggestion stemming from our analysis is that, for as long as additional value is created through market co-creation that can be shared between EPFs and AMNEs, there can be a mutually beneficial cooperative agreement of the market co-creating type between them that can foster innovation and trade. This, however, requires that EPFs have the capacity to enhance the (actual or perceived) characteristics of AMNEs’ products and expand market space. Market co-creation-based co-opetition further depends on the way that host country courts estimate damages as a function of the foregone profits from the sale of the infringing drug. When damages are relatively small (by not permitting “ever-greening” patent practices, or by having restrictive views as to what can be claimed as a patentable invention), the likelihood of cooperation tends to prevail. The homogenization of court practices engendered by TRIPS-type agreements helps mitigate opportunistic decisions and reward genuine “value adding” actions by EPFs.

Our findings contribute to the extant literature in two ways. First, we cross-fertilize, extend and formalize key aspects of IP, IB and strategic management literatures. In particular, our study formalizes the market co-creation perspective and extends it to the
emerging country - multinational enterprise context. In this way, it challenges the conventional wisdom vis a vis the terms of engagement of emerging country firms and multinational enterprises in the very important global pharmaceutical sector. Second, our analysis demonstrates that the extent to which a co-opetitive outcome becomes the preferred solution for both emerging and advanced country firms is endogenous to the way in which the host country’s courts interpret and enforce the IP law in the post-TRIPS regime.

Important implications also follow. Concerning managerial practice, our study suggests that EPFs should invest in developing strategic capabilities which are complementary to those possessed by AMNEs or in developing product innovations that tailor AMNEs’ products to local markets and needs. This might require, for instance, re-orientating R&D budgets and recruitment of scientific talent so that EPFs can appropriately enhance the market space and value of AMNE’s drugs. But it might extend to include more fundamental changes in EPFs’ business models, switching from pursuing incremental process innovation and fast imitation towards a business model designed to generate differentiated products which better serve the needs of local patients and which can be produced and marketed more efficiently. Regarding EPFs IP strategy, our findings are suggestive of possible benefits for EPFs from making themselves aware of their international competitors’ IP strengths and weaknesses (e.g. through carrying out patent landscape analysis) so that they can identify and air possible concerns about aggressive strategic patenting by AMNEs with host country IP authorities. Simultaneously, AMNEs should be cognizant of the possibility for and advantages of market co-creation and co-opetition and refrain from pursuing aggressive strategic patenting (e.g. overly extending the scope and duration of otherwise legitimate IP rights).

Concerning public policy, emerging country institutions could assist with market co-creation in two ways. First, by encouraging local firms to build and leverage knowledge,
complementary assets and capabilities that will complement AMNEs’ assets through appropriate incentives (e.g. through targeted R&D tax reliefs). Second, by seeking to support the creation of a space that fosters the identification of cooperative solutions by rewarding “value adding” EPFs; and by preventing attempts by some AMNEs to capture value by adopting aggressive strategic patenting practices. Finally, the possibility of EPF-AMNE market co-creation cooperative agreements under the new stronger IP regime can help realize the original objective of the TRIPS agreement (such as investment targeting poor country-specific diseases), which are believed to have failed to realize some of their originally intended objectives (Kyle and McGahan, 2009; Lanjouw, 2005). Our findings imply that, even though IP protection will not - on its own - lead to additional R&D investments by AMNEs, it may nevertheless aid negotiations between emerging and advanced country firms for the creation of new products that are best suited for emerging country-specific needs or diseases.

Limitations and Future Work

Our study is subject to limitations which constitute promising opportunities for future work. Concerning the generalizability of our model’s findings, we acknowledge that our model was built around the competitive dynamics in the pharmaceutical sector of the economy. However, its predictions can apply (to different degrees) to other industries where formal IP protection is seen as an effective mechanism for appropriating value from innovation by preventing direct imitation, such as in the chemical, electronics and machinery industries (James et al., 2013).

We also wish to highlight some limitations which are related to the necessary simplifying assumptions of our game theoretic model. First, although damages that are awarded to AMNEs (in the case of IP infringement) are treated as an endogenous parameter shaped by the EPF’s host country policies (and the EPF’s willingness to take action against
AMNEs IP rights), the legal IP framework is taken as exogenous. Recent advances in institutional theory suggest that actors may act as institutional entrepreneurs and transform existing institutions themselves (Battilana et al., 2009; Jones and Pitelis, 2015). Second, our analysis as to how EPFs can become attractive partners for AMNEs highlights the need for the former to develop new sets of capabilities or even reconfigure their business models. It needs to be acknowledged, however, that the requisite (dynamic) capabilities to implement change will not be identical across all EPFs and such organizational changes may be hampered by inertia, sunk costs, lack of legitimacy etc. (Benner and Zenger, 2016; Leonard-Barton, 1992; Teece et al., 1997). Third, despite our plausible assumptions (e.g. about rational decision makers operating in profit-maximizing firms), one cannot rule out the existence of alternative contingencies, once market inefficiencies and information asymmetries become a possibility. Furthermore, the possibility of firms behaving opportunistically needs to be acknowledged. This can involve either of the two parties choosing to co-create market space and then also seek damages or enter each other’s turf/comparative advantages. Such cases cannot be ruled out, but we submit that the original decision to cooperate though market co-creation can make it harder for AMNEs to substantiate the size of the loss – as the market size has been co-created. EPFs may, in turn, be less motivated to behave opportunistically by the possibility of losing the benefits of co-created markets or of retaliation by AMNEs. Last but not least, companies can sometimes take the view that the uncertainty over the anticipated benefits from market co-creation renders market-sharing deals (such as, pay to go away) superior to those of the market co-creation type. This, however, calls for public regulation policy that should aim to foster the social benefits from market co-creation, even at the expense of corporate profitability (Mahoney et al, 2009). Our paper shows that courts can endogenize the outcome, albeit for
the purposes of the paper, other public policy institutions remain exogenous to our analysis and an opportunity for further research.

We, thus, call for further research to examine more systematically how emerging and advanced country firms can foster outcomes that engender mutual benefit to firms while, simultaneously, not failing the poorer consumers of emerging countries in the new global landscape and IP regime.
References


drugs. Health Affairs, 28: 957-968.
Teece, D. J. (1986). Profiting from technological innovation: Implications for integration,
1131-1146.
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<th>No. of Alliances</th>
<th>Indian partners</th>
<th>Overseas partners</th>
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<td>14,600</td>
<td>23</td>
<td>Alembic Ltd, CD Pharma India Pvt Ltd, Cipla Ltd; Dr Reddy's Laboratories Ltd, Ethypharm India Pvt Ltd, Lupin Laboratories Ltd, Nicholas Piramal India Ltd, Orchid Chem &amp; Pharm Ltd, Sun, Wockhardt Ltd, Zenotech Laboratories Ltd, Zydrus Cadila</td>
<td>Bayer AG, City Asucom, Community Invest Hldgs(Pty)Ltd, Davidson Laboratories, DWC Auto 14th Sec Spv, GlaxoSmithKline PLC, Knoll AG(BASF AG), Merck &amp; Co Inc, Microbia Inc, MMV, Nippon Chemiphar Co Ltd, SciGen Ltd, Tiger Brands Ltd</td>
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<td>Dr Reddy's Laboratories Ltd (Hyderabad)</td>
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<td>16</td>
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<td>15</td>
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Sources: Thomson SDC Platinum alliances; number of employees in 2012 by BvD OSIRIS
Figure 1. Strategy Matrix: The Game between EPFs and AMNEs

<table>
<thead>
<tr>
<th>AMNE</th>
<th>Do not litigate</th>
<th>Litigate</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EPF</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Invest in drug for market co-creation</td>
<td><strong>Cell A: Co-opetition</strong>&lt;br&gt;The EPF invests to add value to AMNE’s patented drug and offers it to its local market. The added-value created is shared between the AMNE and the EPF through some cooperative agreement, while the firms compete for value capture.</td>
<td><strong>Cell C: Opportunism-based conflict</strong>&lt;br&gt;The EPF invests to add value to AMNE’s patented drug and offers it to its local market. However, the AMNE tries to appropriate the drug’s added-value via litigation against the EPF.</td>
</tr>
<tr>
<td>Copy drug without market co-creation</td>
<td><strong>Cell B: No conflict</strong>&lt;br&gt;The EPF copies AMNE’s patented drug and offers it to its local market. The AMNE turns a blind eye if the corresponding forgone profits are too small to justify bearing litigation costs.</td>
<td><strong>Cell D: Conflict</strong>&lt;br&gt;The EPF copies AMNE’s patented drug and offers it to its local market. As long as the foregone profits are material, the AMNE protects its IP rights via litigation against the EPF.</td>
</tr>
</tbody>
</table>
Figure 2. The Strategic Interaction Game Tree for EPFs and AMNEs
Figure 3. Competitive Outcomes by Key Model Parameters

- **Conflict**
  - Fig1: Cell C
- **Cooperation**
  - Fig1: Cell A
  - Fig1: Cell B
  - Fig1: Cell D

- Damages awarded to the AMNE for infringement
- Investments in the drug by the EPF