

The Reformulation Regime in Drug Discovery: Revisiting Polyherbals and Property Rights in the Ayurvedic Industry

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Abstract In so-called traditional medicine in South Asia, substances have not ordinarily been prescribed or consumed in isolation, yet the transformations of compound formulations have been comparatively little studied from any position within anthropology or history. Since the early twentieth century, ayurvedic formulations have often been redesigned to address the biomedical disorders of a new global clientele. This has involved overlapping medical cultures and the creation of heterodox epistemologies, which have then allowed the creation of new “traditional” products that suit the demands of the market. In India, these new formulations fall under the category of “Ayurvedic Proprietary Medicines,” which are distinct from classical, textual (shastric) formulations already in the public domain. Proprietary medicines are the object of specific systems of appropriation and protection, which have not only gained central stage in the country but also influenced international regulatory bodies. This article seeks to explore the way in which the “reformulation regime” has fostered the emergence of alternative models of property rights, and their global acceptance, as well as how, in turn, these new forms of property have today come to drive pharmaceutical innovation itself. By analyzing this “looping effect,” this article sets out prospective avenues to study the industrialization of traditional medicine and the complex interface between regulatory systems, innovation processes, and the market.

Keywords Reformulation regime · pharmaceutical innovation · property rights · ayurveda

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In the past fifteen years, the present and future status of the pharmaceutical industry has been at stake in many a controversy and public debate on intellectual property, therapeutic evaluation methods, the procedures governing access to drugs, market regulation, iatrogenic risk prevention, and adverse effects. This technoscientific sector is so greatly affected by the current tensions in the relationships among knowledge, medicine, economy, and society that its ways of mobilizing knowledge for half a century have increasingly been called into question. Before the turn of the twenty-first century, such questioning of pharmaceutical research and development has mostly come from practitioners and public health authorities in economically “developing” and “emerging” countries, and more recently by user and patient organizations. It is now also being questioned by companies and regulation authorities in highly industrialized countries, highlighting what is increasingly labeled as a “crisis of innovation.” The main signposts of this crisis are the declining number of new molecular entities being put on the market and an increasing attrition rate.¹ Many observers are now underscoring that the screening model that has dominated the sector since the end of World War II (large-scale chemical syntheses and standardized clinical trials) has run its course and that the therapeutic results of genetic biotechnology, which were in the 1980s and 1990s seen as the main source of renewal for the model, remain limited.²

The dominant innovation regime in the pharmaceutical milieu based on the chemical synthesis of active substances and on a patent-based economy has itself entered a profound crisis due to rising costs and declining returns of investments in chemical screening (Godfraind and Ardaillou 2007). Large companies, aware that the patents protecting most of the molecules currently generating huge profits (so-called blockbuster) will soon be in the public domain, have implemented a variety of responses—sometimes contradictory—by, among other actions, making intellectual-ownership standards more stringent, intensifying bioprospecting practices, and researching new indications for molecules that have already been marketed. The fragile situation of a flagship sector of the “knowledge economy” is not, however, exclusively of industrial origins. It has been made more acute by changes in medical and clinical practices. What is in question is not only the effects of treatments that, in the industrialized countries, have significantly extended life expectancy and therefore changed the incidence and visibility of a whole series of chronic diseases, but also the fact that the boundaries of medicine have shifted, for example by giving greater importance to working “on” symptoms rather than identifying a nosological category.

Against this background and heightened by globalization processes, the pharmaceutical innovation issue in India has moved radically away from the transfer model associated with postwar development strategies. The industrialization of India’s scholarly medicines and the institution of pharmaceutical infrastructures, which started in the early twentieth century, are experiencing unprecedented developments today. The emergence of a world specialized in the production, sometimes in the invention, and in

¹ This decrease is even sharper when considering the molecules identified by drug-regulation agencies as sources of significant clinical improvement.

² The works that have contributed to historicizing the screening model show that it was only a marginal form of innovation until World War II (Chauveau 1999; Gaudillière 2005, 2010; Lesch 1993, 2007; Swann 1988).

the marketing of therapeutic specialties conveys a radical change in the nature and the scale of the “formulation” practices associated with ayurvedic medicine. However, the extension of procedures for pharmaceutical production and for standardizing laboratory practices in India is not a replica of the dominant innovation model in highly industrialized countries. The innovation processes of the Indian ayurvedic industry indicate a form of alternative modernity (Knauff 2002) that differs from the development models focused on knowledge and technological transfers by drawing from other types of knowledge than that of the molecular paradigm that has been prevalent in pharmaceutical research since the mid-twentieth century. The reformulation strategies of traditional preparations promoted by Indian firms and researchers are in their essence foreign to the chemical-screening model—a model that appears to be “an intellectually reductionist approach” when it is applied to the complexity of herbal substances and the learned knowledge of ayurveda (Zimmermann 2011: 72). Like bioprospecting, which was revived by the rapid growth of biotechnology, Indian firms favor the use of medicinal plants, but unlike the former, the purpose is less to purify the active principles than to exploit the properties of polyherbal compositions.

In a context of accelerated industrialization, the ayurvedic industry is reinventing its remedies and in doing so is borrowing from various medical schools of thought and various techniques such as modern galenics, biomedicine, and traditional medicine as formalized in the framework of professionalization and the integration policies implemented since Indian independence. Essentially based on what its actors call “reverse engineering,” this regime consists in reformulating and simplifying ayurvedic medicinal compositions in order to create new “traditional” drugs for the biomedical disorders of an international as well as Indian clientele. This approach entails a deep change in ayurveda, because it supposes not only industrialization and moving to mass production, but also the emergence of a world of ayurvedic pharmacy focused on the collection and manipulation of medicinal plants in a sphere that had thus far been medical and clinical, claiming a “holistic” and individual approach to illnesses.

The “reformulation regime” characteristic of the ayurvedic industry constitutes the example selected for this article.³ We have coined this expression to qualify contemporary manufacturing and production practices in this industry, as well as their central role in reshaping the way traditional knowledge-based pharmaceutical innovations are appropriated and protected by law. The reformulation regime therefore deeply questions the economic, epistemological, and regulatory context of pharmaceutical innovation. It is affected by fundamental tensions related not only to the epistemic status of the products and their problematic relationship with the ayurvedic texts and practices, but also to their exploitation conditions. This article is divided into three main sections that render these tensions especially visible. We tackle issues pertaining

³ In India, the existence of various differing innovation regimes reflects the existence of various types of medicine as well as of a hierarchy marked by the domination of biomedical knowledge that has prevailed since the colonial age (Pati and Harrison 2001). It should be said, however, that the “cultural authority of biomedicine” (Croizier 1968; Janes 1995) is not undivided. Work on intellectual property rights as applied to local knowledge indicates that hierarchies can be turned upside down, or at least used to the benefit of the latter. For traditional practitioners, bioprospecting and ethnopharmacology, for example, legitimize their own knowledge, underscoring the validity of their drug formulations (Pordié 2008b).

to the *recombination practices*—that is, the practices of reformulation themselves—to *standardization*, and to the *dynamics of property rights*.

The reformulation regime can only be understood by studying all the factors, local and global, converging to determine these new practices. To these ends, we examine the social dimensions of the drug-object in association with the technical dimensions of the drug-in-society and use reformulation practices as a prism to do so. For instance, raising the technical threshold for patenting in India, which makes it more complicated for ayurvedic pharmaceutical companies to file patents (Mueller 2007), is part of the political and economic strategy of the country, which is keen to harmonize its proceedings so it is able to comply with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the international harmonization of intellectual property rights, while at the same time claiming to protect traditional knowledge against “biopiracy.” Even if local patenting practices are still more “open” than those of European or American patent offices, Indian companies producing plant-based preparations are part of a globalized system that is centered on the development of new markets expressed through the global regulations of therapeutic agents and that also seeks responses to the crisis of drug innovation and to mounting critiques of its operations. Indian companies are also trying to expand their domestic market, which is targeted to the country’s urban populations, by exporting products or drugs to the United States, Australia, the Middle East, Central Asia, Japan, and a number of European countries. These products are now part of the fuzzy array of “alternative therapies and supplements.” International marketing and diffusion of ayurvedic drugs are leading to a deep reconfiguration of the “traditional” recipes and remedies produced by the industry.⁴

This article proposes to set out a number of avenues for research on these transformations. It explores new knowledge-building schemes in India, a country playing an ever greater role in the pharmaceutical sector and, more broadly, in the global economy and its regulation.

1 Pharmaceutical Globalization

Economic globalization is often approached as a worldwide unification of markets and the generalization of neoliberal regulations and forms of governance. In pharmaceuticals, a new phase in this complex process began with the changing role of the World Health Organization (WHO) in the mid-1980s and the TRIPS agreement. This resulted in the international diffusion and recognition of drug patents (Scherer 2000), including in India, a country that had excluded therapeutic agents (as well as food) from the sphere of patentability in the 1970s in order to guarantee access to drugs (property rights were seen as leading to monopolies and price increases) and to maintain the freedom to copy foreign technology and strengthen its industry.⁵ The United States initiated the globalization of pharmaceutical patents to put an end to “pirating” by

⁴ On the globalization of Indian medicine, read, for instance, Banerjee (2009), Pordié (2011), Reddy (2002), and Zimmermann (1995).

⁵ For the paths and practices that brought medicine back into the domain of patentable inventions, read Cassier and Sinding (2008) and Cassier (2008).

countries like India—where copying was completely legal for the reasons just mentioned—and to generate incentives to develop local research that could then be appropriated.

Economic reasoning plays an essential role in the realm of pharmacy, including “indigenous pharmacy” (Leslie 1989), but does not explain all the changes engendered by pharmaceutical globalization. Understood less restrictively as a twofold movement—to extend circulation (of commodities, persons, or knowledge) and to set up procedures to govern it—globalization has reconfigured “relations between the singular and the collective, deeply affecting ways of thinking and of acting in all corners of the world” (Abélès 2008: 9). In pharmaceutical globalization, interconnections reach beyond just market trading. Changes in the world of pharmacy in fact are not only related to trade and intellectual property but also have to do with standardizing research and production practices, with the nature of products judged to be useful and useable, and with their use. The extension of circulation thus modified pharmaceutical practices by imposing, for instance, the requirement to adapt products originating in Asian medicine to the regulatory frameworks of certain European and North American countries and to the expectations of consumers in those parts of the world.⁶ As a result, the nature of these pharmaceutical goods, as well as their mandatory production and evaluation standards, underwent radical transformation. In India, biotechnology and pharmaceutical laboratories have wished to demonstrate their excellence by complying with “good manufacturing practices”; they have sought WHO and FDA certification and entered into vast transnational networks including European or American laboratories (academic and industrial).

Like previous waves of globalization, for instance the rise of international public health under the leadership of WHO and other UN agencies, however, contemporary globalization processes have met with resistance and alternatives to the innovation models encouraged by pharmaceutical multinational corporations or by European and North American countries. An immediate explanation—powerfully illustrated by the 1970s debates at WHO—is that the innovations resulting from biomedical research are targeted to health needs that are very distant from those considered as public health priorities in the countries of the “Global South.” Contemporary resistance has also been directed against initiatives aimed at bringing intellectual property procedures, and those used for the development of biological resources and for evaluating therapeutic efficacy, into line with those of the United States and Europe. In the name of a more “holistic” medicine, which is more sensitive to individual variations and less focused on the purity and properties of isolated molecules, opponents are demanding different evaluation procedures from those used in countries of the North to test toxicity and efficacy.

Despite these changes, literature on pharmaceutical innovation in the South is still mostly concerned by technological dependence and technology transfers from laboratories in the North (Bertin and Wyatt 1986; Sahu 1998; Barton 2007). Thus the establishment of an Indian public and private pharmaceutical sector and the low level of patent protection have led investigators to study the learning methods used for copying technologies and adapting them locally (Sahu 1998; Lanjouw 1997; Scherer

⁶ See Millard (2008) for the case of Tibetan medicine in Great Britain.

and Watal 2002). The research underlying this article looks at other dynamics in pharmaceutical globalization by focusing on the local production of knowledge.⁷ While patenting remains an option, albeit less sought after, new innovation “regimes” and new “modes of regulation” are being developed outside of the pharmaceutical proprietary economy.⁸

2 The Reformulation Regime

To understand the magnitude of the change bearing on ayurveda today, a brief reminder of this medicine will be useful here. The “science (*veda*) of life (*āyus*)” is a form of learned medicine originating in Brahmanic tradition and set in Sanskrit texts as far back as the early centuries of the Christian era. The medical theory is based on humoral physiological and pathological principles that explain both the healthy body and its malfunctions. The “therapeutic sections” (*cikitsāsthāna*) in the ayurvedic texts mention the pharmaceutical uses and properties of a number of plants, parts of plants, and drug formulations. Ayurvedic pharmacopoeia was fully expressed, however, in the later literary genre constituted by the Sanskrit *materia medica* dictionaries (*nighaṅṭu*). The pharmacopoeia is also a general taxonomy of living beings, ordered according to Hindu cosmogony. Man and disease cannot be dissociated from their ecological and social context, which makes ayurveda more than simply medicine as generally defined in the West (Zimmermann 1982). Although this medicine is based on an enormous amount of literature, the texts do not constitute the only authority in medical practice and are, besides, the object of multiple interpretations by the therapists, which leads to rather heterogeneous practices. Ayurveda is traditionally learned over many years from a master who acquired his knowledge by lineage, but this way of transmitting knowledge is now disappearing. Masters are being replaced by therapists who have received shorter and less complete educations in the many ayurvedic colleges built by the government since the 1950s. This form of medicine has been completely integrated into national health policy since the mid-1970s. The institutional curricula and individual practices have both strongly integrated the concepts, tools, diagnostic methods, and nosological and etiological categories of biomedicine.⁹ Medical research and some forms of clinical trials aiming to certify the therapeutic efficacy of ayurvedic practices are now being widely promoted (Naraindas 2006; Pordié 2010a). The mass production of drugs and derived products, a large part of which

⁷ This research was funded from 2009 to 2013 by the French National Research Agency in the framework of PHARMASUD, a multidisciplinary program that was developing a comparative approach to pharmaceutical innovation processes in India and Brazil. Over the course of this program, the authors have conducted research in two private ayurvedic pharmaceutical firms, as well governmental institutions and offices and public and private research institutes.

⁸ For the concept of knowledge-production regimes in general, see Pestre (2003). For the concept of “ways of regulating” in the history of drugs and pharmacy, see Gaudillière and Hess (2012).

⁹ Integration of subjects from European medicine such as modern anatomy into institutional training was already noteworthy in the colonial era, which was marked by some hostility to Indian medicine. The growing influence of nationalist discourse in the pre- and post-independence periods prompted traditional therapists to mobilize. Colleges and (small and medium-sized) pharmaceutical companies were then instituted and many aspects related to the traditional sciences were removed from the curricula, which otherwise stressed the importance acquired by the *materia medica*.

are export oriented, has put Indian medicine at the heart of the global market of alternative therapies. As such, ayurvedic drugs are subject to specific authorization and marketing mechanisms that include toxicity-testing procedures, and often efficacy testing as well, that are consistent with the techniques and institutional system of biomedicine. These procedures are gradually penetrating the world of reformulation, in some cases completely. Companies and the government are unquestionably looking beyond just integrating ayurvedic practitioners into health centers: they are increasingly concerned with building pharmaceutical markets (Banerjee 2009; Bode 2008; Madhavan 2009).

Innovation through reformulation must be understood in this wider context. However, the reformulation regime consists neither in integrating plant preparations into biomedicine nor in adapting traditional practices into an industrial context; it consists in reinventing a “traditional” drug by borrowing, for its development, from sometimes very distant medical paradigms. The reformulation regime is a work involving a recomposition based on unique knowledge-prospecting mechanisms and singular industrialization schemes for the remedies. Thus understood, drug “reformulation” redefines knowledge and preparation practices, focusing on the properties of complex medicinal materials produced and sold on a mass scale for uses in which medical cultures are mixed. An essential aspect of reformulation is that it feeds the emergence of an autonomous “pharmacy” (in the sense of a world exclusively devoted to therapeutic substances) that breaks with ayurvedic clinical practice both from a sociological point of view (preparations are no longer made by doctors but by persons specializing in medicinal plants and their manipulation) and from an epistemic point of view (formulations are ready-to-use mixes for specific indications, no longer ad hoc mixes that are part of an individualized treatment regime). Largely overlooking individual humoral variabilities, the mass production of drugs thus tends to simplify and depersonalize the act of healing. This process objectifies medicine by placing the drug at the center of the clinical relationship (Pordié 2010b). These changes coincide perfectly with the needs of the market.

The term *reformulation* thus not only aims at highlighting the fact that this form of industrialization combines Indian knowledge and practices with elements of biomedicine, but also underscores the importance of *drug formulation* in these changes. The reformulation of drugs is thus both the object and the product of industrial practices aiming to produce new drugs based on natural substances and on clinical practices that are deeply modified, given that it links the prescription of these therapeutic agents to the diagnosis of good “indications” by drawing extensively on biomedical categories. In the reformulation regime, industrially targeted “prospection” of the body of traditional literature plays an important role. Its goals are (a) to homogenize and control conventional preparations that are formulations containing as many as several dozen ingredients; (b) to simplify formulations in order to adapt them to mass production—either by respecting that they are mixtures or by simply promoting the use of single plants—and to define therapeutic indications that combine, to some extent, ayurvedic and biomedical descriptions of the diseases; and (c) to change the formulations to adapt them to the global market and possibly isolate active chemical fractions for biomedical research—sometimes done within the ayurvedic industries themselves.

We should not confuse the reformulation regime and its industrial nature with other forms of “reformulation” that characterize individual therapists and are fostered by the availability (or lack thereof) of medicinal materials and the need to find substitutes, by

individual preferences, or again by economic constraints. The reformulation regime we consider in this article is not a local or individual adaptation of drugs' composition. Likewise, this regime takes as a basis the formulations and descriptions of plant properties fixed in ancient texts (*śāstra*), but its singularity comes from the fact that the aim is the industrial reformulation of remedies. This reformulation involves multiple translations in order to create new, ideally global, ayurvedic medicines for biomedically defined ailments. The industry then “stabilizes” these new formulas for and through mass production as well as through appropriation and registration as trademarks under the label “Ayurvedic Proprietary Medicine”—which, compared to patent, for example, appears to be the quickest and most cost-efficient means to enter the Indian market.

In a remarkable parallel with the vocabulary of chemists, certain actors of the industrialization of ayurvedic preparations speak of “reverse engineering” when referring to the development of new drugs based on ayurvedic knowledge. A typical sequence consists of identifying symptoms (and biomarkers) associated in the biomedical literature with the targeted indication (or disease), seeking an equivalence in ayurvedic medicine entities, listing all the formulations mentioning these entities in the *śāstra*, defining a simplified consensus formula (containing half a dozen ingredients at most), and selecting a protocol to produce and test (possibly biologically) this formulation. Such is the case for the drug named Diabecon, invented by the Himalaya Drug Company in Bangalore (see below). As the name suggests, this medicine is indicated for the biomedically defined diabetes (insulin-dependent or not), the symptoms of which find their equivalent in an ayurvedic-defined disease called *prameha* (or *meha*), which translates as “urinary disorders.”¹⁰ The ayurvedic physician leading the drug discovery department in this company told us that this ayurvedic disorder would correspond to polyuria, which includes diabetes (or, according to biomedical nosology, reveals the existence of diabetes). The classical formula used in the treatment of *prameha* stems from a Sanskrit textual source from around the sixteenth century AD, namely, *Bhaiṣajyaratnāvalī*, and comprises, among numerous other things, two important triads of plants: the three myrobolans (*Terminalia chebula*, *Terminalia bellerica*, and *Embelica officinalis*) and the three spices (*Piper nigrum*, *Piper longum*, and *Zingiber officinale*). These triads, as well as the main component in the classical formula (the plant *guggulu*, *Commiphora* sp.) and the paste *Vidangādi lauham* (in which the plant *Embelia robusta* is the main component), remain as such in the newly formulated Diabecon, which counts a total of thirty-three ingredients against a higher number in the original, shastric formula. The new formulation has been chosen among various others, which were all subject to toxicity and efficacy essays (animals and in vivo). The selected formulation then went to the Department of Formulation Development, where it has been stabilized (through galenics) and rendered compatible to mass production. Since it is marketed, the mode of action of Diabecon is presented not in ayurvedic language but in exclusively biomedical terms.¹¹

¹⁰ We refer to Zimmermann (2012), as well as to the many personal communications we had during informal and formal meetings under the PHARMASUD program in Paris and elsewhere.

¹¹ We read on the company website: “The natural ingredients in Diabecon increase insulin secretion in the body. By reducing the glycosylated hemoglobin level (form of hemoglobin used to measure glucose content in the blood) level [*sic*], normalizing microalbuminuria (a condition which is an important prognostic marker

This kind of necessarily approximate approach (incommensurability of medical paradigms, linguistic-translation difficulties and problem of conceptual equivalence, variability of botanical identifications in the reference texts, etc.) is systematically reduced to an ethnopharmacological exercise,¹² renamed for the occasion “reverse pharmacology” in the specialized literature.¹³ Contrary to what the authors suggest, reverse engineering is not self-evident. It is a very complex approach involving many shifts from one range of knowledge to another (and therefore a chain of translations), each step of which requires scrupulous study at the practical, cognitive, and epistemological levels.

A good example of the complexities of the reformulation regime is provided by the activities of companies like Arya Vaidya Sala (AVS), set up in 1903. The firm has both a production and research site and a network of clinics. Clients are patients who are offered a course of treatment, the content and progression of which is defined by one of the firm’s practitioners on the basis of a questionnaire (that can be filled out online) and a consultation (pulse-taking, constitution assessment, and diagnosis of humoral imbalances). AVS offers its clients formulations integrated into a therapeutic regime that underscores the traditional nature of administering preparations and their association with nondrug prescriptions, including diets, purging, enemas, or massages. AVS is, in fact, known to produce “traditional” ayurvedic drug recipes (Varier 2002), that is, recipes that are formulated in detail in very ancient texts: indications, content, dosage, the manufacturing principle for mixtures and associations—or *yogam* (union)—of the raw materials. AVS literature also underscores the traditional roots of the procedures, their relationship with the fundamental texts, their adaptation to the individual, and their cultural and symbolic significance calling on the relationship between microcosm and macrocosm. The drugs draw their legitimacy both from the authority of the texts and increasingly from the development of new forms of knowledge. As far as manufacturing is concerned, powder-reducing techniques and, more generally speaking, the production techniques did change in the course of the twentieth century. This evolution was characterized by the advent of mechanization, the use of evaluation methods for product quality based on chemistry and physics or borrowing from modern galenics. AVS also claims that its services are “modern” and “scientific” in the sense that they apply all the criteria of objective demonstration of the pharmacological efficacy except for statistical clinical trials. On the clinical side, the care of chronic health conditions has come to the fore, combining in the same statements entities from biomedicine (diabetes, hyperlipemia, and hypertension) and terms from humoral and

for kidney disease in diabetes mellitus) and modulating the lipid profile, Diabecon minimizes long-term diabetic complications. The drug also increases hepatic and muscle glycogen content, which enhances the peripheral utilization of glucose” (<http://www.himalayahealthcare.com/products/pharmaceuticals/diabecon-tablet.htm>, accessed 29 January 2013).

¹² Ethnopharmacology is a specialized branch of medicine born in the late 1970s. Its aim is to study care practices, to contribute to their regulation and standardization, to evaluate the biological efficacy of its pharmacopoeia, and above all, to discover new drugs in it. Although there are very inclusive definitions of ethnopharmacology (Dos Santos and Fleurentin 1990; Etkin 1996), the science is essentially based on the plants used in traditional medicine and on identifying active substances (Pordié 2010a: 59–61).

¹³ See, for instance, for the most important teams in India, Patwardhan (2005), Patwardhan and Vaidya (2010), Patwardhan and Mashelkar (2009), Patwardhan, Vaidya, and Chorghade (2004), Patwardhan et al. (2008), and Vaidya (2006).

constitutional imbalances. AVS consultants are graduates of ayurvedic colleges, the curricula of which systematically include a substantial biomedical part. Their clients also often come with previously established biomedical diagnoses and sometimes manage a combination of treatments.

Procedures for reformulation and the industrialization of ayurveda are extremely diverse. The case of AVS is only one along a broad range of positions. The Himalaya Drug Company in Bangalore illustrates the other end of the spectrum. Set up in 1930, the firm distributes its products worldwide and has branches in Europe, the United States, the Middle East, and several countries in Asia. It does not operate like biotechnology firms, seeking only to isolate and synthesize the active molecules of plant preparations; it revisits and adapts traditional formulations according to the principle outlined above or, indeed, invents brand-new plant combinations or uses laboratory processes to isolate and concentrate a particular fraction of the plant (then called “active marker”) in order to enrich the preparation. The firm also underscores its professional, “scientific” relationship with the prescribers. The Himalaya Drug Company thus decided to build a market for its products by relying largely on scientific marketing to biomedical professionals, pitching its practice of laboratory research and clinical trials, and using the positive results of controlled therapeutic trials conducted outside the firm. Himalaya publishes several journals targeted to doctors in which part of its scientific work is presented—the rest of it being mostly published in biomedical journals.

One important question raised by this reformulation regime is therefore whether the globalization of ayurvedic preparations also changes biomedical practices, and how much. This question needs to be approached in two ways: on the one hand, by following how certain products of the Indian companies become an integral part of the range of products prescribed by biomedical physicians in India (60 percent of the drugs produced by the Himalaya Drug Company are prescribed by biomedical doctors) and elsewhere in the West, in the latter case most often as an “alternative and complementary” therapy; and on the other hand, by following the research conducted in India, the United States, or Europe to turn certain preparations into targets for molecular innovation. The first configuration can be illustrated by one of the recent products marketed by the Himalaya Drug Company. Menosan targets the market for menopause hormone-replacement therapy, which went into crisis after the 2002 publication of important statistical trials showing that using synthetic estrogen increased the risk of breast cancer and adverse cardiovascular events (Löwy and Gaudillière 2006). Menosan is a completely new, plant-based preparation whose invention followed the model of reverse engineering, that is, beginning with the mining of ancient texts in search for menopause-like symptoms and their treatment. It is presented as a “phytoestrogenic” drug for which its efficacy on menopause symptoms is guaranteed by statistically controlled trials conducted under FDA standards but leaving out the examination of biological end points in favor of well-being criteria. Although the marketing of the drug at the time of the debates and controversies that surrounded the use of synthetic estrogens is fortuitous, for the Himalaya Drug Company, Menosan is a “natural,” “traditional” response to the impasses of conventional pharmaceutical innovation, in particular to the multiplication of undesirable events among millions of patients resulting from the long-term use of risk-prevention substances.

The second configuration is illustrated by the developments of a plant like *guggulu* (a local species of *Commiphora*) used locally to treat a variety of diseases, which has been reconfigured as an anti-obesity drug. There has been a lot of research on guggulu. In India as well as in the United States, preparations based on this plant have been redefined as lowering serum cholesterol and lipoprotein. Their composition has been analyzed and reduced to a combination of sterones capable of binding a steroid receptor protein. The fate of these studies, however, reveals typical tensions of the reformulation regime. Although the animal modeling of the effects of guggulu resin had been convincing as to their positive effect on the accumulation of lipids, the results of controlled clinical trials mostly performed in India did not trigger the same consensus. It gave rise to a controversy, not only about the validity of the statistical procedures employed but also about the way these studies are ranked and evaluated in the United States, without taking into account the links between the effect of extract administration and the food regimen and without considering the comprehensive nature of ayurvedic treatments (Ulbricht et al. 2005).

These newly formulated ayurvedic drugs circulate within the sociotechnical network of contemporary ayurveda—a network that includes *vaidyas* (ayurvedic practitioners) as well as pharmacologists, pharmacognosists, chemists, graphic designers, salesmen, patent examiners, public health administrators, and so on. Although such constellations involve biomedical specialists, speaking of a “re-networking” (Lei 1999) of ayurvedic drugs in the sphere of biomedicine would miss the originality of the situation. A fundamental reason for that is surely the historical roots and strong identity of the two above-mentioned firms in ayurveda and their reiterated claims to compete with, and therefore resist, biomedicine. Most important, however, is the fact that the forms of innovations that create novel Ayurvedic Proprietary Medicines are exclusively based on plant compound formulations or single-plant fraction extracts. They provide an escape to the biopharmaceutical innovation paradigm and the use of single molecular entities and therefore make difficult, if not impossible, to “materially reducing [these] drugs into the constituents of [the biomedical] network” (ibid.: 345). These new medicines offer a critical alterity to biomedicine: they are conceived, marketed, and consumed as ayurveda, in spite of the effort conducted to “modernize” it. This shows a clear distinction with the “Chinese propriety medicines” studied by Elisabeth Hsu (2009), which include not only plant preparations in the form of compounds but also and increasingly often isolated molecules, as in the case of the anti-malarial artesunate. In this case, Chinese propriety medicines cross the biomedical line, so to speak, and fail to provide the same kind of critic and alternative.

3 Alternatives to the Globalization of Patents on Drugs?

The reformulation regime raises a second category of questions insofar as it is built as an alternative, when not in opposition, to the proprietary economics of drugs; appropriation practices in this regime build property in a different way than that of pharmaceutical patents, as in the case of “proprietary medicines.” For ayurvedic practitioners and industrialists, the idea is to protect traditional knowledge from being filed for patents (in Europe and in the United States), covering uses of biological resources as well as the preparation of plant-based therapeutic formulations. In practice, it is

state administrations (federal and regional) that are defending the stock of traditional knowledge as “commons” by organizing the inventory and codification of “Indian” therapeutic knowledge. Firms, on their side, consider this knowledge as a resource for inventing, industrializing, and marketing preparations. To build their markets, they are filing applications for both trademarks and (Indian) patents on formulations not recorded in the classic texts.¹⁴ Compatibility between these patents and the claims about protecting traditional knowledge against appropriation hangs on two specificities of this mode of appropriation: first, patent applications are filled for “national” rather than international appropriation, thus leaving room for international campaigning against biopiracy; second, the patents seek intellectual property rights on the reformulations and not on the recipes included in the classical texts.

This conjunction between protection, access, and exploitation is now at the core of the attempt by the Indian government to foster international laws on the protection of traditional knowledge. The exploitation of plants from India by a number of Western pharmaceutical companies in the late twentieth century triggered a sharp reaction in the country over intellectual property rights and biological heritage. The main episode involved the neem tree (*Azadirachta indica*), a common tree with medicinal qualities that is held in high esteem in India. In the mid-1990s, the US Department of Agriculture and the pharmaceutical company W. R. Grace studied the local uses of the tree and eventually filed for a patent on the use of extracts that had pesticidal properties. The American patent, which W. R. Grace tried to extend to the European Patent Office, was on the technical procedure used to obtain the extracts (the claimed innovation was to have obtained an active composition without azadirachtin, the substance that had thus far been held responsible for pesticidal activity) and not on the neem tree as such. In India, however, it was considered that the original *knowledge* belonged to the country. From the Indian point of view, the commercial use of the patent constituted a wrong, one compounded by the fact that this was no ordinary tree. Locally, the neem tree is a sacred tree associated with a number of divinities. Its leaves, for instance, are used to decorate pilgrims’ buses. It is used as a home remedy and appears in the centuries-old pharmacopoeias of scholarly medicine; its therapeutic use covers infectious, parasitic, and dermatological diseases. Moreover, the neem tree is part of the composition of a remarkable number of modern cosmetic and hygiene products; villagers use it to smoke dwellings in order to keep harmful insects away. So the whole of India, it was said at the time, was concerned. India made this tree a symbol of its sovereign rights over its biological resources and its national medical knowledge.

The country took the case to court, in India and internationally. It took several years to build a convincing legal case, and the cost of the lawsuit went into millions of dollars.¹⁵ In 1997, an objection procedure was taken to the European Patent Office (a procedure that does not exist in the United States) by the Indian alterglobalist

¹⁴ The Himalaya Drug Company thus diversifies the means to protect its products. For example, the drug Diabecon we mentioned earlier, as well as all other drugs created by the company, is registered under trademark as an Ayurvedic Proprietary Medicine, but this does not preclude the fact that the firm may also attempt to apply for a patent in India or abroad—as it goes global, Europe- or US-based patents are increasingly sought after. Over the last nine years or so, this firm has filed eighty-five patents, with eight granted so far for innovations in therapeutic and personal care products.

¹⁵ This sum also covers expenses for the defense of two other similar cases, involving basmati rice and turmeric (*Curcuma longa*).

activist V. Shiva, the European Green Party, and a European organic-farming non-governmental organization (NGO), with indirect support from the Indian Patent Office.¹⁶ The opponents' arguments met with two difficulties: the first was related to the technical (molecular) definition of the invention, which had to do with the production of a new type of extract and not with its uses; the second difficulty was the absence of "scientific" sources that were acceptable to the patent office and could prove that uses of the neem tree as a pesticidal or therapeutic agent were in fact drawn from "traditional" knowledge. The proceedings lasted eight years and in the end led to the cancellation of the European patent on the neem tree based on the argument that the procedures used by W. R. Grace were not innovative because the claimed protocol had already been used in India, completely bypassing the question of traditional knowledge (Gaudillière 2011). This mixed success was read in different ways.

For many NGOs, the episode has become an exemplary case of unfair trade associated with new forms of prospection for biological resources, but also an example of successful opposition to patenting and defense of a form of traditional knowledge against wrongful appropriation, ironically conducted, in this case, in the name of sustainable, "green" development. As for the Indian government, it concluded that the present working of the international patent system is ineffective for preventing "biopiracy." It gradually developed a specific policy fleshed out with local laws and international pressure for an agreement on the trade, use, protection, and preservation of traditional knowledge and phylogenetic resources (Challa and Kalla 1995; Cullet and Raja 2004; Duffield 1999; Subramanian 1999; Anuradha, Taneja, and Kothari 2001).¹⁷ More generally, indigenous assets and knowledge acquired a central place in national conservation policies (Baviskar 2000: 101). In India, the initial administrative response to the neem tree case consisted in setting up a new task force comprising the patent office, the industrial-research advisory board, and the ministry of health. In 2000, this task force recommended the constitution of a vast databank, the Traditional Knowledge Digital Library (TKDL), aimed at making Indian therapeutic knowledge and practices (ayurveda, unani, siddha, and yoga) available in a form that could be used by intellectual property management institutions so that it could be taken into account during a prior art search. Begun in 2001, the TKDL staff's work consists in "transcribing" in a form adapted to patenting procedures the thousands of medicinal formulations described in the fundamental works used in the colleges that trained the practitioners of Indian medical systems. This translation supposes a set of scarcely obvious equivalences between the vernacular denominations of medicinal materials and the botanical or geological denominations, on the one hand, and the etiological and nosological categories of the various therapeutic sets involved, on the other. The digital library currently presents in five languages thousands of plants and substances used in the local pharmacopoeia and more than 230,000 drug formulations. The European Patent Office has been authorized to consult it since February 2009.

¹⁶ Significant documentation regarding the Grace patent (EP90250319) and the opposition procedure is available on the EPO website (<http://www.epo.org>, accessed 6 February 2013).

¹⁷ Since that period, India has also intensively pursued research and development activities in the pharmaceutical and chemical sectors with a view to improve their competitiveness (Lanjouw 1997).

This formalization option is not purely an Indian phenomenon. It has been strengthened by relations between India and the World Intellectual Property Organization (WIPO). The Indian experience is, in fact, at the core of WIPO attempts to set a legal framework for traditional knowledge. The intergovernmental work group, which was set up in 2000 to develop a framework that could make compatible intellectual property rights, protection of biodiversity (as per the terms of the Convention on Biological Diversity), and profit sharing with societies whose traditional knowledge is industrialized or marketed, not only upheld the Indian project but also adopted its forms of inventory and categorization of traditional resources as a basis to amend the international classification of inventions, which is currently used by patent offices. More generally, WIPO developed a discourse on the nature of traditional knowledge and on the need and the way to protect it, which favors the Indian positions on changes to the law on patents over those of Latin American countries on the institution of an entirely new system of rights (Gaudillière 2011). For the WIPO as well as for the Indian authorities, recognition and protection of knowledge must be made compatible with their marketing and the appropriation of “substantial” innovations through patents (especially those dealing with technological or methodological procedures drawn from traditional knowledge).

Official WIPO documents consider traditional knowledge as radically different from “scientific knowledge.” Traditional knowledge is given a holistic character, and its learning is seen as relying basically on oral transmission (WIPO Secretariat 2004).¹⁸ Traditional knowledge is also held to be rooted in “communities” (in general, undefined) and in collective-property systems, warranting their protection through their registration in the public domain. For the WIPO, specific rights need to be invented that are compatible with commercial uses and the patent system. The privileged tools for this protection would be contracts certifying that the holders of traditional knowledge consent to their use and ensuring a fair distribution of profits. These considerations and developments are partially congruent with the Indian government’s intent as well as that of some ayurvedic pharmaceutical companies. These latter are claiming the “common” nature of the classical recipes so that they will remain accessible and open to mining by all Indian producers.

This definition of traditional knowledge and protection through collection and documentation agreements and the formalization of profit sharing with the local communities recognized as holders of traditional knowledge (the so-called benefit-sharing agreements introduced within the framework of the Convention on Biological Diversity) has at first sight no relevance to ayurvedic written and public formulations. However, in the world of reformulation, there is not always a clear distinction between collection, protection, and exploitation, between indigenous and scholarly traditions. A good example is in the invention of the Jeevani preparation marketed by the firm Arya Vaidya Pharmacy. This new formulation with antiasthenic and immune-system-modulation properties originated in the ethnopharmacological prospection activities of the researchers at the Tropical Botanical Garden (TBG) in Trivandrum among

¹⁸ For more information on WIPO’s work on traditional knowledge, see <http://www.wipo.int/tk/en/tk/index.html>.

the Kani people in Kerala. The therapeutic properties of *aarogyapacha* (*Trichopus zeylanicus*), one of the plants in the composition of Jeevani, were known only to the Kanis until the early 1990s. Informed by the Kanis, TBG researchers confirmed the pharmaceutical interest of *aarogyapacha* through a series of laboratory studies in animals. They then proposed an ayurvedic identity for the plant and chose to include it in an antifatigue formulation aimed at strengthening the effect of *aarogyapacha* extracts. For this purpose, they associated it with three more ingredients that were well known in ayurveda and had effects that were judged to be complementary: long pepper (*pipli*, *Piper longum*), Indian ginseng (*ashwagandha*, *Withania somnifera*), and *shankhpushpi* (*Evolvulus alsinoides*). The first was chosen because of its ability to play the role of adjuvant; the two others, because of their status of rejuvenating remedies. The agreement among the researchers and the Kanis became an international model of benefit-sharing dynamics, and its uneven consequences have been widely discussed (Madhavan 2011). The system of property rights associated with this reformulation is nevertheless not limited to the (formal) recognition of Kani knowledge and its contribution. It includes the patent on the formulation, obtained by the TBG researchers alone; the exclusive license they granted to the ayurvedic firm; and the certification by the Kerala state controller of Jeevani as a proprietary ayurvedic remedy.

Another dimension of the appropriation logic and market building related to reformulation practices has its origin in the conflicts between conservation and collection (Gaudillière 2012). The existence of a crisis in the supply of medicinal plants caused by the rapid growth of the market in the past fifteen years and the massive collection (80 percent of the total supply) of “wild” plants is being highlighted by the firms, international bodies specializing in environmental conservation like the International Union for Conservation of Nature (IUCN), local NGOs, and Indian regional and federal administrations (Ved and Goraya 2008). Many plants used in ayurveda are threatened with exhaustion and even extinction. Theoretically, the sustainable solution would be to move to in situ or ex situ culture. In 2000, the Ministry of Industry thus decided to set up a public-private partnership for the management of medicinal plants. The goal of the National Medicinal Plant Board (NMPB) was to organize the whole “chain” and in particular to increase supply to the market. The NMPB’s initial selection of three dozen strategic plants thus includes a majority of plants that are in high demand on the market, for which the idea is either to improve and standardize cultivation (when existing) or to promote domestication. In addition, the NMPB manages financial incentives to grow species that already are agricultural products. The impact of the program seems, however, limited due to a relative lack of resources and, more important, to the internal contradictions of the domestication paradigm.

The Jeevani/*aarogyapacha* example is also telling here (Gaudillière 2012). *Trichopus zeylanicus* is a species endemic to the reserved parts of the Keralese forest where collection is closely monitored by the government and is limited to the needs of tribal communities. Aware of the raw materials problem, the inventors of Jeevani therefore tried cultivating *Trichopus zeylanicus*, the predominant plant of the preparation. The objective was to allow the Kanis to grow *aarogyapacha* and to stop forest collection. Experimental cultivation in open fields succeeded but at the cost of losing the therapeutic properties of the extracts. Although the botanical garden researchers were not able to explain why, only the plants grown in situ, beneath the forest cover, preserved their active properties and could be used to produce Jeevani. The cultivation project

then faced issues related to rights to forest resources. In charge of a dual mission with the aim of protecting and exploiting the resource, the Forest Department in Kerala opposed the cultivation in situ of aarogyapacha, taking the product of the first two harvests and putting an end to the rise of Jeevani production. While it has been going on for ten years, this conflict may be now resolving with the negotiation of an agreement authorizing the Kanis to grow the plant on condition that they keep it to forest edges.

Patenting Ayurvedic Proprietary Medicine is not unique to the trajectory of Jeevani. The scientists working at TBG hold five patents granting them exclusive right of use of the new formulations they have designed, which include aarogyapacha and ayurvedic plants found in classical texts, among them an anticancer combination. More generally, a simple survey of the Indian Patent Office website shows that during the past ten years, this institution has granted dozens of similar property rights. The office has thus established a practice that actually grounds a new interpretation of the Indian patent law. At the time of its 2005 revision, whose main aim was to align the national law on the international TRIPS agreement, the law quite clearly excluded patents on traditional knowledge. Although understanding reformulations as novelties is not far-fetched reasoning for patent examiners, the IPO jurisprudence is a significant displacement: it potentially gives Ayurvedic Proprietary Medicines an industrial and legal status akin to that of biotechnological inventions based on natural products. This form of appropriation may result in a “looping effect” (Hacking 1995) bearing strong analogies with the situation created by the US and European patent offices in the late 1980s and early 1990s when they started on a routine basis to grant intellectual rights over the “invention” of genes, arguing for the novelty and industrial utility of isolated and chemically characterized DNA sequences (Calvert and Joly 2011). The existence of patents on reformulation is accordingly likely to trigger larger investments in reformulation work, which will in turn favor the appropriation of formulas.

The constitution of a right protecting knowledge drawn from Indian medicine is thus not only opposed to but also articulated with intellectual property rights and with the building of new markets. The industrialization of ayurveda thus fosters irremediable tensions between firms, collectors, practitioners, and local governments.

4 Producing Standardized and Certified Drugs for the Global Market

One additional specific aspect of the reformulation regime is the problem of standardization. The standardization of traditional preparations and medicinal plants in India is one of the effects of the transition to industrial mass production. It is the source of tensions related to whether such homogeneity of products is needed, to the nature of the standardization procedures envisioned, and to the compatibility of these practices with the particularities of traditional formulations.

The discourse on standardization of preparations based on Indian medicinal plants is recurrent. It originates in firms, the Indian government, and a number of NGOs and international organizations. This is not surprising, as we are dealing with products intended for circulation at the regional, national, and international scales, the distribution of which is increasingly bounded by debates about quality, toxicity, and control. This situation is nonetheless problematic in view of the status claimed for preparations

drawn from Indian medicine, which involve complex mixtures whose production must preserve the synergies among constituents deemed essential to their efficacy and their ability to take patients' individual health needs into account. The discourse on standardization is shared, but it covers a variety of different practices and goals.

For the AYUSH department, which is in charge of "Indian medicine" at the Ministry of Health and Family Welfare, respecting formulations, developing the market, and making available products that are free of toxic contaminants are all part of public health policy.¹⁹ This approach considers the preparations themselves as free of major side effects, as would seem to be indicated by their centuries of use. Added to this is the export concern and the risk of having a marketing permit refused (in particular in the United States) because of possible contamination of the preparation by heavy metals, bacteria, and the like.²⁰ Although oversight of the products is limited to their registration in order to determine their tax status (traditional remedies benefit from total tax exemption or a reduced tax rate), the Department of AYUSH has published Good Manufacturing Practice guidelines, and registration of firms has become mandatory.²¹

The globalization of traditional medicines has also had the effect of strengthening WHO involvement. The organization has adopted a strategic plan for their development in which standardization has been selected as the means and condition of their "integration" into health systems and of their "universalization" (OMS 2002). Rather than promoting traditional medicines, which has been on the WHO agenda since the Alma-Ata conference in 1978, this choice extends a long tradition of intervening in the standardization of biological products. The various WHO bodies have thus developed strategic plans to simplify and generalize the procedures for toxicological or pharmacological testing and adapt them to the approval of plant preparations (WHO 2000). One of the indicators of the conflicts between reformulation and standardization is thus the question of the acceptable number of plants: for the WHO or the European Union, and unlike the Indian authorities, there can be only half a dozen at the most; otherwise, safety control and guarantee are impossible. This had direct implications in the reduction of ingredients in the new formulas drawn from the reformulation regime.

It is in the firms themselves that the discourse on standardization is most closely geared to the practices. For the industry, it is not just about ensuring marketing potential, productivity, and quality by avoiding contaminants; raw materials also have to be controlled. Although the health department had drawn up a reference list for traditional preparations since the 1970s, several professional initiatives have recently extended this normalization arena with the writing of professional standards: the Indian association of engineers in the industry has produced its own pharmacopoeia (EIRI 2002), while the National Institute of Industrial Research has established a reference list for the plants used by the firms (NIIR 2003). These corpora refer to the same problematic translations involved in reverse engineering or in the TKDL transcriptions of recipes. In practice, what is being done? What are the targets, the criteria, and the procedures of this standardization of the complex and the traditional?

¹⁹ This department was set up in 1995 as the Department of Indian Systems of Medicine and Homeopathy. In 2003, it was renamed AYUSH, which stands for Ayurveda, Yoga, Unani, Siddha, and Homeopathy.

²⁰ About the debates and controversies on the presence of heavy metals in drugs derived from Indian drugs, see Sébastia (2011: 77–81).

²¹ There is, however, no real knowledge as to whether these measures are applied and in which way.

Two distinct aspects of company activity need to be considered: the organization of mass production and the management of plants.

Let us go back to the example of AVS. Mass production favors the values of product homogeneity, reproducibility, and control of protocols. AVS thus combines two types of procedures that are emblematic of the “pluralism” of this new pharmacy: on the one hand, those of a “traditional” workshop consistent with the recommendations of classical ayurvedic pharmacy; on the other hand, those of a factory extensively using mechanical innovations, machines to cut, dry, encapsulate, package, and so on—a factory complying with the ISO standards of the pharmaceutical sector, where every batch is traced and tested for a small number of quantitative and qualitative criteria. Under these conditions, what is standardized, and how is this done? What happens, for instance, to elements such as the *rasa*, the taste of the remedies? These are at the core of the pharmacological judgment of ayurvedic practitioners; they were codified and related with evaluations of chemical and biochemical composition as early as the 1950s. Their status is now the subject of a new wave of “scientification.” AVS is thus associated with a project aiming at the standardization of tastes supported by the Institute for Ayurveda and Integrative Medicine, formerly the Foundation for Revitalisation of Local Health Traditions (Ganguly 2012). The issue here is not only to standardize the organoleptic judgment for industrial quality control (as in the food industry), but also to stabilize relations between therapeutic activity and sensory properties. These properties are used not to determine a drug’s composition but as signatures of a specific therapeutic action, insofar as the five fundamental properties of the *materia medica* can ideally be derived from sensory attributes (taste, color, texture, smell).

Another specificity in AVS standardization compared to what is done in a biopharmaceutical or biotechnology company is the way it manages raw materials by underscoring a “holistic” approach to plant properties, which is a correlate of using entire parts of plants in the formulations. There are two dimensions here. The first one is the conventional approach to control the collection, and in particular to homogenize the evaluation of the quality of the plants collected for AVS using biological and/or botanical criteria. A second dimension of this form of standardization has taken the shape of specific research to reformulate traditional knowledge as agroecological knowledge, integrating the plants into their ecosystem and exploring and objectifying the links among growing conditions, the dynamics of the plant populations, and therapeutic efficacy in order to avoid the domestication drama illustrated by the loss of efficacy in open-field cultivation of aarogyapatcha. In line with these two approaches of standardization, AVS widely publicizes its investments in (a) a conservatory garden containing seven hundred species; (b) a laboratory for in vitro culture and for the constitution of so-called reference chemical fingerprints to evaluate the composition of the plants intended for production; and (c) a biobank (partly financed by a Canadian foundation) storing DNA, cell lines, seeds, and computer data on the genome belonging to a few dozen species judged to be strategic.

Discourses of standardization are thus particularly revealing of the underlying epistemic, technical, and social tensions in the governance and mobilization of traditional medical knowledge. To explore them, more attention should be given to what is done in practice, to the firms’ operations in particular.

5 Conclusion

The idea of reformulation regime we propose in this article questions the production of new forms of knowledge in the pharmaceutical field, as well as the reinvention of medical traditions—a term obviously inspired by the famous book by Eric Hobsbawm and Terence Ranger (2003). The reformulation regime distinguishes itself from classical formulation and practices but sees in these traditions the foundations of its legitimacy.²² For Hobsbawm and Ranger, traditions are inventions of the present day that relate systematically to the past. They are ubiquitous and serve primarily ideological or political aims. These traditions emerge more easily in periods of accelerated social change, as these transformations threaten “ancient traditions.” While there is a political and ideological component in the new traditions issuing from pharmaceutical innovation in ayurveda—such as the revitalization of Indian traditions considered to be threatened or lost—they cannot be reduced to it. These new traditional drugs are essentially invented to meet consumers’ needs and to enter drug markets. This article also highlights another dimension by considering the changes in the contemporary pharmaceutical milieu as likely to create new codes and new paradigms within the context of globalization and in response to it.

By focusing on the invention of complex extracts and plants combinations, the reformulation regime reorganizes practices around the identification, preparation, evaluation, and mass production of *materia medica*. It creates a world of experts, manufacturers, and consumers whose actions revolves around medicinal plants: from an increasingly problematic collection of raw materials to the multiple translations at stake in the definition of medical uses predicated (or not predicated) upon a physician’s diagnosis and prescription. The new world of ayurvedic pharmacy thus stands at odds with the clinical practice of ayurveda—as revealed by the marginal status of the ayurvedic nosology in the choice of indications—but it also stands at odds with the biomedical world of pharmacy, which, when it comes to the uses of plants, remains centered on the bioprospection model, that is, the mining of local resources in order to select research materials, to identify and purify active molecules, and to make them available through chemical synthesis. The general framework for interpreting contemporary changes in the Indian ayurvedic industry presented in this article thus considers innovation processes in this area as a form of modernity alternative to the development models based on Western knowledge and technological transfers. There are two reasons for this: reformulation draws from other types of knowledge than that of the molecular paradigm that has been prevalent in pharmaceutical research since the mid-twentieth century; and reformulation is rooted in enlarged circulations from South to North as well as between southern countries.

Exploring the reformulation regime therefore discloses conflicting issues related not only to the epistemic status of the drugs and their relationship with the ayurvedic textual sources and practices, but also to the conditions by which these products are exploited. These tensions are especially visible in the areas of standardization, of toxicity (or efficacy) trials, and, above all, of property rights with the association of

²² This is a common feature in neotraditional therapies, which use “tradition” systematically to legitimate new practices. For details, see Pordié (2008a: 9–19) and Pordié and Simon (2013).

systematic documentation practices in the name of protecting traditional knowledge against “biopiracy” and appropriation strategies pertaining to national trademarks and patents. A loop, which links reformulation and the granting of patents over Ayurvedic Proprietary Medicines, has thus been established. In the near future, such looping effects may lead to significant changes in the precarious balance between the invention, protection, and appropriation of medical knowledge deemed traditional.

The reformulation regime is based on knowledge-production procedures that link the local with the global in a new way, since the idea is to create new “traditional” drugs for the biomedical disorders of a cosmopolitan clientele. Rather than turning ayurvedic medicine into a local and marginal form of biomedicine, the practices of reformulation accordingly reveal heterogeneous but deeply rooted processes of specialization, which isolate the manipulation of the *materia medica*, the design and production of polyherbals, from the clinic. Indeed, rather than looking at these processes in terms of “biomedicalization” (Clarke et al. 2010), observers of contemporary ayurveda may consider them as a form of “pharmaceuticalization.” Introduced into the study of Indian medicine by Madhulika Banerjee (2008 and 2009) to insist on the pharmaceutical and commercial status of industrialized ayurveda, this term may also be used to denote the cognitive and social dynamics of reformulation and, therein, its peculiarities. However, what is at stake with the “pharmaceuticalization” of ayurveda is not the disappearance of Indian traditions in the drugs themselves. According to Banerjee (2008: 201–2), “Ayurvedic pharmaceuticals become undistinguishable from any other pharmaceutical. They neither continue to carry the distinctive marks of their original knowledge system nor require their specific context to be effective. Thus the capacity of Ayurveda to be able to pose an ‘alternate’ system is being gradually eroded.” As indicated in this article, these claims do not stand when one closely examines the range of knowledge involved, the practical work of reformulation, and the products it delivers. What we are witnessing today is rather the emergence of a new configuration of ayurveda.

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