Intellectual Property Rights, Innovation and Healthcare: Unanswered questions in Theory and Policy*

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Abstract: Intellectual property regimes are usually presumed to exert positive inducements on technological innovation. However, given the dire nature of access to critical health technologies for most of the world's population, it is worth revisiting this assumption for health technologies. This paper situates intellectual property rights (IPRs) for health technologies at the intersection of three fields: innovation studies, welfare theories, and international political economy. It revisits the conceptual underpinnings of property rights with particular relevance for needs of today's industrializing, or so-called "developing" countries. This paper argues that the debates on IPR have poorly explored counterfactuals in pharmaceuticals and biotechnologies where other means of inducement may exist and innovations may arise in conditions where IPR is either absent or irrelevant. To do this, it first discusses utility as a basis for IPRs and the challenges –philosophical, theoretical and most importantly, practical- in translating this to real-world use. It draws on history to analyze pharmaceutical prior drug generations and alternate inducements. The article offers a novel conceptual framework to study innovation in developing contexts where IPR can

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be specifically situated. If the real goal is accessible and affordable healthcare- an issue of immense importance worldwide- then we may need to cease barking up the wrong tree of intellectual property rights.

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1. Introduction: Patents and health technologies

Patents are one type of intellectual property right. They are discussed here because they, perhaps disproportionately, have been visible in the health debates in terms of innovation, drug pricing and access. However, the discussion in this paper is primarily on technological innovation and its relevance for so-called "developing" or industrializing countries. Innovation here is taken to be "the processes by which firms master and get into practice product design and manufacturing processes that are new to them whether or not they are new to the universe, or even to the nation" (Nelson, 1992, p. 349). Indeed, technological learning means the dynamics of coping with both mature and new technologies. The technologies may be new to the firm in question, if not to the world (Schmookler, 1966, Nelson, 1992, Nelson and Rosenberg, 1993). Patents as institutions are seductive because they are primarily based on the idea that awarding of monopoly rights within the price-mechanism can determine inducements for innovation, and thus establish new bounds for market-based interventions.

Health technologies, especially in pharmaceuticals, have many peculiarities and may benefit from patent regimes in the case of innovation (see Mansfield 1986). However, these gains are off-set by contentious market debates of access to, and pricing of, medicines for poorer communities and countries (e.g. Correa 2004, Coriat and Orsi 2006). It is important to state (as later sections in this paper take up) that patents are only one among a range of institutions and issues affecting drug development on the one hand and access to drugs on the other. In particular, I will argue that pricing is driven not only by patent monopolies, but also by a range of other critical issues such as healthcare within social policy and welfare state institutions. Institutionally, markets can be created for certain types of health technologies and products. These markets and the economic rights embedded in patents are thus not *a priori* given institutions. Of particular concern, are the demand-side institutions other than IPRs such as insurance and procurement that affect inducement (e.g. Srinivas 2006, Srinivas forthcoming). Without ruling out the use of patents, there are thus other troubling microeconomic and institutional underpinnings of intellectual property rights and patents in particular, that have remained quietly unresolved.

Healthcare is beset by several unique problems that reflect these institutional issues. Arrow's papers (1962, 1963a) focus on different aspects of welfare theories: the first attuned to inventive activity itself, the second, the peculiarities of healthcare, more specifically, insufficiently well developed markets for information and the uncertainties associated with provision. His contention was that welfare economics and its optimal Pareto conditions remain unfulfilled because markets are underdeveloped in this respect. As we will see, Arrow's insights come in handy not only to probe whether the rate and direction of inventive activity is best ascribed to patents, but also whether the broader institutional concerns of healthcare are best served by overly-narrow focus on intellectual property itself.

IPRs within their industrial environment

More fundamentally, IPRs need to be assessed within their specific industrial institutional environment which diverge in several respects between industrialized and industrializing countries. There is sufficient evidence that the IPR effects on economic growth are ambiguous at best through quantitative and historical institutional studies (World Bank 2001, Chang 2001), as well as those on FDI inflows (e.g. Rasaiah 2001). Furthermore, patent effects on innovation by sector are highly variable as well (Mansfield 1986, the Yale study, CMS etc). Certainly, inter-country differences in technological profiles have been noted (see, recently Lall 2003) as have been the limits of patents even within industrializing countries (Jaffee and Lerner 2004, Merill et al. 2004). Moreover, a range of other methods may be even better at protecting a firm's R&D investments and spurring incentives for innovation (Levin et al. 1987, Cohen et al. 2000).

But while the overall impact of IPRs may be questionable, this is particularly so for health technologies. IPR impact on diffusion of knowledge in sectors such as pharmaceuticals can be minimal or negative (see Correa 2004). There is a growing consensus that patent rights, particularly through harmonization attempts the TRIPS agreement World Trade Organization, may be doing more harm than good technologies change within industrializing countries, and particularly in lowering cost and increasing access to medicine. This does not rule out patents conceivably influential under some circumstances for some technologies, and for certain types of industrial development. While some prior studies have critiqued the timing of IPRs and argued for a compatible 'stages of growth' perspective, most continue to allude to the problems of pricing and (especially cross-country) econometric studies that seek to remove the institutional context in which price is set and need is valued. However, I will argue here that IPRs have rarely been disassembled into their constitutive institutional elements, discussed in terms of valuations, means and goals, nor their relationship to different types of technological activity both within and between countries.

This paper does not engage with issues of patent scope or with the fact that patents can lead to potential future knowledge spillovers. The approach here is different: first, the utilitarian underpinnings of property rights and their institutional implications are discussed. Second, pharmaceuticals and biotechnology are explicitly discussed as that special case where the institutional aspects of monopoly rights in medicine are central. Third, the approach is to use IPRs not so much as linked to 'stages' of economic or technological development, but as inducements of one technological specialization over others- i.e. as a means of industrial shifts and to highlight the menus of options that are ignored in both industrial and innovation policies. Fourth, other means of inducement are discussed that have important planning and political implications for regulating markets. Finally, an alternate analytic framework (Srinivas and Sutz 2008) is used to discuss health technologies and their market contexts.

This paper does not set aside patents altogether as a possible means of inducement, nor of other means of appropriation. The point, however, is that our understanding and use of patent regimes is somewhat crude when it comes to dealing with technological specialization, especially in health, and its industrial planning and policy implications.

2. Industrial Dynamics and shifts: The argument of IPRs as primary inducements

Intellectual property is industrial and technological dynamics. How should we think about the *means* by which we induce innovation, to shift from one industrial structure to another, or shift from a specific intensity of specialization to another? IPRs are one such means of inducement.

From a microeconomic standpoint, patent regimes are traditionally seen as a second-best solution to dealing with market failure in information/knowledge markets. The underlying rationale for the first-best solution is that public subsidies be channeled to innovators until the point where the subsidy cost equals societal benefits, after which knowledge dissemination is promoted at marginal cost pricing. Even current economic theory recognizes that the optima for such a problem are complex at best, despairingly fuzzy at worst, in determining the size of the subsidy. In part, this is because of the difficulty in determining the optimal social benefit point, and thus patent rights are granted to counter purely static optimization with more dynamic ones. Therefore they represent the second-best practical form of the optimization process where goods are sold at as close to marginal cost (in principle) as possible and that to ensure perfect competition no one can reproduce the knowledge at low or zero cost.

In both sets of first and second-best solutions, the underlying premise is that utility in terms of social benefits is conceptually robust and can be straightforwardly determined by groups of actors. These social benefits can be thought of as the stimulation of innovation by a given enterprise, or stimulation of innovation by other enterprises, the use of new knowledge in technologically useful ways and the diffusion of knowledge to other innovators. It is also premised on the idea that contractual elements can be pre-defined and extended across countries and sectors, indeed across wide segments of technological activity itself.

Thus, it seems necessary to step back from detailed analyses of IPR effects and their more price-conscious and legal characteristics to ask whether the institutional elements underlying its fundamental assumptions of use might not require some further thought in the context of industrializing countries. It is worthwhile dwelling on the idea that means and goals within industrial and innovative activity are institutionalized in extremely different economic ways *between* countries, and *within* countries and sectors. I argue that to view intellectual property regimes as institutions with fresh eyes, we may need to step away entirely from current debates of trade and intellectual property. Instead, it is worth exploring the economic philosophy that underlies the idea of intellectual property regimes to provide some insights into the economic and policy options on which countries can actually draw.

3. Means, Goals and their intertwined institutional nature

To keep to its simplest elements, industrial dynamics for the purposes here can be thought of as being made up of at least two elements: (a) People working with tools in society, where cognition, social dynamics, economics and technology, all play a part (b) The social i.e. collective valuation of means and ends of industrial/technological specialization.

If we think of IPRs as an inducement mechanism, a means of industrial shifts, then we need to acknowledge that perhaps means and goals may not be entirely separable. When we pursue a technological innovation as a goal such as an antibiotic or a diagnostic kit, there may be a variety of intermediate means available to make that choice each with variable certainty. However, every means is related to each other, affecting the goal itself as well as the options left untouched. To quote Gandhi to underscore the policy-philosophy nexus and why the choices of which means to select is important: "*They say 'means are after all means.' I would say 'means are after all everything.' As the means so the* *end.*" (M.K. Gandhi 1924). Economically, this suggests that all choices can be quite inter-dependent, and an effective opportunity cost exists for every choice left untouched. Those means that are chosen influence goals and goal-setting, and goals influence means in turn (which is more evident). From an evolutionary perspective, we could assign statistical probabilities to a series of means and ends, and we are likely to find no clear functional map between means and ends. Nevertheless, we may well find means related to each other, and that the use of any single means may influence the use or non-use of another. The value conflicts between means and ends, is also highlighted in the next section. The examples explored later should make these points clear.

At a slightly more macro-scale, means affect which industrial and technological shifts are induced, and also to varying degrees, which direction subsequent shifts occur. In this sense, means are representations of valuations however implicit they may be, because they favor some options over others and some goals over others. Thus, means affect (and are affected by) (a) social i.e. collective valuation of the technological shift, and (b) the methodologies by which they are evaluated. However, neither means nor goals can be understood without acknowledging utility and preferences, on which private or social utility rests and I turn to this next.

4. Patent rights, utilitarianism and contracts

> "Utility is a metaphysical concept of impregnable circularity; utility is the quality in commodities that makes individuals want to buy them, and the fact that individuals want to buy commodities shows that they have utility." (Robinson 1962, p.47).

IPRs rest on price theory and the acknowledgement that monopoly rights need to exist to create inducement incentives. But price in an economy is simply a measure of exchange value, which is itself a measure of utility or the use value of the good or service. But utility, that strange animal, is the ability of goods to satisfy hedonistic wants, which leads us to the crux of the institutional (and very political) problem-how do we determine wants? Various institutions scholars have written about the difficulty of utility as a concept (see Hodgson 1988, Rutherford 1994 and Toole 1979), as have various other economists such as Robinson (1962). Although many theoretical paths link intellectual property to utility, the measure of use value or utility lies at the core of its subsequent monopoly granting right as an inducement mechanism. This does not remove patents as a means to an end, but it does raise questions as to the institutional foundations of theory and policy.

Let us raise several questions that follow here about this chain of reasoning regarding intellectual property and utility. The first set of these is theoretical, resting on economic basics such as prices, utility and institutions. Even were these theoretical challenges somehow resolved, there remain a series of practical planning and policy difficulties that manifest themselves in IPR realities and controversies as we witness them today. Thus, the second set of questions raised here is more practical, focusing on real-world institutional issues of translation and practice.

5. The Origin and Aggregation of preferences

Theoretically, utility is a messy idea. It requires an explicit preference set, yet does not require that we enquire either where or why those sets of preferences arose in society, or how those preferences are to be conveyed. Theoretically, at least, the preferences are conveyed through the price mechanism, but if wants (expressed as the implicit utility of the good or service) is unspecified, we cannot know that the granting of the monopoly will provide the utility needed. Hedonistic wants of this type are also complicated by the fact that social value is poorly expressed through this calculus. Tool argues, "The effort to use utility as the criterion of judgment in economics and social analysis is flawed for three interrelated reasons. It is inadmissible as a principle of social value because it is *tautological*, because it is *relativistic*, and because it is *inapplicable*". (Tool 1986, p. 91, italics in the original) Indeed, while individual preference s at least theoretically, are assumed to express perceived utility, and that in turn reflected in exchange value or price, the relationship between social value and the individual's utility criterion is at the very least unclear.

A variety of scholars have tried to express how individual wants might translate into aggregate or group wants and social valuations. However, even those branches of economics in Welfare Theory that attempt to do so are significantly troubled in large part because they do not specify where or how the preference set is assembled. Pareto Optimality and Axiomatic Choice Theory also harbor serious institutional challenges because they are unable to articulate the institutional basis for aggregate social needs and corresponding welfare (see Arrow 1963, Boulding 1970, Tool 1986, Hodgson 1998). One does not need to be an emboldened intuitionalist to suggest that the aggregation hides more than it reveals. Indeed, even within a more traditional neoclassical framework, scholars had already seen this challenge. Arrow (1963b) showed, without much institutional back and forth, that fundamental problems linger in "aggregating up" even if all other institutional issues were somehow resolved. Regarding industrial change, it is difficult to a priori distinguish between different industrial structures or dynamics using the utility calculus. In other words, macro-level industrial manifestations of expressed preferences are extremely difficult to show or defend. Equally, if induced technological shifts occur, it is complicated to understand whether this shift in industrial or technological specialization necessarily reflects some underlying shift in utility by consumers. Of clear value for development as a process of change, is whether institutional demand mechanisms reflect needs, (since demand is not equivalent to needs) and accounting for the fact that collective institutions of demand are always socially and politically embedded.

6. Creation of Public policies and Value Conflicts

Second, one can certainly see that 'needs' pertain to a form of specified preferences. In continuing to retain the language of strict choice and utility theory, models that study innovation inducement suffer from the inability to understand how communities might express their preferences, and are unable to specify the institutional channels through which needs are defined and met. They are then unable to shape public policy in novel ways to respond to these (unspecified) needs, or find channels of inducement that deliver the goods and services to various (needy) communities.

From a philosophical standpoint, IPRs force us to acknowledge value conflicts in public policy when policies do not necessarily seek a single, overarching goal. The case of health technologies is particularly emblematic of this value conflict because it is served by multiple domains of policy-industrial, health, innovation, other social policies and so forth. An instrumental rationality falls short because it contributes primarily to understanding how policy actors can achieve each of the goals in isolation but not necessarily how to resolve value conflicts between the various goals (see Thacher and Rein 2004). An example of this is how much of the IPR debate is currently devoted to calculating a trade-off between health benefits and industrial innovations in the pharmaceutical sector. Fundamentally, IPR may raise problems where a single metric-such as utility- to evaluate different goals may be impossible, but this does not imply that public policy is not worth pursuing. It simply means that other responses exist (not all of which rest on a necessary equality of values or goals), and are understudied.

7. Contracts and Proxy institutions: individual vs. institutional demand

Third, there are real-world problems using utility and non-explicit preferences. First, imagine a community is interested in a particular good or variant of a good (let us say certain drugs) and we need to find ways to induce innovators to provide it. Based purely on a utility calculus, we might wait for clear signals driven through market-expressed preference as price; that the community is willing to pay for the good. However, many practical pitfalls await such an approach to inducement.

We know that patents are a form of contract. Classic liberalism sees the world as made of a network of contractual relations. In this view, society is then a sum of contracts between people plus many enforcing agencies, and all of this, contract plus enforcement, is driven by self-interest (see discussion in Hodgson 1988, Rutherford, 1994). Various scholars have suggested that contracts do not spring from nothing. They arise from a web of community relations and understandings of pre-existing economic (and other) relationships. They also entail the necessity of non-contractual elements growing at same time as contractual elements (Durkheim 1893/1984 pp.154-160). In other words, an institutionalist would suggest that the Invisible Hand of the contract, only functions with a very Visible Hand for enforcement alongside. (Hodgson 1988, Durkheim 1893). These non-contractual elements, based on incomplete knowledge, the law, and societal responses to crises for example, are manifestations of collective social relationships, and may not be neatly indivisible into individual behavior. More problematically from a programmatic standpoint, perhaps, these contracts are often not based on contracting individuals (as in some aspects of patent law). Thus, although the patent holder may negotiate contracts individually, the beneficiaries of the innovation are not contracting individuals involved in approving the price or the means utilized. In other words, the proxy nature of intermediate institutions (often the government) plays a very important role in determining what the need is, how it is to be determined, and how it is to be satisfied (and by whom). This 'social regulation' has important industrial implications, especially in health. Thus, the specific process of institution building around inducement is equally important. These may emerge from formalized methods for the relevance and prioritization of research, action, outreach, determination of the modes of expression of community needs and how these map to explicit (and also more theoretical) preference set, the types of innovations to encourage, and the means of shifting from one technological specialization to another in order to better respond to communities. Each of these will encounter to varying degrees the value conflicts in public policy and planning processes and a range of possible means to achieve goals that may resolve these conflicts. This becomes especially important in explaining alternate inducements to innovation such as social insurance or public procurement as we see later.

8. Varieties of utility measures by different actors with the same goal

Fifth, determining whether utility is served and how it is to be measured is complicated by the fact that multiple parties engage in creating the innovation milieu. Each may have a different measure of utility and how it is communicated and responded to. Health after all, is a part of broader social policies, and a link exists between these policies and the conditions under which innovation is rewarded. In the realm of health, as in pharmaceuticals and biotechnologies, certain drugs being covered by private health insurers, or reimbursements through social welfare systems may tie innovations to various non-technological inducement sources. This link between induced product mix and the nature of social policies remains understudied, as does the contrast of how utility is measured and served by different actors for the same goal.

9. Methods Conflicts

A final difficulty with regard to the utility approach is that for the above-stated reasons, it is difficult to resolve different methodologies in analyzing effect of IPR on inducing certain industrial and technological shifts. The lack of explicit valuation of market creation for innovations leads not only to value conflicts as we saw earlier, but also to methods conflicts. For instance, econometric calculations on the effect of IPRs on innovation that may use specific forms of utility and pricing may be irreconcilable with institutional analyses on IPRs that are grounded in understanding how national innovation policies or 'systems' arise, and/or how communities express their preferences for such innovations. The objects of investigation in the two cases, although intellectual property rights, have entirely different levels of questioning of root causes, social effects and socio-economic and cognitive assumptions. It is conceivable that the outputs of an institutional study could conceivably make its way into much more robust assumptions for an econometric study. However, such instances of collaboration and communication between the different communities of economics scholars are yet rare. It should be clear that current tools to use utility theory as the conceptual basis for property rights is tautological, and has considerable theoretical and programmatic challenges for economics as a discipline and for economic development in practice.

10. The Political Economy of Industrial Structure[1]–seeking an alternate approach

Rosenberg asserted that "…It is obvious that only those inventions which are compatible with a country's needs will be widely adopted. I am making here a stronger assertion that a high proportion of the *inventions made* will reflect the particular needs of the economic environment in which they are developed." (Rosenberg, 1995: p.111, italics in the original). However, countries are never isolated. Abramovitz's approach to the "….trade-off between specialization and adaptability" (p. 388) remains central, as well as his unfortunately less developed and propagated ideas of the multiple forms of interaction between countries.

> "The catch-up hypothesis in its simple form is concerned with only one aspect of the economic relations among countries: technological borrowing by followers. In this view, a one-way stream of benefits flows from leaders to followers. A moment's reflection, however, exposes the inadequacy of that idea. (….). Moreover, the knowledge flows are not solely from leader to followers. A satisfactory account of the catch-up process must take into account of these multiple forms of interaction." (Abramovitz 1986, p. 398).

It is these multiple forms of interaction that require substantially different inducements, even for those capabilities that may be far less connected to world trade. However, considerable technological and institutional heterogeneity already exists within the South. A more useful approach would recognize this technological variety at its core.[2] Despite this variety, it is not obvious that inventions and adaptations in ICs have lived up to Rosenberg's expectation stated above except in aligning their production structures increasingly to their export, not necessarily domestic, environments. The important question to consider is whether IPRs or other inducements might be better able to orient inventions and innovations to their domestic environment. In the case of healthcare, this needs little explanation. In the case of domestic pharmaceutical, vaccine, or diagnostic productive capabilities, the inter-dependencies between countries can make the health situation of some all the more insecure, complicating the make versus buy choices available (witness global shortfalls in vaccines, or fluctuation in prices of essential drugs that are imported).

To discuss these interdependencies as well as special means and goals, I introduce here an alternate conceptual framing of the IPR issue, which views it as one among many inducements to innovation.

11. An alternate framing of innovation and industrial change

What we need therefore is some framework where the cognitive elements of innovation are tied to both local needs and international political economy. The cognitive elements of innovators are critical because they have often been the less investigated elements of IPR-induced innovations. Moses Abramovitz acknowledged insufficient attention paid to the interaction between "followers and leaders". "A satisfactory account of the catch-up process must take into account of these multiple forms of interaction" (Abramovitz, 1986, p. 398). The framework proposed rests on technological and cognitive interrelationships of innovation situated between advanced industrialized and industrializing nations.

A possible framework linking the cognitive and political economy elements of industrial development is captured by Srinivas and Sutz (2008). Consider 4 possible ways in which industrializing countries could describe their technological specializations. AICs are advanced industrialized countries. "Advanced" here refers not to any value statement about better or worse, but as a fraction of industrialization within the economy relative to agriculture i.e. the structural and related institutional components of industrial change. Loosely computed, AICs correspond to what we think of as "Northern" economies, and ICs, industrializing countries, are those in the "South". Figure 1 describes a first view of four permutations of inter-country technological relationships. The international component is displayed in the diagram such that at least four different technological inter-relationships between countries become visible. The point is that "catch-up" is more complex than any single pathway when the matrix in Figure 1 is analyzed.

Fig 1. AIC-IC Industrial dynamics and innovation

	Problems for which solutions have been found in AIC	**Problems for which solutions have not been ssearched or found in AICs**
Problems for which solutions-solutions suitable for ICs conditions exist	The vast majority of solutions acquired through technology transfer through minor modifications	Solutions to problems mainly posed in ICs and developed locally II
Problems for which solutions suitable for ICss conditions do not exist conditions	"Canonical" solutions exist, but for different scarcity reasons they are not suitable for IC III	No solutions (yet) IV

Source: Adapted from Srinivas and Sutz (2008)

As such, the utility criteria which I discussed earlier are doubly problematic in this context because:

1. The social valuation of each quadrant and what it represents is different for different actors

2. The participation of innovators and production of the innovations in each quadrant is different in terms of capabilities (e.g. access to education, exposure to international knowledge pools, influence of the North etc.)

3. Each quadrant's innovations have different inducement policy possibilities

4. Social benefits can be appropriated in different ways in each case, which is a critical economic planning and institutional question.

Means, goals and their intertwined nature for each type of effort are important. A straightforward utility calculus cannot differentiate which to these to provide weights at any one time (since these are structurally and institutional determined in specific historic ways) and cannot *a priori* determine how the "preference set" is expressed, by whom, and how it is negotiated (through what specific organizations and instruments). As discussed earlier, patents signify not only a very specific valuation for certain types of innovations but are also invariably negotiated through a set of proxy institutions. For example, government policy in many ICs often masks (or at least selectively interprets) unmet needs in ICs in ways that may be heavily influenced by Quadrant I goals to the detriment of others. This does not necessarily mean that inducement policies for innovation do not work. It does mean, however, that valuation of different efforts should be as explicit as possible in science and technology policies, industrial policy, and the rules within academia, since one-size-fits all prescriptions across technology capabilities, sectors, regions, and nations are quite meaningless.

The quadrants prove useful for IPR debates as well as a discussion of market structure and possible policy interventions. Naturally, industrializing countries (ICs) and advanced industrializing countries (AICs) are simply points along a spectrum for visualizing the interrelationships between the countries, the different types of problem classes, and the quadrants in which more theoretical and policy attention may be deserved. Unsurprisingly, the debates on IPR from the North focus almost exclusively with problems inherent within their own economies. On the other hand, debates from the South, most notably of the "dependent development" variety equally miss the point. Their great strength (from studies of Prebisch and other ECLAC scholars) lies in the acknowledgement and theorization (that Abramovitz and others refer to only in passing) that technological interdependencies exist and are critical. This insight is worth its weight in gold. However, the dependent development school underplays two issues: The first is the importance of varied types of interdependencies (situated in the multiple quadrants above) and their independence (some quadrants are far more linked than others since the technological problem or solution may not always arise in the North/AIC). It also under-emphasizes (although does not ignore) that it is precisely in the skewed planning and policy-setting environment of the South, that goals of technological development itself may need to be questioned if local needs are to be preferentially met. Thus, by underscoring the importance of the dependency, the goals may unduly shift in emphasis towards becoming "freer" in ways that are imitative of the North's own trajectories and policies (Quadrant I), instead of asking whether other "independent" varieties of technological effort do not already exist (such as in Quadrants II and IV). Moreoever, other sets of policies need to be in place to build up such capabilities since these may be closer to local needs and the construction of relevant local markets.

The inter-relationship is deliberately emphasized to indicate that in some cases, some part of industrializing country effort may do well in focusing on especially those local problems that are not of interest in AICs and for which IC capabilities already exist-such as cotton gins specifically for local cotton varieties or therapies that integrate Indian Ayurvedic medicines which may be cheaper, or construction using local materials, and local communities in their manufacture. Table 1 provides some examples of these innovations.

Furthermore, regarding the *input* capabilities required for innovation, the 2X2 framework presented here provides an alternate approach to viewing how certain types of problem-solving skills exist and how some might be more immediately relevant (but insufficiently captured) relative to health and other needs.

Table 1 Innovation typology for industrializing countries (ICs)

Quadrants	Description	Examples of innovations
I	Problems for which solutions have been found in AICs AND Problems for which solutions suitable for IC conditions exist with minor modifications	Cars adapted with higher chassis for roads in ICs, telephones,
II	Problems for which solutions have NOT been searched or found in AICs AND Problems for which solutions suitable for IC conditions exist (EVEN if using AIC technologies)	Cotton gins for local varieties in India, entirely indigenous solutions to agricultural and industrial problems in Africa, transforming dirty water into drinkable water using Northern technologies (but which final products are not available in the North)
III	Problems for which solutions have been found in AICs AND Problems for which solutions suitable for IC conditions DO NOT exist	Synthetic vaccine for Hib B, developed in Cuba, some types of "reverse engineering".
IV	Problems for which solutions have NOT been searched or found in AICs AND Problems for which solutions suitable for IC conditions DO NOT exist	"Neglected" diseases

Source: Adapted from Srinivas and Sutz (2008)

For the purposes of IPR, each row requires a different set of inducement options as well as perhaps a different appreciation of metrics that capture such effort and allow suitable resources to be available. Furthermore, each quadrant in the 2X2 can still use different levels of "make versus buy" both for problem definition as well as sourcing materials. An added advantage is that it provides us a lens into the sustainability debate from the standpoint of local capabilities for local needs. This is *not* to suggest that local needs should only be solved thorough local capabilities (i.e. an autarkic approach), but could provide ways of managing societal needs through local capabilities in a way that can thrive long-term, with local materials, with lesser expense and so forth. Notice importantly that these solutions need not at all be "low tech", nor purely for poorer communities. These are distinct from older appropriate technology approaches (for a fuller discussion, see Srinivas and Sutz 2008).

As may be clear from Fig. 1 and Table 1, a menu of options exist in reality, and quadrants II and II in particular receive the least attention from scholars, the media and from policy. In these two quadrants, particularly "idiosyncratic" ways of doing things emerge that are far more compatible with local technological realities than technological efforts in the other quadrants. In addition to this, each quadrant has some unique characteristics that require variegated inducement efforts. For example, in quadrant II, efforts may thrive outside formal R&D establishments (although many will occur within the establishment). For such efforts, inducements occurring through formalized market-oriented policy systems such as patent regimes may not be appropriate. These innovations first, often do not come to the same markets as others, second, they may not scale up and diffuse in the same ways, and third, they may be quite invisible in the first instance to most metrics that currently capture innovations.

Furthermore, one can analyze technological changes in sectors such as (bio) pharmaceuticals and agricultural biotechnology, where at different times in history, different variants of existing drugs (or hybrids) from the North have been used, or entirely new drugs or disease targets have been developed. One can understand the sectoral evolution by expressing quadrants I-IV via different country specializations (e.g. India in certain types of process innovations for generics, Indian and Chinese vaccine progressions, the historical changes in pharmaceutical capabilities of the former Soviet republics and so on). For each country, the question must be answered about which sets of capabilities, or mix of them, is important at any time, how they can be induced, and how to recognize and strengthen hitherto invisible ones.

Quadrant I is centre stage in discussions of technological advance or traditional "catch-up". Figure 2 has been adapted below to indicate that institutional efforts have been redirected disproportionately to some quadrants perhaps based on realities borrowed from other geographic locations, or from institutions formulated for multilateral harmonization, such as IPR regimes, technical standards and regulations. Furthermore, production heterogeneity in many industrializing countries is a significant issue but is almost entirely absent from technological debates. Figure 2 indicates that most production heterogeneity characteristics such as firm size, relationship to family units (home-based and contract work of certain types), use of technologies, regulatory or legal status, etc. are situated in quadrants other than I.

Fig 2. AIC-IC institutional and structural factors represented

	Problems for which solutions have been found in AIC	**Problems for which solutions have not been ssearched or found in AICs**
Problems for which solutions-solutions suitable for ICs conditions exist	The vast majority of solutions acquired through technology transfer through minor modifications [1]	Solutions to problems mainly posed in ICs and developed locally II [2]
Problems for which solutions suitable for ICss conditions do not exist conditions	"Canonical" solutions exist, but for different scarcity reasons they are not suitable for IC III [3]	No solutions (yet) IV [4]

Source: Adapted from Srinivas and Sutz (2008).

[1] Dominant political economy discourse here
Most debates of technical standards homogenization rest here
Most debates of IPR rest here

[2] Extreme heterogeneity in IC production (e.g. organizational forms, capability levels and access to skills and social protections). Occurs in I, but primarily in quadrants other than I where it is mostly ignored in policy

[3] Not just "reverse engineering" but truly idiosyncratic solutions
Extreme heterogeneity in IC production (e.g. organizational forms, capability levels and access to skills and social protections). Occurs in I, but primarily in quadrants other than I where it is mostly ignored in policy

[4] *Most debates of IPR rest here*
Extreme heterogeneity in IC production (e.g. organizational forms, capability levels and access to skills and social protections). Occurs in I, but primarily in quadrants other than I where it is mostly ignored in policy

Fig 2 is useful not only because they highlight how IPR has been selectively used as a study of industrial dynamics, but also because quadrants II and III are precisely the sorts of innovations that occur to some significant degree *without* formalized IPRs in place (indeed, in some cases, without even formal R&D institutions in place). II and III represent some extremely innovative outcomes in response to local needs that use "non-canonical" approaches to problem solving.[3] It is certainly unclear whether IPRs are necessary for such innovations. At the very least, they provide a rationale for why alternative inducement mechanisms and metrics need to be in place to capture the full range of technological effort occurring.

12. Other Counterfactuals: Varieties of Inducements

The fact that utility is a problematic concept may by itself not perhaps a compelling enough reason to study alternative ways to IPR of thinking of inducement. However, let us suggest here a variety of other reasons why we need alternatives. These arguments rest on the fact that (a) the counterfactual for inducement is improperly studied (b) important structural and institutional factors in industrializing countries have been under-researched, thus most models of innovation promise "trickle down" benefits in the worst sense. With regard to counterfactuals that are compelling in history and current debates, I next discuss three: technical standards, social protection/welfare regimes, and the cases of India and Brazil's pharmaceutical policies.

13. Technical standards and IPR-unresolved tensions

Standardisation is a very important component of industrial dynamics. Technical standards especially, signify new ways of doing this. These may range from quality standards to those of safety, health and the environment. The conflict between intellectual property and technical standards is a complex and unresolved one, often extremely context-specific (see for example, Lea and Hall 2004, Liotard and Bekkers 1999). A way to think of this shift is that two underlying processes in standardization are occurring at once: increasing complexity of tasks in any one unit and increasing diffusion of tasks across units (Srinivas 2005). Although technical standards discussions have been embedded within discussions of the World Trade Organization (WTO), the capabilities and institutions required to standardize are industrialize are important even without trade. Certainly, trade influences the pace of standardization but it does not exclusively determine it.

In general, IPR and technical standards may have different effects on innovation depending on what the type and goals of standardization are. For example, *de jure* standards are those developed by a professional group in certain specialization areas that is overseen for example, by the government, industry associations or even international organizations to ensure that publicly beneficial standardization occur. Once such standards are fully developed, they are officially recognized by standards-setting bodies, and disseminated as (voluntary or required) standards. On the other hand, d*e facto* standards, often attributed to market dominance and more often than not arising from proprietary technologies or platforms (e.g. Microsoft's operating system standards, or those used in the Apple iPod) may make the conversion of a *de facto* standard into a *de jure* standard a messy, often costly process for the consumer in an industrializing country. The property right-holder may be required to abdicate in favor of making the technical (proprietary) standard public. Moreover, standards setting and information dissemination assumes active participation in standards setting organizations, and the full knowledge and legal expertise of participants, conditions that are rarely fulfilled in most industrializing countries. While many scholars have made this argument on historical grounds for IPRs, they have rarely discussed the way IPRs and standardization are being forced to go hand in hand today and how this differs from history (for a discussion of needs-necessitated and harmonisation-necessitated industrial standards, see Srinivas 2005).

In prior periods of 20^{th} century industrial history, technical standards developed often without IPR playing as strong a role (as today) in electronics, semi-conductor technology, construction technologies, or automobiles. Whether or not IPR affects standardization in positive or detrimental ways for broader development concerns is a crucial question for policy.

Standards challenges can be found in other domain areas. These challenges, it is worth emphasizing, relate to both the innovation and diffusion of new knowledge, areas where IPRs are intended to have great benefits. Lea and Hall (2004) in analyzing the IT sector, for example specify that the following are important in decreasing order of importance in discussing technical standards and IPR: patent rights, utility models/petty patents, *sui generis* rights over semiconductor topographies, copyright and related rights (especially in software or databases), rights in industrial designs. They claim no inherent conflict, but one that has specific tensions dictated by mismatches within the control of negotiating parties. However, they argue that specific legal and policy instruments then come into play such as antitrust legislation against monopolies, or refusal to license conflicts.

In the case of GSM mobile devices for example, Bekkers, Duysters, and Verspagen (2001) highlight the potential complementary nature of IPR and technical standards, but acknowledge that the tensions are also notable. GSM standardization required critical 'essential' GSM IPRs without which standardization would have faltered as would have widespread use and the structuring of markets. Market power was closely correlated with network centrality and ownership of IPRs, but there are some notable exceptions (Ericsson and Siemens, but which rectified these partially through strategic technology agreements).

However, the lessons for countries industrializing today are far less clear. From a production standpoint, few of their companies are able to compete with those with early IP positions in terms of this story. From the access side, it is clear that as markets for GSM and other mobile communications have grown and competition increased, prices for consumers in these countries have dropped, lending themselves to various beneficial e-health, entrepreneurial and other aspects of the economy. In pharma and biotech, these complexities for IPR may be even greater. Within both pharmaceuticals and biotechnology, a variety of cGMP and clinical practice standards are not simply challenging to suppliers (what Srinivas 2004 calls "learning-by-proving"); they often require new intermediary platforms to achieve these standards, many of which are proprietary or expensive. In the biological domain, some of these intermediary 'tools' may be patented genes themselves, vital for further research in areas such as oncology and diabetes.

Therefore, in the case of developing countries as a group, the tensions between IP and technical standards are more palpable. When international trade "harmonization-necessitated standards" come up against "needs-necessitated standards" (dictated by not only local consumer profiles, but also the needs of diverse industrial production systems) conflicts arise with unresolved intellectual property issues. These are:

1. Ownership of the de facto technical standard and its associated costs.

2. Conditions under which these new technical standards are diffused

3. Ownership of tools and intermediary platforms to attain the technical standard

4. Conditions where a private standard becomes a de jure standard.

Each of these standards-related conflicts in national and regional varieties of production arise in part from contractual and utilitarian conflicts related to IPR such as licensing challenges regarding private control of technologies, platforms, products or processes of benefit to the public. Many depend on regulatory functions of the state and the decisions to restructure markets. Fundamental questions of industrial change remain regarding the ability of IPR and policy to ensure that 'utility' is served (for whom, for how long, at what cost?). These complex institutional issues are extremely challenging to model with partial or general equilibrium models, and most econometric methods cannot answer such questions. Because there is such a significant diversity of production types, many of which are outside Quadrant 1, and because there is little economic understanding of non-network industries where standardisation occurs, processes such as complexity and diffusion may lead to conflicting norms, utility and institutional divergence. Furthermore, we cannot extrapolate too freely from historical paths of industrialization. After all, the enforcement of IPRs in a homogenized way across the globe was absent at the time that these standardized shifts were occurring in many of today's advanced industrialized nations. Even within a neoclassical approach, IPRs and standards are jointly dysfunctional. "Moreover, due to the IPR problem, the standardization process can be prolonged or can even fail because patent holders are not willing to license their IPR. Therefore, sectors with a very high number of patents tend to standardize less." (Blind 2004. p.95).[4]

Production heterogeneity and mix of standards has implications particularly for large sectors, where an effective 2-tier of technologies exist in the industrialising world. One tier is involved with proprietary technologies (perhaps sourced from elsewhere, made at home, or in combination). The other tier employs the majority, is technologically less sophisticated, but may possess significant potential for enhancing capabilities, or for further work. Examples of such sectors, which have been quite ignored in the standards and IPR debate, in comparison with pharmaceuticals and health biotechnologies, are industrial and agri-biotech, garments and design and the construction industry and services. For instance agricultural biotechnology has been much more visible in IPR discussions but far less visible on standards.

14. Social and welfare policies as inducement factors of pharmaceutical innovations

The next issue counterfactual to IPRs here is a much understudied element of pharmaceutical innovations: health policy and wider welfare regimes. While standards provide one set of concerns other than IPR, there are others. I argue here that these may be social policies, but also the wider organizational context resulting from a surge of public supports for certain goals. In pharmaceuticals both technical standards and IPRs abound, but there is an additional feature that situates this sector in an entirely more important public dimension than GSM phones: Health innovations arising from pharmaceuticals (but also vaccines and diagnostics) enjoy disproportionate transfers from the public exchequer and close-to-guaranteed (if not guaranteed) market structure and access for their products and processes (and increasingly services as well) (see also Coriat et al. 2006, Correa 2004, and Srinivas forthcoming on relevant aspects of the access to medicines debate). However, because of these characteristics, the IPR case for pharmaceuticals, that IP may be the best tool for inducing innovations, needs to be revisited drawing from examples of industrial innovation history. While today, biotechnology provides new paradigms for this debate, several older aspects still dominate access to health technologies. Today's industrialized countries had regulatory context for appropriation that were set by their own domestic priorities and under different patent regimes (Orsenigo et al. 2006). It is often forgotten in today's IPR debates that pharmaceutical innovations arose from a complex set of scientific, technological and social factors. The last is often absent in these debates as to why technological innovations occur in practice and how they are shaped at many different stages and levels by social regulation of healthcare and work and employment status.

In general, pharmaceuticals and biopharmaceuticals afford considerable opportunity for investigating other means by which innovations emerged or potentially be supported. The SAPHHO study (Freeman et al. 1971, 1972) and a study on the Chemical Industry (Achilladelis et al. 1982. 1990), both identified seven highly influential forces that dictated the nature and scope of technological innovation exogenous to innovating institutions. These were scientific and technological advance, raw materials, market demand as evaluated prior to innovation, competition, societal needs (which could not be evaluated in terms of market demand prior), government legislation, firm-based S&T and market specialization (see Achilladelis and Antonakis 2001). As is clear, only the last is particular to the company, the rest are "environmental". Rosenberg's idea of 'focusing devices' provides us a sense of the varied sources of technical change that move beyond factor change analysis alone. However, this innovation environment is remarkably difficult to crack conceptually. What is clear, however, is that a range of inducement factors act on an innovating firm, patents being one of these. This comment on innovation environments as difficult to conceptualize in economics holds true not just for the inducement side for innovation, but also for spreading knowledge. Only a very initial foray into this complex topic is attempted here.

Consider, for example, that pharmaceutical innovations have emerged against a backdrop of a range of possible inducements. Between the years 1820-1992, a range of inducements created substantially different environments for scientific and technological innovation. Between 1820-1880, IPRs were quite absent from debates of innovation. In those years 1st generation drugs were developed, and these were "induced' so to speak, not through concerted innovation policies, but through a series of other institutional factors. As Table 2 indicates, 2nd generation drugs were also developed in the face of considerable societal pressures which signaled potential new markets and local demand, from rising negative effects of industrialization itself. These societal needs-"which could not be evaluated in terms of market demand prior to the decision to proceed with the development of an innovation" (Achilladelis and Antonakis 2001, p. 539), were enormously important. Indeed, the late era of colonialism also spurred a new approach to public health needs at home and abroad, requiring Britain to find new ways of combating disease and containing ill-health to prevent its colonial officers from falling ill overseas.

Table 2. Pharmaceutical drug generations and their varied inducement factors

Drug generations	Years of innovation and introduction	Inducement factors
1^{ST} generation drugs	1820-1880	Chemical Revolution (French School of Chemistry), largely mercantilist institutions, trade in medicinal inorganic chemicals and various indigenous medicinal products, importance of apothecaries.
2^{nd} generation drugs	1880-1930	Industrial revolution effects, overcrowding, disease, colonialism and public health-linked geography
3^{rd} generation drugs	1930-1960	WWII needs, public funds for cooperative projects, Welfare State legislation
4^{th} generation drugs	1930-1960	Public research institutions move into long-term exploratory work, regulation soars, (thalidomide), series of legislations
5^{th} generation drugs	1980-1992	Unemployment, aging populations, decrease in public support for health insurance, re-emergence of various international diseases

Source: Adapted by the author from Adilladelis and Antonakis (2001)

Whatever the reasoning, however, the inducement measures had little to do with private property rights alone and much to do with expanding markets and scientific advance. The explicit public involvement in institutionalizing the inducement was certainly clear for 3^{rd} generation drugs both in "mission mode" science for the war effort but also through various compacts made with the private sector to induce innovation. Private property rights were beginning to be clearly visible. Even here, however, they existed alongside a range of other inducements spurred by the post-War re-building of economies and creation of Welfare States with state subsidies, state procurement, health insurance and patent rights all existing alongside. Even in the 4th and 5th generation phases, which we have come to consider synonymous with patent rights and their inducement effects, innovation was shaped by a series of institutional shifts as Table 2 shows. Furthermore, the 1930s to 1960s saw significant government regulatory efforts putting curbs on pharmaceutical manufacturers after some high-profile disasters such as the thalidomide tragedy. Even in more recent times counterfactuals are challenging to establish for patent rights. For example, unemployment shifts, population demographic trends of aging populations and longer life expectancies, the diminished role for public expenditure on health insurance and the increase in various infectious diseases globally once thought to have been eradicated: all these have considerably shaped not only what companies research and develop, but how long they take to do it, how much they charge for their products and processes, and how willingly governments interfere with this process. For example, some of these beneficiaries may only have conditional rights to health (e.g. certain types of workers) and social regulation can significantly shape both product demand and pricing. Social insurance for example, affects not only the system of production, therefore, but also the system of consumption and access. In "developing" countries, the majority of citizens have few work-related health benefits. Systems of industrial production and varieties of work may be sufficiently heterogeneous that substantial ingenuity is required to institutionalize access to healthcare and social insurance in a robust way given its current fragmentation for 'informal' workers who form the majority in most countries (e.g. Lund and Srinivas, 2005). These multitudes demand-side effects on innovation have yet to be systematically studied and it is fair to say that the effects of patent rights as the sole inducement mechanism may be vastly over-stated. Given the Arrowian concerns of uncertainty in health economics, the roles of welfare regimes in large part reduced market risks and uncertainty associated with the size and sustainability of market structure (see Srinivas, forthcoming)

Furthermore, institutionally, technological innovations have arisen under very different forms of technological and economic organization i.e. "isms" over time, each with varied interpretations of the trade-off between private and public property rights. For example, although patent rights under capitalism are today taken as synonymous with innovation, numerous innovations occurred under socialism as well, or under rudimentary capitalism as in the 19^{th} century for pharmaceuticals. Even within specific forms of "isms", the inducement for significant or radical discoveries and innovations also occurred from a variety of causes. Moreover, specific types of patents (e.g. drugs, natural antibiotics, bioengineered proteins) have resulted in specific forms of social benefits but under highly *context-specific* conditions. In the case of vaccine history from 1945-2000, see Wilson, Post, and Srinivas (2007)

Table 3. S&T inducement from raw materials and government legislations, 1770-1980s

Inducement factors	Examples	Years	Pharmaceutical industry innovations
Raw Materials	Cotton	1770s	
		1820s	Tropical medicinal plants
	Coal and less costly Steel	1830s	
	Coal tar	1880s	
		1880s	Organic chemicals from coal tar
	Oil and Petrochemicals	1930s	
Government legislation (GLs)	Creation of public research labs	1880s	
	WWII efforts for drugs	1940s	Penicillin, malaria, corticosteroids
GLs especially for Patenting	Drugs, Germany	1880s	
	Natural Antibiotics, USA	1940s	
	Bioengineered proteins, USA	1980s	

Source: Adapted by the author from Achilladelis and Antonakis (2001)

In addition, even during the post-War years, after substantial changes in patent coverage for significant classes such as natural antibiotics such that the private sector could participate and innovate, a range of public research organizations continued to play a vital role. For example, the Sloan-Kettering Institute in New York hired scientists right after WWII from the Chemical Warfare Service to work on anticancer agents. Table 4 indicates the different public and private organizational forms between the two-decade period from 1949 onwards, that were responsible for various anti-cancer innovations and different scientific and technological specialization, although no obvious separation is evident of scientific activities in universities and technological activities in industry. Both are intermingled, thus raising the possibility of further experimentation in inducement incentives varied as organizational forms.

Table 4 Post-WWII mix of innovative organizations 1949-1967

Innovation	Year	Organization	Type of organization
Isolation of actinomycin	1949	University of Gottingen	University
Demonstration of actinomycin's anti-tumor effect in mice, treatment for Hodgkin's disease and later marketed as Sanamycin	1949	Bayer	Private company
Isolation of actinomycin D (dactinomycin, Cosmigen), and subsequent effectiveness for kidney, bone tumors and Hodgkin's disease	1953	Rutgers University	University
Discovery pf mitomycin (Mutamycin) for stomach and pancreatic cancer	1956	Tokyo Institute for Microbiological Chemistry	Public Research Institute
Discovery of bleomycin (Blenoxane) for head, neck and testicular cancer	1962	Tokyo Institute for Microbiological Chemistry	Public Research Institute
Discovery of daunorubicin (Cerubidine) for leukemia	1962	Farmitalia	Private company

Source: Adapted by author from Landau et al. 1999

In recent years, organizations such as One World Health in San Francisco also point to how innovations that have been found to be unprofitable and abandoned within the private sector can also be taken up and converted to actual treatments through the non-profit sector.

The innovation process arises from the point at which the innovation is conceived to the point where the product is created for specific clinical indications. As should be clear from the discussion thus far, patents alone cannot determine the source, size, cost or success of this window of endeavor. Even in highly industrialized contexts, Flowers and Melmon (1999) show through 5 detailed case studies that clinical champions, or "clinician-champions who pull the application of basic findings toward particular treatments", are *critical* determinants of drug development success (Ibid, p. 362). "Push by basic scientist or other industry professionals does not appear to be sufficient for rapid drug development" (Ibid. p. 363). Thus, in the creation of inducement incentives, such details are necessary in understanding to some degree customized inducements that reflect the institutional and organizational realities and needs of industrializing countries.

Vaccine history, for example, suggests that governments (and armies) have bargained considerably on behalf of companies to source in key vaccine technologies across the globe (Wilson, Post, and Srinivas, 2007). Furthermore, vaccine procurement and development has also been driven by national health insurance systems, demographics of the disease, and the size of populations, among other variables. Market failures in knowledge and information have thus been 'solved" through such bargaining and their institutional arrangements. Even for industrializing countries today, "mission-mode" R&D, new institutional and organizational hybrids for appropriating social returns, and reward/recognition at grassroots are under-studied.

This is buttressed by evidence on multiple US sectors, a country that is often taken to be the epitome of technological change induced by patent regimes. Within the US, a range of institutional antecedents has become more visible with closer study, alongside IPRs. For example, large public funding and public domain institutions were prominent (Nelson 1993), as were significant shifts in antitrust legislation (e.g. Mowery and Rosenberg 1998), and changes in the structure of university funding (Nelson and Rosenberg. 1993). Moreover, important relationships between knowledge bases, 'change agents' and work reorganization evolved and did not emerge fully-formed via patent regimes alone. For example, in the US they depended in large part on institutional markers such as the Hatch Act (1887) for agricultural research funding, and which linked university researchers to farmers. This was followed by the Smith-Lever Act (1914) where agricultural extension services were created "*To aid in* diffusing among the people of the United States useful and practical information on subjects relating to agriculture and home economics and to encourage application of the same." (cited in Rogers 1995, p. 158). As Rogers underscores, a range of governmental attempts in education, transportation, energy conservation and family planning tried to replicate the agricultural extension model but failed. Clearly, even within one country, lessons on innovation, technology diffusion and institutional change do not automatically transfer across sectors or regions, on the contrary. Thus we may need to be exercise caution about directly extrapolating IP harmonization and causation attributed to patents within industrializing contexts.

Next, I turn briefly to highlight two countries, Brazil, and India, which have differently dealt with IPR in recent years.

15. The Malaria case-Brazil and India

Stepping away from the advanced industrialized countries and pharmaceutical innovation history there, let us look at a major health problem worldwide: malaria, for which IPRs have been discussed as an inducement mechanism in AICs and ICs alike to spur scientific and technological efforts. However, the disease is a good example of the complexity of certain types of economic problems, and the need for multiple simultaneous (often non-product) efforts to find solutions. For most industrializing countries, the post-independence years were driven by some desire to make domestic R&D institutions relevant to local problems. De Fialho and Srinivas (2004), have studied the malaria case in India and Brazil, and analyzed 60 years of published scientific research from 1945-2003 on malaria encompassing natural, behavioral, social and other types of published research. Brazil and India are particularly interesting for the IPR debate, because they possess not only sophisticated R&D capabilities, but they also have active, manufacturing pharmaceutical and biotechnology sectors and significant health challenges. However, unlike India, Brazil chose a different path and *did* re-institute a product patent regime prior to the TRIPS 2005 deadline within the WTO. Nevertheless, it too, like India, lacks a significant patenting profile. Therefore, while not denying the possible *future* impact of patenting in India or Brazil, S&T output measures other than patents are necessary not only to analyze the relative participation of developing countries in malaria-related knowledge production and innovation but also to explain performance, which these traditional measures may hide. First, patents primarily reflect science and technology efforts that are more product-oriented such as bio-medical approaches, and diminish the visibility of life-saving gains on other social or behavioral fronts. Ideally, no approach should be sidelined. Even within bio-medical science, product patents may not be the only inducement factor. Second, health research spending and the emphasis on patents are still visible mainly in AICs and much IC research continues to be in public funded institutions where patenting has not been a priority (this is slowly changing under TRIPs pressures). Fourth, even though there have been some arguments that the absence of product patents has meant low investments in R&D for tropical diseases, the paper claims that the argument is weak.

In the Indian pharmaceutical case more generally, two arguments related to patents are surprisingly popular. First, most common explanations for the vibrancy and international market success of India's pharmaceutical sector rest on the historical absence of product patent regimes (although process patents existed) as an inducement factor for the innovations that do exist. At the same time, an argument is also made that the absence of a product patent regime in India explained the lack of innovative activity as well. Nevertheless, there is considerable evidence to suggest that a range of policy options beyond patents were highly influential in setting industrial capabilities to emerge (Sahu 1998) and a range of innovation environments beyond IPRs shaped specific technological expertise and innovation paths in dictating the priorities and extent of the market (Srinivas 2004). Particularly interesting is that the industry and innovative capabilities advanced to some degree despite standard markers for technological advance (such as R&D spending) being relatively contained. Thus inducements arose within different innovation environments in a fifty-year period. These were characterized by periods of focused technological activity and specific industrial specialization (Ibid.). For example, one phase of learning was associated with the rise of international vaccine procurement programs on Indian suppliers (Srinivas 2006). However, despite the technological advances, considerable gaps continue to exist in the regulatory frameworks for procurement that cause a divergence of industrial and health goals (Ibid.) Madhavi (2006) describes the further challenges to vaccine production especially given the actual closing or threat of closure facing many public sector suppliers. These were sites of considerable earlier investments. Such a link of shifting policies and innovation environments with technological change is conceptually different from arguing for patent policies or strategic firms as the sole markers of industrial change. It is also clear that no matter what the marker, technological change in the Indian pharmaceutical sector has not automatically delivered all fruits of this change to Indian health needs. IPRs were situated at an important juncture in Indian pharmaceutical policy, but could not have had the impact they did without a range of other institutions of industrial regulation.

16. Conclusions

Health technology data exist to indicate that the counterfactual for innovation inducement is imperfect at best, and certainly insufficient to place all laurels at the door of patent rights. It is likely that patents cannot be entirely dispensed with (nor should they be), but we need a much greater appreciation of the difficulty in specifying exactly what conditions are necessary to ensure that innovations emerge that are vitally necessary for industrializing country conditions. As Srinivas and Sutz (2008) emphasize, the time may have come for altering the fundamental debates about innovation in these countries, and health innovations form the vanguard of this analytical and empirical charge.

Pharmaceutical and biotechnology history suggests as well that different forms of economic and industrial organization representing different emergent and directed valuations of technological activity, dictate the ability of economies to innovate and re-distribute. In this sense, social welfare benefits and international competition may not necessarily have to be pitted against each other, and economic efficiency and social welfare can potentially be viewed as two sides of the same coin (e.g. Esping Andersen 1990, Edquist and Lundvall 1993, Lundvall 2002, Benner 2003). While the process of coming to such an explicit valuation is a test of institutional and economic participation, it is a closer step to ensuring that both innovation and re-distribution can evolve alongside. Some of the very tense debates in IPR have occurred because of value and means conflicts. It seems misguided and problematic to attempt adaptation of existing IPR regimes without understanding the conflicting underpinnings that this paper has attempted to show.

A future conceptual and policy research agenda needs to answer the questions raised here to some greater degree. Not only do we require better counterfactuals contrasting IP-induced and Other-induced, but we also need better specification of the (thus far) implicit social valuations inherent in different technological and industrial choices that clearly have different value conflicts with health policies. A straightforward utility metric across all circumstances and goals is likely to prove insufficient and inconsistent not only theoretically but methodologically.

As an immediate effort, both policy/public and scholarly debates could better balance (bio) pharmaceutical or other patent debates with non-contractual industrial means and ends to achieving health policy goals. These may occur through more mundane (less technological) means but have hardly been exhausted as options, such as universal health care, clean water, safe working conditions and minimum incomes. From an S&T policy standpoint, a range of R&D incentives could also be instituted such as societal recognition, awards and prizes and encouraging organizational hybrids. These may make less urgent many of the value conflicts arising from using intellectual property as the primary mechanism to induce innovation, but eventually cannot escape the unanswered questions regarding the importance of IPR in the health sector.

Notes

[1] This section draws substantially on Srinivas and Sutz (2008).

[2] Alvares captures the under-recognition of the technological components: "For those whose idea of what an engineer is, is restricted by the role of the engineer in highly industrialized societies, what comes now may seem difficult to accept. (...) The economically insecure man in the Southern nations is (...) engaged in the task of survival, but this time, primary survival. Considering the range of odds against which he must struggle and his experience thus far in using all his wits about him to remain alive, he comes very close to being an engineer par excellence." (Alvares 1991, p. 16-17).

[3] There is a relevant mapping of the 2X2 developed by Srinivas and Sutz (2008) and that of Stokes' (1997), particularly for "use-inspired" research. This is not explored here.

[4] Furthermore, as Blind continues: "In contrast to the property rights, formal standards are decisive for the diffusion of new technologies. They make information about new technologies available to everyone, for a small fee, and come near to being a classical public good, which is particularly distinguished by non-rivalry in consumption and application. The economic benefit is optimal if all economic units have free access to the public good...To sum up, it must be said that the economically optimal, strong property rights in the phase of knowledge generation must be relaxed at the beginning in the stage of wide diffusion of innovative technologies, From this it can also be derived that in the standardization process, property rights must be at least coordinated, better moderated for the promotion of the diffusion, in order to enable new standards to be produced." (Ibid. p. 118). These are also echoed in compatible ways by Eisenberg and Nelson and others.

Direitos de Propriedade Intelectual, inovação e o cuidado da saúde: questões não respondidas na teoria e na política

Resumo: Geralmente, presume-se que os regimes de propriedade intelectual induzem positivamente à inovação tecnológica. Sem embargo, dada a difícil natureza do acesso a tecnologias de saúde críticas para a maior parte da população mundial, vale a pena revisar esta assunção para as tecnologias da saúde. Este artigo situa os direitos de propriedade intelectual (DPI) na interseção de três campos: estudos de inovação, teorias do bem-estar e política econômica internacional. Ele revisa os pilares conceituais dos direitos de propriedade, especialmente, para as necessidades dos hoje chamados países industrializados ou desenvolvidos. Este artigo argumenta que o debate sobre DPI tem explorado pobremente assuntos contra-factuais em farmácia e biotecnologia em que outros meios de indução podem existir e onde as inovações podem surgir em condições nas quais os DPI são ausentes ou irrelevantes. Para fazer isto, primeiro se discute a utilidade como uma base dos DPIs e os desafios filosóficos, teóricos e, mais importante, os práticos- de trasladar isto tudo ao usos no mundo real. Este artigo oferece um novo arcabouço conceitual para estudar inovação no contexto do desenvolvimento, onde DPI pode ser situado especificamente. Se a meta real é promover o amplo acesso aos serviços de saúde – um assunto de imensa importância no mundo –, então nós precisamos acabar com "a tala de árvores" dos direitos de propriedade intelectual.

Palavras-chave: direitos de propriedade intelectual, instituições, inovação, planificação e políticas de saúde, economia do desenvolvimento.

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