Bio-Piracy or Prospering Together? Fuzzy Set and Qualitative Analysis of Herbal Patenting by Firms

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BIO-PIRACY OR PROSPERING TOGETHER? FUZZY SET AND QUALITATIVE ANALYSIS OF HERBAL PATENTING BY FIRMS

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Since the 1990s, several western firms have filed patents based on medicinal herbs from emerging markets, evoking protests from local stakeholders against ‘bio-piracy’. We explore conditions under which firms and local stakeholders share rents from such patents. Our theoretical model builds on two distinct strategy literatures: firms appropriating rents from new technologies and firms managing stakeholders. We predict that a win-win outcome emerges when the patent strength is moderate and when local stakeholders form a coalition with larger national stakeholders to initiate litigation against the focal firm. We test our predictions using a two-pronged empirical strategy. Our empirical context relates to herbal patents from emerging markets and given that we have a small sample (N=17), we employ a fuzzy set QCA methodology. In addition, we develop four in-depth qualitative case studies to support our predictions.

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INTRODUCTION

In the strategy literature, there is a long tradition of studying how firms can create and appropriate rents from new technologies. Scholars have used the resource-based theory of the firm to outline how newly developed technologies with ‘missing markets’ can create competitive advantage for the firm owning the technology. To quote Arora, Fosfuri, and Gambardella (2001: 4), one of the questions that the scholarship has focused on is ‘analyzing the consequences of ‘missing markets’ for intangible assets and how the behavior of companies can be affected once markets for such assets arise.’ As Arora et al. (2001) outline, firms could chose to embody newly developed technologies in their products and services or could chose to license the same. Whatever the decision, scholars in the strategy literature have outlined the importance of creating and enforcing property rights for these new technologies through patenting. Patenting the new technology protects the firm from imitation in the case of in-house use of the technology and reduces transaction costs in case the firm licenses the newly developed technology.

However, a white space in this literature relates to how firms can appropriate rents from ‘newly discovered’ traditional technologies such as herbal medicine. Such technologies are mostly embedded in emerging market societies and local communities around the world and often the local communities and indigenous populations have been users of such traditional technologies for decades, if not centuries. There is, however, no prior research on whether and how firms can appropriate rents from such traditional technologies by creating well-defined and enforceable property rights such as patents. If patents are granted and not contested, the focal firm is able to appropriate all the rents from the traditional technology by either embodying the same in its products or by licensing the patent. However, patents filed by firms based on traditional technologies are often contested by the affected emerging market local communities.
Dealing with local communities in emerging markets involves dealing with multilevel stakeholders, e.g., national governments, national NGOs, research labs, local farmers, indigenous tribes, and other members of local communities.

In this paper, we develop a theoretical framework to explore whether both firms and local stakeholders can benefit from the focal firm patenting and appropriating rents from traditional technologies. We examine conditions that lead to the focal firm sharing rents appropriated from the traditional technology patent with affected local stakeholders. In our theoretical framework, we define this outcome as a ‘win-win’ scenario. Our theoretical analysis builds on two additional theoretical antecedents—stakeholder theory and the notion of stakeholders, including local stakeholders forming networks. Stakeholder theory has long suggested that firms can create value by effectively managing their stakeholders (Freeman 1984; Preston and Sachs, 2002, etc.). The recent strategy literature in this area has documented that firms can increase their financial valuation by building stakeholder support (Henisz, Dorobantu, and Nartey, 2011; Dorobantu et al., 2012). We also build on the literature on stakeholder networks (e.g., Rowley, 1997; Nebus and Rufin, 2010) in identifying how the emergence of a coalition of local and national stakeholders can affect the outcome of whether or not the focal firm shares rents with affected stakeholders.

In summary, our theoretical framework suggests the emergence of a ‘win-win’ outcome under certain conditions, where both the focal firm and the local stakeholders share the rents appropriated from patenting a traditional herb. Our framework suggests the following two conditions for such an outcome to emerge: (1) the claim of the focal firm patent should be moderately strong (i.e., not very strong; not very weak); and (2) the local stakeholders should form a coalition with larger national stakeholders in contesting the patent of the focal firm.
Forming a coalition enables affected local stakeholders to leverage the financial, legal, and technological resources of the national stakeholders; on the other hand, the presence of local stakeholders in the coalition enables a mechanism for directly distributing rents by the focal firm to the affected communities.

The filing of herbal patents by firms, (where the ‘technology’ is embedded in emerging market communities), offers us a unique empirical context to test our theoretical framework on traditional technologies. In many cases, the focal firm does not discover any new use for the herb; it merely patents the known medicinal use of the herb. As a result, firms patenting the medicinal uses of such herbs have to deal with multilevel stakeholders that include government actors, R&D labs, large national NGOs, and affected local communities.

To test our propositions, we employ a dual empirical strategy. Firstly, we perform fuzzy set analysis of 17 hand-collected case studies. We further conduct four in-depth qualitative case studies to validate our theoretical propositions. Our fuzzy set empirical analysis is based on the method of qualitative comparative analysis or QCA (Ragin, 1987, 2008). QCA was introduced by Charles Ragin as a way to bridge the divide between qualitative and quantitative methods and works well for our small sample size of 17 case studies. We find that a ‘win-win’ results when the strength of the patent claim is moderately high, and when a strong coalition is formed by the local stakeholders.

We also document four in-depth qualitative case studies to further validate our framework. We first analyze the case of turmeric, an integral component of Ayurveda for centuries, which was patented by the University of Mississippi Medical Center. Turmeric is an herb used by Indians at large and there were no directly affected local stakeholders involved. The Council of Scientific and Industrial Research in India (CSIR) led the legal pushback against the
patent, leading to the patent finally being revoked. Turmeric is a case of a patent with a weak claim being overturned. No stakeholder coalition was formed and the resulting outcome was a loss of the patent and no rents being appropriated by any party.

We then analyze the case of maca, an herbaceous plant used to increase the fertility of humans. Peruvian farming, cultural, and environmental organizations formed a coalition with the Lima-based International Potato Center (CIP) to initiate litigation. However, Pure World, the patentee, was able to retain its patent on grounds that its patent claim was legitimate. Maca was an instance of a focal firm having a strong claim over an herbal patent and being able to extract all rents from the patent, notwithstanding the formation of a strong coalition of affected stakeholders.

The case of the Kanis in India showed a strong coalition between the local community and external stakeholders taking on a moderately weak patent claim over *Trichopus zeylanicus travancoricus*, an herb with antifatigue properties. In this instance, the TBGRI, the body that uncovered the indigenous use of *Trichopus zeylanicus travancoricus*, actively explored options for sharing rents with affected local stakeholders. Kanis is a case of a win-win where the focal firm and the affected local stakeholders shared rents from filing an herbal patent.

Finally, the case of hoodia was that of a cactus-like plant used to suppress hunger and thirst. Scientists from South Africa’s Council for Scientific and Industrial Research (CSIR) patented the active ingredient in hoodia, which they licensed to a British company called Phytopharm. A very strong stakeholder coalition was formed to fight the patent, and while the claim had moderate strength, a win-win situation emerged where the focal firm shared rents with the affected local stakeholders.
THEORETICAL FOUNDATIONS

‘Missing’ markets for technology and firm strategy


Arora et al. (2001: 8) start with a general discussion on ‘missing markets for assets’ that help firms distinguish themselves from their competitors. These assets include newly developed technology. The authors build on the resource-based theory of the firm to conclude that newly developed technologies that enable firms to create sustainable competitive advantage must be valuable, must be rare, and must be perfectly mobile (Barney, 1991; Peteraf, 1993; Markides and Williamson, 1996). Hence, by this extension, a firm may get a sustained competitive advantage only when it is supported by technologies for which there are no well-functioning markets. Arora et al. (2001) also posit that as there is a missing market for such technologies, firms must look internally to develop these and must exploit the technology in-house. In other words, the newly developed technology has to be embedded in the goods and services sold by the firms. When such goods and services have ‘lower costs or command higher prices to deliver returns that are greater than the competitive rate of returns; firms earn quasi-rents.’ (Arora et al., 2001: 9). This is in line with Teece (1988), who argued for firms appropriating rents from technology by embodying it into goods and services.

However Arora et al. (2001) also point out that firms can derive value and appropriate returns by licensing the newly developed technology. When the knowledge base of the asset is largely codified, is not context-specific and when intellectual property rights are well defined and
sufficiently protected, there exists an opportunity for licensing (Williamson, 1991; Kogut and Zander, 1993). The authors quote Lamoreaux and Sokoloff (1997, 1998) in documenting how markets for new technologies in the form of patents in the U.S dates back to the nineteenth century. The authors also mention how, from 1985 to 1997, there were 15,000 transactions in technology, amounting to a total value of more than $330 billion. These growing markets for technology have a marked effect on strategies adopted by various firms, especially firms in industries such as software, electronics, chemicals, etc. Hall and Ham (1999) document how the semiconductor industry has seen a significant rise in patenting and licensing deals. Arora et al. (2001) also point out that the decision to exploit a new technology in-house or not depends on several factors, most importantly on the distribution of complementary assets. If the focal firm lacks the complementary assets to appropriate rents from the newly developed technology, it may consider licensing the technology. Other factors that affect the transaction costs for technology licensing include well-defined and well-enforced property rights. When the knowledge is articulatable, property rights become easier to define and enforce, and transaction costs fall (Winter, 1987). Arora and Gambardella (1998) demonstrate the importance of property rights and patents through an example of the market for chemical processes and engineering services. Lerner (2002) provides a historical analysis of the evolution of the strength of property rights related to patents.

In summary, once a focal firm develops a new technology with a missing market, creating well-defined and enforceable property rights (e.g., patents) is instrumental for the focal firm to appropriate rents from the patent. The focal firm could choose to embody the new technology in its products and services and the patent would help the firm protect itself from imitation. However, if the focal firm decides to license the newly developed technology, well-
defined property rights in the form of patents help the firm reduce transaction costs of licensing. We use these theoretical antecedents in analyzing how firms can appropriate rents from newly ‘discovered’ traditional technologies.

**Stakeholder theory and local stakeholders**

The literature on appropriating rents from new technologies has focused on firms developing new technologies in-house. Alternatively, firms can also look to ‘discover’ traditional technologies that are embedded in local societies around the world. These traditional technologies have existed for long periods of time, but property rights for these technologies have not been claimed by any other firm. A focal firm filing a patent in this area becomes the first entity to look to appropriate rents from newly ‘discovered’ traditional technologies.

When a firm seeks to appropriate rents from such traditional technologies, there are several decisions to be made. The firm has to decide on either embodying the patent in its own products or licensing it. But most importantly, the firm needs to consider managing the affected local stakeholders. Generally, traditional technologies that firms ‘discover’ have been used for several decades, if not centuries, by local stakeholders in emerging markets. Local stakeholders then treat the traditional technology as their own, and any firm looking to appropriate rents from the technology must manage the local stakeholders.

The strategy literature has a long tradition of thinking about stakeholder management. The literature has used stakeholder theory that suggests that firms can create value by effectively managing their stakeholders (Freeman, 1984; Preston and Sachs, 2002, Hillman and Keim, 2001). Moreover, in the recent strategy literature, Henisz, Dorobantu, and Narrey (2011) support the principles of stakeholder management by providing empirical evidence that shows that increasing stakeholder support enhances the financial valuation of a firm.
Stakeholder theory is based on the premise that firms need a ‘social license to operate’ (Boutilier, 2011). The social license to operate implies the acceptance of a firm by the local stakeholders who also believe that the value proposition offered by the firm is legitimate (Boutilier, 2009, 2011). Boutilier (2011) defines seven levels of the firm being granted some degree of a social license to operate—the levels range from ‘withholding/withdrawal,’ to the firm crossing a ‘legitimacy boundary,’ to receiving ‘acceptance.’ In the next level, the firm crosses the ‘credibility boundary’ to receive ‘approval.’ Finally, the firm crosses the ‘trust boundary’ and achieves ‘co-ownership’ with stakeholders. Boutilier (2011) illustrates this framework through the case of Newmont Mining Corporation, which defined the social license to operate as ‘the acceptance and belief by society, and specifically, our local communities, in the value creation of our activities, such that we can continue to access and extract mineral resources’.

Extending this thesis, in the recent strategy literature, Dorobantu, Henisz, and Nartey (2012) talk of the concept of ‘stakeholder capital’ as the level of recognition, understanding, and trust the firm establishes with the stakeholders. The authors build on the concept of ‘social capital’ (Adler and Kwon, 2002) and state that multiple activities like community interactions, CSR, public relations campaigns, etc., go into building and shaping a focal firms’ stakeholder capital in a host country. Stakeholder capital is analogous to the currency of goodwill, recognition, and acceptance that the focal firm enjoys in the host county. To summarize Dorobantu et al. (2012), building stakeholder capital serves a twofold purpose. First, it creates economic value and protects the firm during rough times. The second utility of stakeholder capital focuses on dealing with conflict. Dorobantu et al. (2012) argue that stakeholder capital acts as protection for a focal firm, as it reduces the probability that a negative event from the
perspective of stakeholders would ultimately lead to the cancellation/revocation of the social license that allows the firm to operate in the host country.

The literature on firms managing stakeholders has also outlined the disaggregated nature of the stakeholder community and the importance of the local stakeholders. While firms look to ‘discover’ and appropriate rents from traditional technologies in emerging markets, they have to engage with local stakeholders. Calvano (2008) points out that among the various stakeholders, local stakeholders are often most affected by actions taken by the firm. Local stakeholders often also lack the ability to effectively engage the focal firm. According to the stakeholder salience model, three factors go into determining the influence a particular stakeholder has on a focal firm—power, legitimacy, and urgency (Mitchell et al., 1997). Local stakeholders tend to possess very little power to engage large firms; this is driven by their lack of financial, legal, and technical resources. Hence, local stakeholders are often unable to directly influence the firms’ decision-making process. Here, it is crucial to understand that stakeholders are not a single monolithic entity, but a network. The formation of stakeholder networks has been studied by the strategy and international business literature. Rowley (1997) studies the theory of stakeholder influences and the formation of stakeholder networks where the firm tries to manage multiple, interdependent stakeholders with their own demands and predicts the reactions of firms to the various local stakeholder reactions that occur simultaneously.

We use these antecedents to now outline a theoretical framework that explores a focal firm securing an herbal patent and whether or not the rents appropriated from the patent are shared with affected local stakeholders.
THEORETICAL FRAMEWORK

Based on the antecedents documented earlier, we now outline our theoretical framework. We want to analyze interactions between a firm seeking to patent and derive rents from a new technology and the local stakeholders who have historically been the users of this technology.

The two sets of actors involved in this interaction are the focal firm and the local stakeholders. In Figure 1, the firm is represented on the x-axis and the local stakeholders on the y-axis. Each of these parties can either come out of the conflict with either of the following two outcomes - ‘win’ or ‘lose’. A ‘win’ means there is a favorable outcome for the actor in question, whereas a ‘lose’ indicates an unfavorable outcome.

----INSERT FIGURE 1 ABOUT HERE----

When a firm files a patent for a locally embedded traditional technology, the *ex-ante* assumption is that the firm is seeking to extract quasi rents from such a patent. When a firm gets to retain the patent and appropriate rents from it, it is a ‘win’ for the firm. When events lead to the firm not retaining or not appropriating rents from the patent it is a ‘lose’ for the firm.

A ‘win’ for the local stakeholders is when they are able to share rents from the patent. If the local stakeholders get a patent overturned and/or prevent the firm from extracting rents, it is *not* a ‘win’ for the local stakeholders, as they too do not accrue any rents from this outcome. Hence, only when the local stakeholders receive rents, do they ‘win.’ Any other situation—one where the firm retains exclusive rights to the patent, the patent is overthrown, etc., is considered a ‘lose.’ Figure 1 and Table 1 summarize this.

----INSERT TABLE 1 ABOUT HERE----

Having defined the possible outcomes, we now outline the possible interactions between the firm and the local stakeholders that results in these outcomes.
We assume that a focal firm files a patent related to a traditional technology that is being used by local stakeholders. Given our theoretical antecedents, we also assume that the local stakeholders lack the technical and financial resources to litigate and challenge the patent. Building on stakeholder network theory, we assume that to counteract this disadvantage, local stakeholders may form a ‘coalition’ with other local or national stakeholders (NGOs, R&D labs, host country government actors, etc.) who have access to such resources.

Next we consider the possible outcomes of litigation between the focal firm and local or national stakeholders and/or a coalition of stakeholders. When litigation occurs, the focal firm has to defend its patentable claims. We assume that if the focal firm has a novel patentable claim and the strength of the claim is strong, the firm retains the patent post litigation. This results in a win for the focal firm and a loss for the local stakeholders. Hence, a strong claim results in a win-lose outcome (as indicated in Box 2 of Figure 1).

If the focal firm’s patentable claim is weak, the patent should be invalidated if the litigant has the financial, legal, and/or technical resources to mount a strong case. However, when local stakeholders litigate independently, the pushback is often not strong enough. The local community may be unable to provide technical information to counter the claims of the focal firm or may lack financial or legal resources to carry on litigation. This often leaves the focal firm with the patent, again resulting in a win-lose outcome—the focal firm derives rents from the patent and the local community does not benefit. The same is true when a firm’s claims are moderate in strength and the litigant is a weak, solo local stakeholder.

However, if the litigant is a coalition of local and national stakeholders, there might be a different outcome. When the coalition is strong, the legal pushback is stronger. If the focal firm’s claim is weak, the patent is invalidated. This results in a lose-lose outcome (as shown in Box 3 of
Figure 1), where neither the local community nor the focal firm appropriate any rents from the patent.

A win-win (as shown in Box 1 of Figure 1) outcome can emerge when the claim of the focal firm is not very strong, neither very weak and the local stakeholders form a strong coalition with national stakeholders who have access to financial, legal, and/or technical resources. In this situation, one of two things may happen: (1) the focal firm foresees strong litigation and knows it may lose the legal battle, so it tries to appease the local stakeholders by sharing rents and keeping litigation at bay; local stakeholders agree to this as the claim of the patent is ‘moderately’ strong or (2) the local stakeholders push back with the support of the coalition and, due to the moderate strength of the firm’s claim, the focal firm and the local stakeholders meet midway and there is an agreement to share benefits. Either way, the focal firm agrees to share rents from the patent, and having local stakeholders in the coalition ensures that there is a mechanism for distributing rents to the affected local community. Figure 2 outlines these scenarios and the outcomes.

----INSERT FIGURE 2 ABOUT HERE----

In summary, we expect to see the emergence of a win-win outcome if the patent claim is moderately strong and the local stakeholders form a coalition with larger national stakeholders.

DATA AND VARIABLES

Empirical context: herbal patents

Our empirical context is herbal patents, i.e. patents based on medicinal herbs where the medicinal use of such herbs has been known to emerging market societies for decades if not centuries. Patenting of these herbs by western entities started in the 1990s. Figure 3 describes the
summary trend of herbal patent filing; to conduct this trend analysis, the authors had to search for herbal patents on the USPTO based on keywords of medicinal herbs.

---INSERT FIGURE 3 ABOUT HERE---

In many instances, the filing of traditional herbal patents by Western entities could be arguably framed as ‘bio-piracy.’ This is based on the provisions of the Trade-Related Aspects of Intellectual Property (TRIPS) agreement signed in 1994. Article 27.1 of TRIPS laid three requirements for patentability: (1) the invention is new; (2) the invention involves an inventive step; and (3) the invention is capable of industrial application. Interpretation of these three requirements was left to the domestic laws, which lead to different standards across the globe. Internationally, ‘new’ means never published, used, or known anywhere in the world (absolute novelty standards). Unlike other laws, ‘new’ in United States patent law means never published anywhere in the world or used/known in the United States one year before filing of the patent application (partial novelty standards).\(^1\)

Around the same time as the introduction of TRIPS, many countries around the world— with the exception of the U.S.—joined a treaty called Convention on Biological Diversity (CBD). Under this treaty, if a research team enters a CBD-contracting host country to gain access to biodiversity of the host country for their research, they have to sign an agreement with the host country detailing access terms, profit sharing, etc. The United States is the only country that has not signed the CBD and has shielded its pharmaceutical companies or researchers from any profit sharing agreement.\(^2\)

The surge of Western patents based on traditional knowledge evoked a strong reaction from scientific and agricultural communities around emerging markets. The Council of Scientific

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\(^1\) United States Code (USC) 35 § 102(b)
\(^2\) http://www.cbd.int/countries/
& Industrial Research (CSIR) in India was among the entities that initiated litigation against the Western firms securing such patents. In several instances, litigation was successful in revoking the patent. Two of the prominent examples of USPTO herbal patents being revoked include the cases of turmeric and basmati rice.

In this paper, we conduct quantitative analysis with 17 case studies of herbal patents around the world and outline four detailed qualitative case studies to illustrate the concepts outlined in our theoretical model. All these case studies were hand collected by the researchers and Table 2 summarizes the case studies.

----INSERT TABLE 2 ABOUT HERE----

Definition of variables

The dependent variables are *firm win* and *stakeholder win*. When the focal firm retains its patent post litigation and appropriates rents from it, it is a ‘win’ for the firm. It is a ‘win’ for the local shareholders only when they, too, receive rents from the patent.

Our first independent variable accounts for the *strength of stakeholder coalition*. This variable represents the extent of support the local stakeholders receive from external bodies who can add legitimacy and strength to their pushback. The *strength of stakeholder coalition* variable measures whether or not local stakeholders form a coalition with larger national stakeholders and additionally measures the strength of the coalition. The next variable to consider is the *strength of patent claim*. The focal firm’s patent might be for a new discovery or for indigenous knowledge. The *strength of patent claim* reflects the legitimacy of the claim of the focal firm. The strength of claim ultimately determines how deeply the focal firm is affected by the legal pushback of the local stakeholders (and the coalition they form).
Quantitative analysis: fsQCA method

Having generated theoretical predictions for the emergence of a win-win outcome and having defined the dependent and independent variables, we quantitatively test predictions from the framework. We use fuzzy set analysis, a variant of qualitative comparative analysis (QCA). fs-QCA is a method that combines the benefits of qualitative case analysis with the strength of quantitative rigor.

fs-QCA was introduced by Charles Ragin (1987) as a way to bridge the divide between qualitative and quantitative methods. A relatively new method, it is being increasingly used by scholars in the strategic management field (as well as in other fields such as medicine and electrical engineering). Recent work includes research on institutional capital (Schneider, Schulze-Bentrop, and Paunescu, 2010), organization design (Grandori and Furnari, 2008), foreign direct investment (Pajunen, 2008), and firms' responses to institutional pressures (Crilly, Zollo, and Hansen, 2012).

QCA relies on Boolean algebra and, given a set of possible causal variables and outcome variables, QCA tries to recognize the multiple causal variables associated with an outcome, i.e. tries to find various configurations of the causal conditions which are linked to an outcome. Standard QCA requires all causal conditions be binary (1 or 0) or dichotomous. A variable is either ‘fully in’ (1) or ‘fully out’ (0) in terms of membership. However, fuzzy set analysis of QCA relaxes this constraint and lets cause-effect variables take any score between 0 and 1.

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QCA generally uses anchor scores to define meaningful groups. The anchor scores are defined, and a qualitative meaning is given to each score, giving rise to the formation of groups. For instance, a four-level scale may be used, where the various anchor scores become 0, 0.33, 0.67, and 1. A 0 score refers to complete non-membership in a set, while a 1 score refers to complete membership. The others—0.33 (more out than in) and 0.67 (more in than out)—act as intermediate anchors. For this reason, a fuzzy set is often considered a ‘continuous’ variable. Thus, fs-QCA allows ‘fuzzy’ variables without abandoning theoretic set principles like the subset relation. ‘Fuzzy-set analysis works from the assumption that the life isn’t black and white…it provides a way to capture this grey data’ (Greeley, 2013).⁷

Another benefit of fs-QCA is that it works well in research with small sample sizes. Unlike regression analysis and other statistical techniques that derive their power from significant sample sizes, fs-QCA allows analysis using small sample sizes. In the present study, fs-QCA is used to test the robustness of the proposed theoretical framework, and to verify the causal variables associated with a particular outcome. As our research is based on 17 cases, fs-QCA is a very viable tool, given that it works well with small samples.

According to Ragin (2008), fs-QCA works well in concert with knowledge of cases to aid in causal interpretation. This makes fs-QCA further appropriate for our research, as we examined multiple case studies of herbal patents around the world.

In this analysis, we take a sample of 17 instances of firm-local stakeholder engagement, to find configurations of strength of patent claim and strength of stakeholder coalition that lead to a win-win scenario for both the local stakeholders and the focal firm. We include instances only where stakeholder initiated pushback took place. The fuzzy set analysis is a multistep process that begins with collecting qualitative data about each instance of stakeholder pushback.

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We hand collect relevant data about each instance of pushback so as to correctly define set membership for our variables—level of coalition, strength of claim, firm win, and stakeholder win. After accumulating qualitative data, we calibrate set membership, with the aim of identifying meaningful groups of instances. We calibrate our data using the qualitative information we have for each case study. The firm win variable captures, on a scale of 0 to 1, the level of the firm’s win, based on our previous definition. A score of 1 indicates a complete win for the firm – an instance when the focal firm retains its patent post litigation and appropriates rents from it. The stakeholder win variable similarly captures the level of the stakeholder’s victory, reflecting whether or not the stakeholder was able to appropriate rents from the patent. For the causal variables, we allocate full membership (1) in case of level of coalition when the level of coalition was high, i.e. strong formation of a coalition with larger national stakeholders. For the strength of claim, we allocate full membership (1) when legitimacy of the claim of the focal firm was high.

The next step in the analysis is the construction of the truth table. Given \( k \) causal variables, there can be \( 2^k \) possible logical combinations of causal conditions. The purpose of the truth table is to identify which combinations of causal variables are associated with the outcome. While \( 2^k \) combinations are possible, not all causal combinations have cases associated with them in our 17 cases. We delete these combinations, so we are left only with those causal combinations that show at least one observation. Logical operations work on fuzzy variables as well, and we take only those causal combinations where the resultant fuzzy score is greater than 0.5; this indicates that the particular case belongs to the causal combinations.

Having taken only the causal combinations, we then examine the consistency, which is a measure of the extent to which a causal combination is reliably linked to the outcome. We define
a consistency threshold, which specifies the minimum consistency for our analysis. The approach we use to decide thresholds is to choose a threshold which corresponds to a significant jump or a break in the distribution of consistency scores.

We then employ the truth table algorithm to simplify the causal combinations. In cases of large $k$, this generates a range of solutions, each with its own consistency score. As one solution does not completely define the outcome, the algorithm generates all possible combinations, along with the logically simplest solution—the ‘parsimonious solution.’ The parsimonious solution contains the core conditions only, while the ‘intermediate solution’ is a more conservative solution, which contains the core conditions and the peripheral conditions.

**Outcome of the fs-QCA analysis**

Using qualitative data, we code the fuzzy scores of the two independent variables—*strength of stakeholder coalition* (Coalition-FZ) and *strength of patent claim* (Patent_Strength-FZ).

Similarly, we also code the fuzzy scores of the dependent variables—*firm win* (Firm-FZ) and *stakeholder win* (Local-FZ). We define our anchors as 0, 1, and 0.5—each representing a level of membership toward each set. Through the qualitative case analysis, we assign a fuzzy score to each instance. We run the fs-QCA analysis twice to study both outcomes—to find the causal conditions in which the firm wins and the causal conditions in which the stakeholders win.

**Results**

We provide the calibration results in Table 3, which shows details of the instances that were studied and the calibrated scores of each causal condition and outcome. This table is the input for the fuzzy set analysis through the truth table algorithm.

----INSERT TABLE 3 ABOUT HERE----
We first perform the fs-QCA analysis with the *firm win* score as the outcome variable. We find no remainders, as all causal combinations have cases associated with them. For the consistency threshold, we find that there is a large leap from 0.93 to 0.65 and, hence, we take 0.93 as our consistency threshold, and run the truth table algorithm to obtain the results.

We then perform the fs-QCA analysis with the *stakeholder win* score as the outcome variable. We find no remainders, as all causal combinations have cases associated with them. For the consistency threshold, we find that there is a reasonable large leap from 0.65 to 0.56 and, hence, we take 0.65 as our consistency threshold. *Prima facie*, we see that the consistency score is comparatively lower, which means that a wide variety of outcomes is possible and the pinpointing of outcomes is difficult. The results are shown in Table 4. We demonstrate the complete configuration results using a format based on Ragin and Fiss (2008).

### Analysis of the Results

Table 4 reports results of the fs-QCA. For the *firm win* score, we obtain a large consistency of 0.94 and for the *stakeholder win* score, we obtain a consistency of 0.65. While the consistency for the *stakeholder win* score is relatively lower, we find that the theoretical framework does well to predict individual cases. Coverage for the *firm win* is 0.65, while for the *stakeholder win* is 0.7, implying that both solutions are empirically almost equally powerful. We obtain one configuration for the *firm win* and one configuration for the *stakeholder win*. We discuss the configurations and what they imply.

### Firm Win

The fsQCA predicts that when the strength of claim is high for a firm, the firm almost always wins (high consistency). However, when strength of claim is low, the outcome cannot be predicted with sufficient consistency. This aligns with our theoretical prediction, which states
that in cases where the claim is strong, the focal firm always wins. However, if the claim is weak or moderately strong, we cannot predict with sufficient consistency whether the firm would win or lose. This is further exemplified in the qualitative case study on Maca, which is an instance of a strong claim leading to a firm keeping the patent, resulting in a win. Furthermore, the case studies of turmeric, hoodia and the Kanis all demonstrate that a strong patent leads to a firm successfully expropriating rents.

**Stakeholder Win**

The analysis concurs that a necessary condition for a stakeholder win is the formation of a strong coalition. Without the coalition, the local stakeholders cannot counter the claims of the focal firm as a cohesive structured unit. Additionally, the causal combination mentions that the strength of the claim cannot be low. For the local stakeholders to win, the patent cannot be invalidated. Hence, the patent must be at least moderately strong. This result forecasts that when the patent is at least moderately strong, and the local stakeholders (through a strong coalition) oppose the patent, the local stakeholders and the focal firm can reach a middle ground where a benefit sharing arrangement maybe setup. Alternatively, if the patent is weak, it would be squashed, leading to no benefits for the local stakeholders.

This result is clearly demonstrated in the instances of the Kanis and Hoodia – both of which show a moderately strong patent claim, and the formation of a strong coalition, which led to a win for the local stakeholders. In summary, both instances of the fs-QCA provide quantitative proof of our theoretical predictions.

**Robustness Checks**

We further tested for the reduction of the consistency threshold in the fsQCA, based on suggestions by Epstein et al. (2008). On reducing the consistency threshold to 0.52 from 0.65, the
causal combination for the stakeholder win evaluates out to be different. It evaluates that the stakeholder wins when either the coalition strength is high or that the patent strength is high. However, the consistency for the solution is comparatively much lower (0.40) and very below acceptable norms.

QUALITATIVE CASE STUDIES

Having quantitatively tested our theoretical predictions, we now use four in-depth case studies to further validate our predictions. The case studies are:

1. Turmeric: No coalition, weak strength of patent claim = lose-lose
2. Maca: Strong coalition, strong claim = win-lose
3. Kanis: Strong coalition, moderately weak strength of claim = win-win
4. Hoodia: Strong coalition, moderately high strength of claim = win-win

Case study of turmeric

*Curcuma longa*, or turmeric, is an herbaceous perennial plant of the ginger family that is native to the tropical belts of South Asia. Turmeric needs temperatures from 20 to 30 degrees Celsius and a substantial amount of rainfall to grow. Hence, it is commonly grown only in tropical South Asia. Turmeric grows in abundance in the forests of Southeast and South Asia. The turmeric plant contains rhizomes, which are boiled for many hours, dried in hot ovens, and ground into a deep orange-yellow power. This makes for the popular turmeric powder, which is the most common form of usage of turmeric in India. The active component of the powder is curcumin, which has a bitter pepper taste. It is the curcumin that is responsible for the medicinal properties of turmeric. Turmeric is popularly used for its medicinal benefits, as a dye, and as a spice.
Turmeric has been used in India for more than two millennia and is a core component of various medications in India’s traditional medicine system, Ayurveda. Ancient India had discovered turmeric’s uses both as a dye and for its medicinal properties. Apart from having a dominant role in Ayurveda, Chinese medicine also made use of turmeric. Indians and Chinese have found turmeric useful for skin diseases, epilepsy, bleeding disorders, breathing problems, digestion issues, and liver and spleen troubles, as well as for purifying the mind and body. Turmeric’s use as an anti-inflammatory was the most predominant and documented use. Due to the potent anti-inflammatory nature of its active ingredient (curcumin), turmeric was used to treat conditions like jaundice, menstrual difficulties, bloody urine, hemorrhage, bruises, chest pain, and colic.\(^8\) Ayurveda also recognized the antibacterial effects of turmeric. Hence, it was used to treat wounds. Ayurveda advises the application of turmeric to wounds, due to its antibacterial and anti-inflammatory nature. The Unani system of medicine—the ancient Persian system of medicine that forms the bridge between Ayurveda and Greek medicine—also relied on turmeric. In Unani, turmeric is considered to be the go-to herb for all blood disorders since it purifies, stimulates, and builds blood. Moreover, it has been used in India for its cosmetic benefits: turmeric paste is commonly used by Indian women to improve skin, as an antimicrobial, and as an anti-aging element.

Turmeric and turmeric powder have their roots deep in South Asian culture and, more predominantly, Indian culture: so much so that turmeric was nicknamed ‘Indian saffron’ in Europe, as it served as a replacement for saffron spice in medieval Europe. Turmeric can also be used in food as a spice or along with milk as a cure for colds and a comfort to throat irritations. Turmeric is also used as a spice in South Asian and Middle Eastern cuisine—and forms a key ingredient in Indian, Persian, and Thai dishes. Turmeric is used differently in some regions in the

Indian subcontinent, with some cooking styles choosing to wrap and cook food in turmeric to impart a different flavor. Turmeric also works as a dye, used indigenously for Indian clothing. In parts of India, turmeric is used to paint doors due to its insecticidal properties. Turmeric is also used as a coloring agent for food items, but this use is a modern, not indigenous, use. Turmeric is used to impart a yellow color to a whole spectrum of food products, ranging from dairy products to juices to biscuits. Turmeric additives protect food products from sun damage.

In May 1995, the USPTO granted a turmeric patent to the University of Mississippi Medical Center, Jackson, U.S. The patent was titled ‘Use of turmeric in wound healing.’ This patent allowed the patentees the exclusive rights to sell and distribute turmeric. The patentees were nonresident Indians—Suman K. Das and Hari Har P. Cohly—at the University of Mississippi Medical Center. The patentees, under the blanket of the patent, enjoyed exclusive rights to certain formulations of turmeric that were successful in wound healing. The patent gave them exclusive rights to sell and distribute turmeric. It was an attempt to secure a monopoly on turmeric powder’s use in wound healing. The fact that the patent was filed implied that the researchers that they had invented a ‘new’ use for turmeric powder.

The USPTO’s defense on the patent was that turmeric was indigenously and publicly used for healing wounds only as an ointment. The patent was an application in the powder form. At the same time, the patentees asserted that they would not seek a patent in India for the same. From 1995 to 1997, turmeric was the subject of a patent dispute. The patentees’ assertion of not seeking a patent in India did not mitigate the piracy of the invention: as turmeric was indigenous knowledge, the patent was an act of bio-piracy.

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The patent had an immediate impact, both economic and social. The patent revolved around turmeric and its uses; the patent had the potential to disrupt the trade of turmeric. A patent covering turmeric would imply that the use of turmeric would require a royalty payment to the patentees in any country where the patent would stand. Any turmeric product manufactured, any export of turmeric, and local use of turmeric would all require licensing fee payment.

Ironically, if an expatriate Indian in America were to use turmeric in his/her daily life, he/she would be infringing U.S. patent law and would be open to prosecution. Consumers would have to pay to apply turmeric to their wounds. The patent, if not overturned, had the potential to cause a huge outflow of money from India to the U.S. in the form of licensing fees. The patent holder had exclusive rights over any turmeric drug and could make substantial profits from it, as no Indian pharmaceutical company could export its products to the U.S. without paying royalties to the Mississippi Medical Center. This would mean that India would lose one of the largest export markets it had.

The turmeric patent triggered two forms of potential losses for the Indian community: royalties out of India in the guise of licensing fees and royalties and deadweight losses that came from pricing a good far higher than its production costs. This was simply the economic losses and excluded the social cost to India and Indians who had to pay for using the herb for its medicinal properties. It is difficult to estimate the total social cost that India incurred due to the turmeric patent. However, it was discovered that the total estimated cost of adhering to TRIPs was nearly $3 billion.\textsuperscript{10} Moreover, the turmeric patent threatened a very dominant chunk of

\textsuperscript{10} \url{http://www1.american.edu/ted/turmeric.htm}
India’s exports—spices. India accounted for 46 percent of the world’s spice trade volume in 2004.11

Activists in India immediately took notice of the patent. While drug companies regularly filed pharmaceutical patents to protect their developed products and recover R&D costs, activists felt that patenting an herbal medicinal practice that was centuries old was unjustifiable. As Vandana Shiva, director of the Research Foundation for Science, Technology, and Natural Resources, said, “This is yet another blatant example of bio-piracy. How can anybody patent something that has been the collective wisdom of a people for centuries?”12

Driven by the initial protests led by NGOs, the government took notice. In 1997, a complaint was filed by the Council for Scientific and Industrial research (CSIR) in India. The challenge was led by the head of CSIR, Dr. R.A. Mashelkar, an Indian scientist actively working to protect India’s intellectual property. The complaint was directed at the novelty of the discovery made, claiming that the qualities of turmeric that were patented were, in fact, India’s indigenous knowledge. India had been using turmeric for thousands of years, including for its medical benefits.

The legal criteria surrounding any patent are the novelty of the patent, the non-obviousness of the patent, and the utility. Activists claimed that the patent did not meet the check boxes of novelty and non-obviousness. U.S. law allowed a patent on a medicinal substance if a new medicinal property was found; however, the substance could never be patented. This complaint by the CSIR triggered a USPTO examination of the patent.

Examination continued for four months. Ultimately, on August 13, 1997, the patent was revoked. The six claims made by the patent were rejected. Ancient Sanskrit writing that

11 http://www1.american.edu/ted/turmeric.htm
documented the uses of turmeric in Indian history—especially its use to heal wounds—dove the nail in the coffin for the patent. CSIR provided compelling evidence of turmeric being used as a powder for years in India. The University of Mississippi Medical Center did not opt for reexamination of the patent.

In the case of turmeric, no coalition was formed between any local community and an NGO/government body. Instead, the pushback was almost entirely driven by the CSIR. More importantly, the patent claim had no strength. The patent on turmeric was a very clear instance of bio-piracy. As CSIR pushed back, litigation was triggered and the weak patent fell apart. Ultimately the turmeric patent was invalidated, resulting in no ultimate benefit to the local community and no long-standing benefit to the patent holders.

Hence, the turmeric case is an instance of (i) no stakeholder coalition and (ii) weak patent claim strength leading to a loss-loss situation. If the external stakeholders had not pushed back, it would have resulted in a win-loss.

Case study of maca

Maca, scientifically called *Lepidium meyenii*, is a herbaceous plant natively found in the Andes Mountains in Peru and Bolivia and, to some extent, Brazil. Maca is part of the mustard family and is usually grown in altitudes of 8,000 to 14,500 feet. It grows well in cold climates with relatively poor agricultural soils. The maca root has a fleshy hypocotyl (the stem of the germinating seedling), which develops into a tuberous root, and it is used for two prime purposes—as a root vegetable and as a medicinal herb.

For almost 2,000 years, maca has been a traditional source of food (as a root vegetable) and a medicinal herb, and was called ‘one of the lost crops of the Incas’ by the U.S. National
The local people regard it as a very nutritious food that is quick to provide energy, and at the same time, as a medicine that enhances strength and endurance and functions as an aphrodisiac. Maca is grown and traded for other staples that cannot be grown locally.

The prime use of maca by the indigenous people is, however, not for food. For centuries, local Andean people have been using maca to increase the fertility of humans and animals. Peruvian herbal medicine uses maca as a stimulant for the immune system (as an immunostimulant) and to treat anemia, tuberculosis, menstrual disorders, menopause symptoms, stomach cancer, and sterility (and other reproductive and sexual disorders), and to enhance memory. In modern day, maca is commonly consumed as a health drink or with fruits and vegetables. While maca is appreciated for the rich nutrition it provides in the form of vitamin and protein content, it is most sought after as a fertility enhancer. Maca is generally consumed as a health drink, blended at market stands or even roadside stands along with other fruits or vegetables.

The world came to know about maca’s medicinal properties as early as 1961. Researchers tested maca on rats and found an increase in fertility, confirming its fertility-enhancing qualities. A Peruvian company called Quimica Suiza (the Peruvian distributor for the pharmaceutical giant AstraZeneca) was the largest company marketing maca derivatives for medicinal purposes.

Multiple U.S. companies purchased maca in its raw form directly from farmers or grew small chunks of it themselves. An example of such a practice was that of Herbs America, which marketed a product called Maca Magic. Herbs America worked directly with farmers in Peru and produced raw tubers, then collaborated with local manufacturers to produce the maca derivative.

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14 http://rainforest-database.com/plants/maca.htm
Maca was valued for its putative properties; it acted as ‘natural Viagra.’ While certain firms were sensitive to the concerns (both cultural and economic) of the indigenous farmers, there were no regulations regarding maca production and purchase. Many companies had tried and succeeded in patenting the maca extract for different uses and applications and had also patented the maca extraction techniques. The patenting activities of one company, Pure World, received the most attention.

In July 2001, Pure World Botanicals, Inc., a U.S. pharmaceutical company based in New Jersey that specialized in botanical extracts, patented the extracts of the maca plant and began selling it to treat sexual dysfunction. Pure World received a U.S. patent for exclusive commercial distribution of maca extracts, which the company branded as MacaPure.\textsuperscript{15} The company took an extra step, going so far as to patent the extraction technique. Pure World filed for two patents—Patent No. 6267995 titled the ‘Extraction of \textit{Lepidium meyenii} roots for pharmaceutical applications’ and Patent No. 6428824 titled ‘Treatment of sexual dysfunction with an extract of \textit{Lepidium meyenii} roots.’ The first patent secured the method of extraction and the second patent used the extracts of maca to boost fertility.

Both the medicinal use of the maca extract and the extraction techniques were known indigenously to the local people of Peru. The extraction technique that Pure World patented was an alcoholic extraction of the maca root. The alcoholic extraction technique had been used in the regions of Junin for centuries. Also, Pure World was using the extraction technique to extract the active ingredients from maca and selling powders and capsules that would boost fertility. The patent translated to exclusive commercial distribution of maca extracts, the libido-enhancing components of maca, which the company went on to brand as MacaPure.\textsuperscript{16}

\textsuperscript{15} \url{http://web.williams.edu/go/native/maca.htm}
\textsuperscript{16} \url{http://web.williams.edu/go/native/maca.htm}
Maca became a part of a rapidly expanding market and was recognized as a product with huge potential, particularly in Europe, the U.S., and Japan. However, as Pure World had exclusive rights over maca in the U.S., if Pure World enforced the patent, the company could prevent other companies from importing maca of Peruvian origin to the United States (or, for that matter, to any country where the patent was recognized).

Pure World operated the largest botanical extraction facility in North America, where it extracted close to 15,000 pounds of botanical materials on a daily basis, and maca was one of the 1,000 plant extracts that were extracted out of the facility.

Pure World claimed it was not harming Peruvians, but was helping them, as the money Pure World invested into maca research made it a useful commodity and created a market that did not exist before. This had increased market demand for maca extracts. But, demand for maca increased manifold, resulting in overproduction and, consequentially, depressed prices and losses for some small farmers.

The patent was boosting the demand for maca, mainly from the U.S. The patent actually went on to triple Peru’s exports of maca from "$1.3 million in 2000 to more than $3 million annually since 2003, according to the Exporters Association of Peru."17

Still, the patents caused quite a stir in Peru and all over Latin America. Local stakeholders contended that patenting indigenous knowledge was unethical and unacceptable, as traditional knowledge was being stolen from farming communities. In 2002, almost a dozen Peruvian farming, cultural, and environmental organizations got together with other maca farmers and international activists, formed a coalition, and began seeking support from the Lima-based International Potato Center (CIP), one of the research centers of the Consultative Group on

17 http://web.williams.edu/go/native/maca.htm
International Agricultural Research (CGIAR). They gathered and formally protested the patents covering maca.

The coalition was not trying to claim maca for itself, but simply wanted to return the plant to their cultural domain. The Andean communities were benefitting from the increased exports, but were not receiving any royalties, as the patentees were mining gold through the sale of maca and using extraction techniques that were indigenous knowledge. Indigenous people in Peru considered suing the companies in question to overturn the patents on maca. Peruvian officials called the patent an ‘emblematic case’ of bio-piracy.\textsuperscript{18} The patent could prevent maca extracts produced in Peru from being imported in the U.S.

The farmers wanted the CIP, as the promoter and protector of the maca seed, to take action against the claims. They demanded action not only against the seeds and the genetic material, but also on the traditional knowledge that they felt the indigenous communities held.

A Peruvian IP protection group formed a working group to analyze the patents and determine the effect the patents would have on Peru. The working group consisted of representatives from the Ministry of Foreign Relations, the Ministry of Foreign Trade and Tourism (MINCETUR), and the CIP, among many others. This working group prioritized three maca patents that they first wanted to fight. The group worked with scientists and exporters of maca to build a solid case; they compiled documents on the prior use of maca and the preparation techniques, making sure the dates were, in fact, prior to the filing dates of the patent applications. In May 2003, the working group submitted a report highlighting the issues that plagued Peru in the domain of bio-piracy to the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge, and Folklore.

\textsuperscript{18} http://web.williams.edu/go/native/maca.htm
The coalition, led by the farmers, began by calling on two U.S. companies to take back their patents related to maca—and began seeking the help of the Peruvian government and the World Intellectual Property Organization (WIPO)—to help them investigate their claims that maca was developed from traditional knowledge.  

The working group pushed the Embassy of Peru in the U.S. to supply them with the copies of the official documents of the patents held by Pure World, as well as some other documents. In November 2002, the group wrote to Natalie Koether, president of Pure World, mentioning their concerns about the effect the patents would have on the Peruvians. No reply was received.

Certain claims found in two of Pure World’s patents (6,267,995 and 6,428,824) were analyzed by INDECOPI and determined to not meet the inventiveness level.

‘Qun Yi Zheng, Pure World's former president and chief scientist, says that the company invested more than $1 million and three years of research in the endeavor and that it popularized maca as a worldwide Peruvian export. Peruvians ‘should not be so narrow-minded,’ Zheng said, but should instead be grateful. ‘After we studied it, put money into the research, (maca) has become a useful commodity.’”

In 2005, a French company called Naturex bought Pure World. The marketing manager of Naturex, Antoine Dauby, acknowledged that the indigenous Peruvians had discovered the beneficial properties of maca long before and mentioned how the patent did not interfere with them or their cultivation in any which way. He contended that Peruvians were still allowed ‘grow, sell and use maca as they have for centuries.”

The company’s defense was that their patents covered the extraction and the isolation of the active ingredients in maca and did not cover anything else. A positive step that Naturex took was to open up the Pure World maca

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19 Peruvian Farmers and Indigenous People Denounce Maca Patents, ETC Group
20 http://web.williams.edu/go/native/maca.htm
21 http://web.williams.edu/go/native/maca.htm
patents to all Peruvian entities, which allowed Peruvian companies to freely use the techniques and information that were patented by Pure World and also market the resulting products.

After all the litigation and the efforts, the working group did manage to trigger inspections of the patents covering maca. In 2010, the EPO cancelled several patents on maca following action by the Peruvian National Anti-Bio-piracy Commission. However, the U.S. patents granted to Pure World stand ground. While Naturex has extended a hand of ‘kindness’ to the Peruvians, the case still remains as a stark example of bio-piracy where the indigenous bearers of the knowledge did not benefit. It was too difficult for the local stakeholders to provide scientific proof that Pure World's formula and extraction techniques were not novel and useful.

The case of maca is a case where a very strong coalition was formed between the local community and an NGO/government body. More importantly, the patent had considerable strength. As pushback was initiated, litigation was triggered, but the patent survived, as it was considered a novel invention. Ultimately, the maca patent remains, resulting in no ultimate benefit to the local community, but considerable benefit to the patent holders.

Hence, the case of maca is an instance of a (i) strong stakeholder coalition and (ii) very strong patent claim strength leading to a win-loss outcome.
Case study of Kanis

Kanis (*Trichopus zeylanicus*) is a rhizomatous, perennial herb, found in Sri Lanka, Malaysia, and southern India. In each of these locations, the herb is found in different conditions—in lowly sandy forests near water bodies in Sri Lanka, in low-lying forests in the Malay Peninsula, and in altitudes around 1,000 meters in India. Only the Indian version of the herb (*Trichopus zeylanicus travancoricus*) has strong medicinal properties, and these medicinal properties are strongest in the plants that grow in the wild or are cultivated in forest areas.

The Kani tribes have been the traditional users of *Trichopus zeylanicus travancoricus*. The Kani people are traditionally nomadic, but have gradually eased into settled life in the forests of the Western Ghats, a mountain range along southwestern India. The Kani tribe population was around 25,000 in late 2012. Most of the forest area in and around the location of the Kanis has been classified as a reserved forest under the Indian Forest Act of 1927. A reserved forest implied that in the area, acts need to be ratified and approved by the forest officer or the state government. The forest department would regularly issue a list of minor forest produce that could be extracted by the tribes.

The Tropical Botanical Garden and Research Institute (TBGRI), located in Kerala, India, is an autonomous institution and the largest botanical garden in Asia. It is a center for plant research spreading over 300 acres, having 50,000 accessions belonging to 12,000 genetic variants of 7,000 tropical plant species. The TBGRI had an active R&D wing, which aimed at conserving and sustainably utilizing the plant diversity of tropical India.

The discovery of the potential of the *Trichopus zeylanicus travancoricus* began in December 1987 when a team of scientists led by Dr. Pushpangadan from the All India Coordinated Research Project on Ethnobiology (AICRPE) began a botanical expedition into the

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22 http://www.downtoearth.org.in/content/kani-learning
Agastya forests of the Western Ghats. The group was led by three guides from the Kani tribe. The trek was exhausting, but the scientists noticed that the Kani men were full of energy after eating the black fruit of a plant. The scientists tried the fruit and they, too, felt stronger and more energetic. The scientists were eventually able to collect some specimens of the plant to study.

Once back at the laboratory, the team began work to isolate the active ingredients. It turned out to be *Trichopus zeylanicus travancoricus*. Scientists had heard of the plant before, but were unaware of its uses. The scientists determined that the leaves of the plant were also useful as they had immunodulatory/immunorestorative, anti-hepatotoxic, and antistress properties.

In 1995, scientists developed a drug called Jeevani, which contained *Trichopus zeylanicus travancoricus* as one of its ingredients. The scientists were using the leaves, not the fruit, in Jeevani as a restorative, immune-enhancing, antistress, and antifatigue agent.

Back at TBGRI where Dr. Pushpangadan now worked, scientists identified one compound from the plant and a patent application was filed for it. Thus, in 1996, TBGRI filed a process patent application to manufacture an herbal sport medicine, in granule or suspension form, based on the compounds isolated from aarogyappacha.

Post his move to TBGRI, Dr. Pushpangadan began exploring options for benefit sharing and value addition. Eventually TBGRI was authorized to transfer the technology for manufacturing Jeevani to interested parties, for an appropriate license fee. In 1996, Arya Vaidya Pharmacy Ltd. was selected to manufacture Jeevani for a period of seven years for a license fee of Rupees 10 lakhs. In addition to the license fees, Arya Vaidya Pharmacy would have to pay the TBGRI 2 percent of the sales as a royalty.

The TBGRI was looking at sharing the benefits of the commercialization of Jeevani with the Kani people, as it was these tribes who had initially discovered the properties of the fruit. A
resolution was passed that gave the Kani tribes 50 percent of the license fee and 50 percent of the royalties obtained by TBGRI on the sale of the drug. Thus, the TBGRI was looking to share half of what it would be getting from the commercialization of the drug with the Kani people.

TBGRI had been interacting with the Kanis from the Kuttichal Gram Panchayat area (the Kanis who had been the guides for the scientists)\(^{23}\). This section of Kanis has been supportive of TBGRI’s role. However, Kanis in other areas—the Vithura and Peringamala Panchayat areas—had not been a part of the discussions and some were offended by TBGRI’s actions. They saw it as TBGRI pirating their indigenous knowledge.

In mid-1995, opposition grew. The legislative assembly at Kerala felt the royalty amounts the Kanis would receive were too low. The government owned Kerala Institute for Research, Training and Development of Scheduled Castes and Scheduled Tribes (KIRTADS) also made the case that the agreement was unfair. These groups organized the Kanis and shared their concerns that (1) not all Kani tribes had been involved in the discussions; (2) the benefit-sharing package was not fair to the Kani people; and (3) once the commercialization of the plant began, the company would deplete the natural abundance of the plant.

The TBGRI responded that while it had been in communication and consultation with the Kanis of one area, it has not involved all tribe members. However, it would now set up a mechanism to share rents with the Kani tribe. Since the community did not have a formal method of receiving its share, the Kerala Kani Samudaya Kshema Trust was formed in November 1997. The plan was for the trust to have all the adult Kanis in Kerala as its members. By December 1997, the total membership stood at 500, while the membership drive had covered about 40 tribal

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\(^{23}\) The Panchayati Raj system is a governance method. Each Panchayat area has a number of wards in it, and each ward is made up of a village council of 1,000 to 2,000 members.
settlements by then. The most encouraging point was that there had been no opposition from any of the Kanis in the 40 tribal settlements.

The first licensing fee payment (Rupees 5 lakh) and royalties (Rupees 19,000) of the benefit-sharing formula were deposited into the trust in 1999. The Kanis were also granted Rupees 50,000 as a special incentive for providing the information to the scientists. Apart from this, the trust received Rupees 1.5 lakh annually as royalty payments until 2008.24

Over time, the drug has made headlines. Its potential was acknowledged in prestigious journals like Nature and magazines like Time. The latest U.S. research shows that the plant has antioxidant and DNA-protecting properties.

Hence, the Kanis case is an instance of (i) strong stakeholder coalition) and (ii) moderately weak patent claim strength leading to a win-win outcome.

**Case study of hoodia**

Hoodia gordonii (or simply hoodia) is a cactus-like plant primarily found in semi-desert regions of South Africa, Namibia, and Angola. Hoodia belongs to the family Apocynaceae. Hoodia grows well in extreme heat, but can withstand the cold as well. The plant grows in harsh conditions and is a spiny succulent which, in its mature form, can have as many as 50 branches and can weigh as much as 65 pounds. Hoodia bears large flowers, smells of rotten meat, and has a bitter taste. Hoodia is a protected species in Southern Africa, so activities related to hoodia require permits. The only active ingredient present in hoodia is a steroidal glycoside called ‘p57.’ Out of the 20 species of hoodia, only hoodia gordonii contains p57.

Hoodia is commonly eaten raw, after removing the spines from the plant. The San Bushmen of the Kalahari Desert have known about hoodia’s properties—it suppresses hunger (appetite) and thirst and increases alertness—for thousands of years. The San people have used

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24 http://www.downtoearth.org.in/content/kaniking-learning
hoodia to ward off hunger and thirst while on long hunting trips where food and water would be unavailable for days. The Bushmen would slice off a stem of the cactus nearly the size of a cucumber and eat it over a couple of days, alleviating hunger and thirst and increasing their awareness.

Scientists from South Africa’s national laboratory, CSIR, began studying hoodia in 1963. In experiments, they observed that lab animals lost weight after ingesting hoodia. These animals did not suffer from any side effects, which made hoodia an ideal choice for an appetite suppressant in humans. (The drug used in diet pills in the Western world at the time was ephedra paired with caffeine, which left the consumer feeling jittery.)

The scientists at CSIR were working with a British company, Phytopharm. These scientists found that hoodia contained a previously undiscovered molecule that was responsible for the plant’s appetite-suppressing effects. CSIR then isolated the active ingredient in hoodia gordonii, which they named p57.

The scientists at CSIR patented p57 in 1996, so as to license the rights for future development. Under the patent, CSIR could allow other companies to use the active agent in their products. In 1997, they licensed p57 to Phytopharm and, at the same time, set up a sustainable production system for Phytopharm as well. Phytopharm has, since then, spent more than $20 million on hoodia research. In 1998, Phytopharm sublicensed the rights to develop p57 to Pfizer for $21 million for the development and global commercialization. Pfizer wanted to develop a prescription drug that they estimated would have a market potential of $1 to $8 billion annually.25

None of these companies involved with hoodia earmarked any of the projected royalties to the San people. When news of the licensing spread, the media negatively focused on

Phytopharm, which defended its actions by stating that the 100,000-strong San people were all dead.\(^\text{26}\)

While the patent had no economic impact on the indigenous people, it was an instance of bio-piracy—equal to theft.\(^\text{27}\) As companies kept securing the rights to sell hoodia-based products and as licenses were expanded and granted, there was not a single mention of the San people receiving any benefits from the commercialization of their traditional knowledge.

Indigenous knowledge led to discovery of the first plant that could become a commercially viable appetite suppressant (diet pill). The market for such a pill was huge. The most shocking and disconcerting aspect of the hoodia patent was that the patentee itself was a governmental organization, the CSIR.

Only when CSIR licensed the development rights to Phytopharm and the media extensively covered the incident did the San people find out about the patent. The San threatened CSIR with legal action in order to get their fair share of benefits. CSIR had failed to consult with the San early in the commercial development of hoodia, and this considerably strengthened the San’s bargaining arm and political leverage. Hoodia became a high profile case followed throughout the world. The media jumped in, showing contrasting images of emaciated San and certain obese Americans, and reinforcing the instances of bio-piracy by large companies against helpless indigenous people. Public pressure was galvanized, compelling CSIR to enter into negotiations with the San.\(^\text{28}\)

A few years after the patent was filed, the South African San Council launched a claim against the CSIR. The claim stated that the body had failed to comply with the rules of the 1992 Convention on Biological Diversity (CBD), which required prior informed consent.


\(^{27}\) [http://www.rebirth.co.za/hoodia/san_tribe_and_bio-piracy.htm](http://www.rebirth.co.za/hoodia/san_tribe_and_bio-piracy.htm)

Consequently, a memorandum of understanding was reached between the parties in March 2002, after three years of the council negotiating with the CSIR on behalf of the San in Angola, Botswana, Namibia, Zambia, and Zimbabwe. The memorandum of understanding formally recognized the San as the originators of the traditional knowledge associated with human use of hoodia. The San, at the same time, acknowledged the need of the CSIR to protect its investment in hoodia (as the CSIR had worked for years to isolate the active ingredient in hoodia).  

At a ceremony in Andriesvale, a remote area of the Kalahari, the South African San Council and the CSIR signed an agreement that recognized and rewarded the San as holders of traditional knowledge of hoodia. Along with a share of the profits, the San people would receive access to educational and computer training programs as well as jobs cultivating hoodia. In terms of a benefit-sharing agreement with the CSIR, all the San communities in the range states would benefit from the development of p57. The San people were to receive 6 percent of CSIR’s royalties and 8 percent of all milestone payments that were received from Phytopharm. The income would go to a San hoodia benefit-sharing trust. The trust would then invest the money in improving the well-being of the San and their standard of living.

This deal was one of the first instances where indigenous people received a share of royalties for their traditional knowledge. Hoodia’s case is a stark example of victory for the holders of traditional knowledge. It was an instance where a bilateral agreement could be reached and the matter could be resolved. Such bilateral agreements on access and benefit sharing are rare.

An interesting chain of events followed once the memorandum of understanding was signed with the San people. Soon after, Pfizer decided to terminate its p57 research and it

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returned the rights to Phytopharm in 2002. This hinted that Pfizer felt that hoodia did not have merit in oral use. Pfizer researchers noted that it was difficult to synthesize p57 and that they had seen some undesirable effects on the liver.

In December, 2004, Phytopharm gave the hoodia license to a larger company, Unilever. Unilever was already producing diet products, such as Slim Fast and others. Unilever claimed that it would not make pharmaceuticals from hoodia, but would instead sell ‘functional food’ products that would be made from hoodia. Unilever had planned to cover the new products with a new set of patents, again with no mention of the San people. The previous benefit-sharing agreement had not involved Unilever, only Pfizer. Phytopharm received $12.5 million from Unilever and was to receive $27.5 million more plus an undisclosed royalty once the Unilever products were commercialized. However, in 2008, even Unilever went on to abandon plans to use hoodia in any of its diet products. Unilever announced that it was abandoning its plans to use hoodia, as ‘products using hoodia would not meet our strict standards of safety and efficacy.’

Due to the hype created by hoodia, a series of intellectual property claims have been filed. In October 2004, hoodia was placed in Appendix II of Convention on International Trade in Endangered Species (CITES). Companies continued to market products that allegedly contained hoodia extracts. Up to 2009, Phytopharm had spent more than $20 million on research, including clinical trials with obese volunteers that yielded positive results. By 2010, the San trust had received around $100,000.

In the hoodia case, a strong coalition was formed between the local community and an NGO/government body. The CSIR’S patent had moderately high strength. As pushback was initiated, the patent did not get squashed, but some value was created for the local community.

31 http://en.wikipedia.org/wiki/Hoodia
Hence, the hoodia case is an instance of a (i) strong stakeholder coalition and (ii) moderately high patent claim strength) leading to a win-win situation. The gains for the local stakeholders have however not been as extensive as the kanis case, given the moderately high strength of the original patent and subsequent patents.

**DISCUSSION**

Our paper contributes to several streams of the strategy literature. We contribute to the strategy literature that looks at firms appropriating rents from new technologies (Arora *et al.*, 2001; Teece 1988). We contribute to this literature by studying newly discovered technologies that are embedded in emerging market traditional communities. We outline conditions for the focal firm to appropriate rents from patenting such traditional technologies and both theoretically and empirically show that whether or not the focal firm is able to appropriate rents depends on the strength of the patent claim.

We also contribute to the recent literature in strategy that studies firms managing stakeholders (e.g., Henisz *et al.*, 2011; Dorobantu *et al.*, 2012). We build on stakeholder theory and the literature of stakeholder networks to theoretically identify conditions under which local stakeholders using the traditional technologies can appropriate part of the rents from patenting the traditional technology. We show that this depends on whether or not the affected local stakeholders form a coalition with larger national stakeholders with access to legal, financial, and technological resources. In summary, our theoretical analysis identifies two conditions under which rents from the patent are shared between the focal firm and affected local stakeholders: (1) the strength of the focal firm patent should be moderate; (2) local stakeholders should form a coalition with larger national stakeholders in contesting the claims of the focal firm.
We empirically study this in the context of firms filing herbal patents and employ a two-pronged empirical strategy to test our theoretical predictions. On the one hand, we employ a fuzzy set QCA analysis based on the methodology outlined by Ragin (1987, 2008). This methodology is particularly suitable for our analysis given that we have 17 case studies of herbal patenting. We follow this up by conducting four in-depth qualitative case studies. Both the fsQCA analysis and the case studies support our theoretical predictions.

Our results also make a contribution to the literature in strategy and international business that looks at multinational firms (MNCs) dealing with disaggregated state and civil society actors in host countries (e.g., Delios and Henisz, 2002; Henisz and Zelner, 2005; Holburn and Zelner, 2010, etc.). In this literature, the core periphery framework in Choudhury et al. (2012) outlines the disaggregated nature of state actors in emerging markets and how MNCs have to deal with actors in the periphery. In the current study, a focal firm having to manage local stakeholders is an example of dealing with the periphery.

Finally, from a policy perspective, our results contribute to the ‘North-South’ innovation literature in trade economics and policy (Grossman and Lai, 2004; Chen and Puttitanun, 2005). This literature has traditionally characterized Western entities as innovators and emerging market entities as imitators. However, in the context of herbal patents, these roles can be reversed if the Western firm engages in bio-piracy and appropriates all rents from filing an herbal patent. In this paper, we provide theoretical and empirical validation that bio-piracy is avoidable and outline conditions under which both the potentially ‘northern’ firm and the ‘southern’ local stakeholder can both benefit from herbal patenting.
REFERENCES


Figure 1. Potential outcomes of litigation between firms and local stakeholders

Notes:

The X axis refers to outcomes for the focal firm and the Y axis refers to outcomes for the local stakeholder. Table 1 provides detailed descriptions of these outcomes.
Figure 2. Firm-local stakeholders litigation scenarios

Notes:

**W,L** – firm wins, local stakeholders lose
- No litigation or no pushback from the local stakeholders or from any other external stakeholders; the firm keeps patent
- Litigation/pushback takes place, but the patent claim is strong, and the patent is a novel invention; firm keeps patent
- No coalition formed and weak litigation/pushback takes place; even if the patent claim is weak or moderately strong, the firm retains the patent in a W,L

**L,L** – Both firm and local stakeholders lose
- Firm has a weak claim on the patent; coalition is formed and a strong pushback takes place; patent is squashed

**W,W** – Both firm and local stakeholders win
- Patent has a moderately strong claim; coalition is formed and a strong pushback takes place; firm agrees to share rents to subdue pushback
- Patent has a moderately strong; coalition is formed and a strong pushback takes place; litigation rules that firm should share rents with local stakeholders
- Firm recognizes the claim of the local stakeholders and wants to appease the local stakeholders to keep any conflict at bay; agrees to share rents
Figure 3. Frequency distribution of herbal patents as compared to the overall patents filed under USPTO (1977-2010). Data collected by researchers based on keyword search of herbal patents
Table 1. Description of potential outcomes in litigation between focal firm and local stakeholder

<table>
<thead>
<tr>
<th>Outcome Type (Firm, stakeholders)</th>
<th>Overall outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1</strong> W,W</td>
<td>This outcome refers to a condition where both the focal firm and the local stakeholders win—the focal firm continues to extract rents, and the local community shares the rents. This outcome is a result of two conditions – (i) the patent claim having moderate strength and (ii) the local stakeholder forming a strong coalition with other stakeholders who have access to financial, legal and technical resources.</td>
</tr>
<tr>
<td><strong>2</strong> W,L</td>
<td>This outcome refers to a condition where the focal firm wins, while the local stakeholders lose. Hence, the firm continues to extract rents, while the local stakeholders get no benefit. This situation arises when there is no pushback or when the firm has a strong claim and wins the litigation, thus retaining the patent.</td>
</tr>
<tr>
<td><strong>3</strong> L,L</td>
<td>This outcome refers to a condition when both the focal firm and the local stakeholders lose. For the firm, this refers to a case where the firm cannot continue to derive rents, while for the local stakeholders, it means that no benefit was derived from the firm. This outcome occurs when the patent is invalidated, leading to no rents for the firm and no benefit for the local stakeholders.</td>
</tr>
<tr>
<td><strong>4</strong> L,W</td>
<td>This outcome is not possible, as it is an instance where the firm loses and the local stakeholder community wins. In case of the patent being invalidated, the firm may merely exit. In no plausible circumstance would the local stakeholders benefit without the firm also benefiting.</td>
</tr>
<tr>
<td>Name of the Herb</td>
<td>Country of Origin</td>
</tr>
<tr>
<td>------------------</td>
<td>------------------</td>
</tr>
<tr>
<td>Maca Extract</td>
<td>Peru</td>
</tr>
<tr>
<td>Large variety of herbs</td>
<td>Costa Rica</td>
</tr>
<tr>
<td>Turmeric</td>
<td>India</td>
</tr>
<tr>
<td>Neem</td>
<td>India</td>
</tr>
<tr>
<td>Basmati</td>
<td>India</td>
</tr>
<tr>
<td>Hoodia</td>
<td>Africa</td>
</tr>
<tr>
<td>Sacha Inchi</td>
<td>Amazon</td>
</tr>
<tr>
<td>Pelargonium</td>
<td>South Africa</td>
</tr>
<tr>
<td>------------</td>
<td>--------------</td>
</tr>
<tr>
<td>Tipir</td>
<td>Amazonia</td>
</tr>
<tr>
<td>Quinoa</td>
<td>Around the Andes</td>
</tr>
<tr>
<td>Enola</td>
<td>Mexico</td>
</tr>
<tr>
<td>Rosy periwinkle</td>
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<tr>
<td>Ayahuasca</td>
<td>Amazon region</td>
</tr>
<tr>
<td>Pudina</td>
<td>India</td>
</tr>
<tr>
<td>Kalamegha</td>
<td>Southern and Southeastern Asia</td>
</tr>
<tr>
<td>Genetic samples collected from Solomon Islands.</td>
<td>Solomon Islands</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Trichopus zeylanicus</td>
<td>South India and other Asian nations</td>
</tr>
</tbody>
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Table 3. Calibration table for fsQCA

<table>
<thead>
<tr>
<th>Herb</th>
<th>Coalition-FZ</th>
<th>Patent_strength-FZ</th>
<th>Firm-FZ</th>
<th>Local-FZ</th>
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</thead>
<tbody>
<tr>
<td>Maca extract</td>
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<td>0.6</td>
<td>0.9</td>
<td>0.3</td>
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<td>Turmeric</td>
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<td>0.1</td>
<td>0.1</td>
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<td>0.1</td>
<td>0.1</td>
<td>0.1</td>
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<td>0.1</td>
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<tr>
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<td>0.8</td>
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</tr>
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<td>0.1</td>
</tr>
<tr>
<td>Pelargonium</td>
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<td>0.1</td>
<td>0.1</td>
</tr>
<tr>
<td>Tipir</td>
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<td>0.7</td>
<td>0.8</td>
<td>0.1</td>
</tr>
<tr>
<td>Quinoa</td>
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<td>0.7</td>
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<tr>
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<td>0.7</td>
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<tr>
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<tr>
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<tr>
<td>Solomon Islands</td>
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<tr>
<td>Trichopus zeylanicus</td>
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<td>0.3</td>
<td>0.7</td>
<td>0.7</td>
</tr>
</tbody>
</table>

The postfix of ‘FZ’ in variable names indicates that the variables are fuzzy, and can take any values from 0-1
Table 4. Results of fsQCA analysis

<table>
<thead>
<tr>
<th></th>
<th>Firm Win</th>
<th>Stakeholder Win</th>
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</thead>
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<tr>
<td>Strength of Stakeholder Coalition</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Strength of Patent Claim</td>
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<td>●</td>
</tr>
<tr>
<td>Consistency</td>
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<td>0.651</td>
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<tr>
<td>Coverage</td>
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<tr>
<td>Unique Coverage</td>
<td>0.649</td>
<td>0.7</td>
</tr>
</tbody>
</table>

Solution Coverage: 0.649  Solution Consistency: 0.943
Solution Coverage: 0.7    Solution Consistency: 0.651