A Generic Solution?

The Politics of Bioscience Research and Development in Public

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Note to readers: This is a draft and comes to you for the moment without a bibliography, for which, many apologies. The paper is both an outline of a much larger project and potentially the basis for a stand-alone article. I would definitely appreciate your suggestions on both aspects. Many thanks in advance. cph

Introduction: The pharmaceutical "in public"

Does the recent, embattled emergence of a market for generic medicines in Mexico signal a "re-publicization" of Mexican public health? This question animates my ongoing ethnographic research on the politics and practices surrounding generic drugs in Mexico,

currently Latin America's largest and fastest-growing pharmaceutical market. In 1997 and 1998, following several years of economic crisis, medication shortages, and spiralling drug costs, Mexican government agencies, health activists, and companies joined forces to actively promote the domestic manufacture and sale of generics –legally copied and cheaper versions of patented, brand-name drugs --well beyond their circulation in the Social Security medical system. Resonating with high-profile international and domestic campaigns over access to medicines – particularly, HIV/AIDS drugs in Brazil and South Africa--, the Mexican efforts have sparked intense political, regulatory, and public relations battles within the country. They have also provoked fierce opposition from U.S. and European drug companies, whose monopolies are deliberately being broken – or certainly, targeted-- by the introduction of a national generics industry and market.

It would seem at first glance that in Mexico, as elsewhere, the emergence of an increasingly vigorous generics market is very much part of what we might call a broad resurgence of a *política pública* (literally, public policy, but I might also translate the term as a public politics) as a challenge to globalized intellectual property regimes. Anthropologist and lawyer Rosemary Coombe, political scientist Steve Weber, and others have noted that the globalization of intellectual property (IP) regimes – literally, the extension and harmonization of IP rights across many national lines and administered by a global body (the WTO) --has produced powerful imbalances in more ways than one. Working IP regimes, Coombe argues, are necessarily and fundamentally national and as such come with a notion of the "public good" as a counterbalance to or even function of

intellectual property. But the public goods provisions of IP fall off the map when these regimes are 'globalized' (Coombe, personal communication, October 2003). This has generated some fairly substantial backlashes – particularly where pharmaceutical patents and pricing are concerned.

Indeed, a key to a growing number of recent calls to reimagine the very infrastructure of pharmaceutical research and development has been the argument that intellectual property has become a hindrance rather than a help in fostering knowledge production, innovation, and public health. The industry argument of course is that strong intellectual protection and monopoly prices, extended into ever-greater markets through trade bodies such as the WTO and agreements such as NAFTA and CAFTA, are necessary to recoup high research and development costs, and thus to reward and generate innovation, and *thus* to foster health and well-being. But, from novel proposals for global research and development treaties (Hubbard and Love) to the emergence of non-profit drug discovery consortia (such as San Francisco's Institute for One World Health (IoWH), a counter-argument has emerged with rather powerful effects. Given the preponderance of "me-too" drugs (drugs that offer slight variations on existing blockbuster products, or that have been subject to minor modifications in order to extend the life of a patent at the end of its initial 20 year period), as well as the resistance that big companies have had to developing drugs for diseases such as malaria and tuberculosis (for which there is enormous need but, in terms of the purchasing power of those who are likely to get these diseases, no "market"), a strong argument is taking hold in many circuits that there is no

natural or necessary relationship between "innovation" and strong intellectual property protection/profits, and that in fact the relation might be an inverse one.

This argument is familiar, not incidentally, from the free/open source software movements. "Open source" has become a powerful source of inspiration for biotechnology and genomics researchers, health activists, and not a few economists (such as Jamie Love, of Ralph Nader's Center for the Project on Technology) who are making various calls to "liberate" pharmaceutical and biotechnology research from the constraints of patent protection, the way that Linux code writers and users ostensibly "freed" their software from the Microsofts of the world. [1]

If Microsoft has undeniably had to adjust to the new realities and ubiquity of open source software, it seems that the transnational drug industry –which relies heavily on strong, globalized patent protection-- is facing some powerful political challenges as well. That may be a strange thing to say of an industry that boasts one of the highest profit margins of any (roughly 20% in 2002). Yet, as noted above, the infrastructures and narratives stitching together these profits are facing some significant challenges on a number of fronts. Highly pitched battles over prices and access to HIV/AIDS drugs in southern Africa and Thailand have certainly not done the industry any public relations favors

[1] This analogy has been mobilized in, among other places, U.S. national debates and state policies on pharmaceutical pricing and Medicare. Dennis Kucinich's proposal for "public patents," for example, would ostensibly bring costs down by turning pharmaceutical research over to a network of publicly funded government labs and forcing drug companies to compete in their commercialization, as they currently do for generics in ths U.S. Kucinich is clear about the source of his inspiration. The proposal, he argues, would "improve the quality of R & D by using an 'open source' system that makes data and findings publicly available. This will allow us to tap the collective genius of the world community of scientists. … If smart people across the world can do this for computers, can we not do it for the sake of public health?" (Kucinich 2003).

(even the Vatican, under John Paul II, accused the transnational industry of genocide on this front). Brazil's much-vaunted measures to offer universal, free access to HIV treatment has meant threatening to override patents on anti-retrovirals unless the transnational labs lower their prices, while also looking to domestic and Indian companies, primarily, for cheaper alternatives (Biehl 2004). (One of the key actors in this south-south circuit of pharmaceutical exchange, the Indian generics company Cipra, has just announced that it will start manufacturing a generic version of Roche's Tamiflu in anticipation of a global avian flu pandemic [NYTimes October 14, 2005]). Contested as they are by the patent-holding transnational firms, measures of this kind are potentially legitimated by none other than the World Trade Organization, whose members passed an exemption in 2001 (in the Doha Declaration), which grants nations the right to circumvent still-valid patents in the case of public health emergencies (a process known as compulsory licensing). Even the World Bank has issued calls over the last several years to develop "local" (i.e., national) generic manufacturing capacities in the developing world as a route to addressing health inequities.

Generics – the right and capacity to produce them, as well as the right to buy them-- are absolutely crucial to these ever-proliferating efforts to reorganize what anthropologist Joao Biehl calls "the international pharmaceutical contract" (Biehl 2004). The generic promises so much precisely because of its "public-ness" –its non-property status, its seemingly natural alignment with a politics of public health. But such alignments are not the least bit predictable or self-evident: to make a simple but important opening observation, what we might call (in an ethnographically open-ended sense)

pharmaceutical publics are not everywhere the same. In this paper, I track some of the histories, textures, and character of the emergent move to generics in Mexico, and I argue that these matters can help us – in fact force us – to reconsider what we might mean by this/a pharmaceutical "public" at all.

The project of which this paper is a part aims to subject the generic to ethnographic attention, and in so doing to understand what ostensibly lies "outside" or beyond the pharmaceutical patent, in Mexico. The question is framed by my interests in a few separate discussions which the generics question itself demands that we put together. To state the matter in somewhat truncated form, there is a conversation that needs to happen between the lively and largely U.S. and European-focused literature in anthropology, law, and science studies on intellectual property and the public domain, and work on what Mexican sociologist Gustavo Verduzco calls *lo público* in Mexico (and elsewhere in Latin America, see Forment 2005), which propels us towards a daunting range of questions about the state, "civil society," citizenship, populism (see Laclau) and *lo popular* (see García-Canclini). Bringing these two conversations to bear on each other is my larger project; for the moment, I take a first step in that direction by highlighting the kinds of concerns that surface when we ask about the content and contours of the pharmaceutical public domain –what constitutes the space 'beyond the patent'– in Mexico. In granting a certain specificity to the project of the generic, this essay is an opening salvo in my ongoing efforts to understand the processes through which Mexican pharmaceutical publics are currently coming to life.

Take 1: An embattled marketplace and the health of the nation

The emergence of a vigorous national generics market in Mexico began in the late 1990s and has generated an extraordinary amount of conflict, category proliferations, and debate. As with Brazil, the question of AIDS/HIV drugs has certainly played its part, but the epidemic is much smaller in Mexico and has actually not been the driving force behind the generic-ization of the domestic pharmaceutical economy.[2] There are also some other crucial differences worth flagging briefly here, since Brazil is perhaps the world's flagship example of what a generics revolution might look like: Brazil's remarkable moves to make anti-retrovirals universally available have been fomented by what Joao Biehl diagnoses as the "activist state", a key aspect of which has been the government's ongoing commitment to supporting a domestic biomedical and pharmaceutical industry. It is this, among other things, which has enabled the Brazilian government to make credible threats to simply start reverse engineering patented drugs should the transnational firms not lower their prices sufficiently. The combination of pharmaceutical R& D infrastructure and political "will" is intensely germane here: Mexican researchers within and outside the pharmaceutical industry often lament the lack of coordinated support for a domestic industry (see Hayden forthcoming), and, very much unlike Brazil, Mexico's close economic "integration" with the U.S. makes a trade war (actual or threatened) over compulsory licensing fairly unthinkable at the moment.

As I will discuss in the next twenty pages or so, the generics wars in Mexico have played out in other terms altogether. The struggle here has focused on introducing to a broad

[2] Ballpark statistics suggest that at the end of 2003, Brazil had 650,000 people living with HIV/AIDS out of a population of over 186 million and Mexico had 160,000 people living with HIV/AIDS out of a total population of 106 million.

consuming public an affordable, legally copied pharmacoepia of antibiotics, analgesics, digestive aids, antiparasiticals, and other drugs whose patents have already expired. It is a somewhat prosaic biochemical diet, to be sure, but one with extraordinary market reach: as I noted above, Mexico has recently taken the honors as Latin America's leading pharmaceutical market, with total estimated sales in 2003 at *$8.2 billion* USD (epsicom business intelligence, April 11, 2003).

It is important to note there *has* been a domestic generics industry in Mexico since the 1950s, comprised of companies that have primarily imported their raw materials (the active substances which form the basis of a pharmaceutical), packaged them in consumable form, and sold them to the public health sector, and specifically to the Instituto Mexicano de Seguro Social (IMSS), which is paid for by employers and offers health care and free medications to roughly half the population[3]. In 1983 and 1984, in concert with the World Health Organization's campaigns to broaden access to essential medicines in "developing" nations, the Mexican Secretary of Health established the country's first efforts to establish a generics-based public health policy when it established a *cuadro básico*– a basic pharmacoepia of medicines that would be prescribed in IMSS and the other public sector health institutions. Precisely because the point of this exercise was to lower the cost burden of medication purchases on the public sector, the majority of these drugs were – and remain—generics. IMSS and its sibling institutions were the lifeblood of the small generics manufacturing and packaging

[3] The public sector health instituions are the Instituto Mexicano del Seguro Social (IMSS) (for those with regular work, registered by employers); the Instituto de Seguridad y Seguro Social para Trabajodores del Estado (ISSSTE), for state employees; the military; the state-run oil industry (Pemex); and the Secretary of Health (Ssa), which administers hospitals for the 40-50% of the population not covered by any of the above (ie those without regular employment).

industry in Mexico for roughly forty years, from the 1950s until the 1990s. But then, in late 1997 and early 1998, generic drugs started their somewhat complicated travels out of the social security/public health system and into the reach of consumers through (private) pharmacies.

Thus, we might usefully start by thinking about the *de-publicization* of generics: or rather, their move out of the captive market of the public sector and into the public sphere of the marketplace. This recent move was precipitated in large part by a crisis in Mexico's social security system in which, as in many other nations (the US and the UK included), the cost of medicines has been a crucial factor. From 1994-1997, annual drug prices increased overall by 141%, and the price of analgesics in particular increased by 231% -- this, in a time of generalized, and severe, economic crisis. Newspaper reports at the time noted that IMSS was, on a regular basis, out of at least 100 of the 500 medicines in its *cuadro básico*, with over 150 regularly running precipitously low. Patients thus had to buy their own medications in private pharmacies, where on offer were almost exclusively patented products, the costs of which are significantly higher (especially compared to the fact that IMSS patients get their medicines for free). The Secretary of Health thus made a deliberate policy decision to start encouraging a broader market in generics. How might a Secretary of Health actually do that?

As in Argentina more recently (precisely in the midst of its own economic crisis in 2002), the Mexican government went straight for the jugular: to physician's prescription practices. As Mexican pharmaco-economist Raul Molina described it to me, when you

get doctors to stop prescribing by brand name, you've already broken monopolies. (Argentine economists describe the same philosophy as a challenge to "deregulationist [neoliberal] prescription policies"). A reform in the Mexican health law, taking effect on the first of January, 1998, required doctors working in the public sector to prescribe the active substance of a drug, in addition to a brand name. Thus technically doctors cannot simply prescribe Clarityn™; they have to prescribe 'Loradatina', (the name, in Spanish, of the active substance on which Clarityn™is based), and if the doctor in question so chose, *also* or preferably the brand name of the patented "original" or *medicamento innovador*. This has been a rather unevenly applied shift: many doctors with whom I have spoken have told me that they continue to prescribe by brand name only – this is particularly the case among those working in the private sector, to which this decree does not technically apply. It is this fact which prompts public health officials, domestic companies, and generics aficionados to call for the creation of a "culture of the generic."[4]

But of course another necessary element to reconfiguring the domestic pharmaceutical market is "supply." Here, ready to step into the opening provided by the Secretary of Health in 1998 was a man named Victor González Torres. Like most good pharmaceutical magnates (note the rather insistent references to the humble 'family pharmacies' that pepper many transnational drug firms' origin stories), González Torres lays claim to a pharma-family legacy. He is, among other things, the great grandson of the founder of Laboratorios Best, a company that started in the 1950s manufacturing

[4] I address these public-education and physician-education efforts elsewhere.

generics for sale to IMSS and the other public sector health services.[5] After Victor took over leadership of Laboratorios Best, he started his own transport and packaging companies for Best products. In 1997, just as the Secretary of Health (Ssa) was announcing its new enthusiasm for generics, he announced the opening of the first branch of his new pharmacy chain, Farmacias Similares – a chain that would distribute only copied drugs, either made in-house (by Laboratorios Best) or purchased from other generics companies.

The similar

The name is worth dwelling on for a very, very long time. The idea of a "generic" drug (medicamento genérico) had very little purchase in the public eye in Mexico in 1997. Pharmaceuticals were known, prescribed, and purchased in pharmacies primarily by brand name; the alternatives were simply the cheaper medications "that IMSS gives you." Given the low visibility of the idea of the generic as such, González Torres's pharmacy chain picked up the idea of "the similar" as its commercial hook: "ask your doctor to prescribe the economic [cheap] brand, known popularly as similares," one of their leaflets urges. But the similar has a politico-technical meaning as well: *medicamentos similares* <u>can</u> refer to those which have the same biological *activity* as a patented drug, but are not based on the same *molecule*. (González Torres insists that their drugs are based on the same molecules). Insofar as patents cover molecules and not activities, "similar" could be construed as a cautious choice, protecting its purveyors from accusations of patent infringement. In this sense, it would be also a *different* drug than a generic, and many commentators and physicians with whom I have talked about this question in Mexico

[5] The González Torres family is illustrious on more fronts than one: Víctor's brother is the founder of the Green Party of Mexico, another sibling was the founder of a competing pharmacy chain, Farmacias del Ahorro (Discount Pharmacies, or, literally, "Pharmacies of Savings").

define a “similar” drug in exactly these terms: one that is not quite “the same.” But the potential ambiguity contained in the commercial name has been mediated by Farmacias Similares’ rather more bold motto: “the same but cheaper!” (lo mismo pero más barato!). Cheaper indeed: the drugs produced and sold under the Similares name are up to 75% cheaper than their branded counterparts. The chain’s ubiquitous mascot is the aptly named Dr. Simi, whose image adorns flags, pharmacy store fronts, coffee mugs, and calendars and who appears live, Mickey Mouse-style, at pharmacy openings, medical symposia, press conferences, and in the Alameda central on sunny Sundays. Dr. Simi cuts a cheerily avuncular figure, meant to convince would-be consumers that they are in good hands with Similares.

Such reassurances about the quality of the similar do not come easily, neither to Farmacias Similares, nor to the office of the Secretary of Health (la Secretaría de Salud, or Ssa), whose change in prescription laws accompanied Dr. Simi’s arrival on the scene. The opening of a broader generics market was not looked upon at all kindly by the transnational pharmaceutical industry (represented here prominently by companies such as Novartis, Merck, and Roche), which, in 1997, had dominion over roughly 90% of the Mexican pharmaceutical market. The threat that a shift in prescription practice presumably posed (and still poses) to this market share quickly became evident in the massive media battle that ignited in 1997 and 1998. While the Secretary of Health’s office initiated a public education campaign on the importance of the creation of a market for generics, the transnational pharmaceutical industry– led by their domestic (Mexican) trade organization--responded in an equally full-scale campaign warning the public about

the poor quality of generics; the threat they pose to health; and the danger this new policy posed to physicians' freedom to prescribe with "patients' best interests" in view.

Directed first at the government's prescription decree, these attacks soon put Farmacias Similares in their sights as well. The U.S. Pharmaceutical Manufacturers' Association (PharMa) registered a complaint with the U.S. Trade Representatives' Office that the claim "the same but cheaper" trespassed on the distinctiveness conveyed by corporate trademarks. The Mexican pharmaceutical industry organization (representing the transnational companies with manufactuing plants in Mexico) also registered a formal complaint with the Office of Consumer Protection in Mexico that the claims of Similares--: "the same but cheaper," and the rather compelling, "we don't have everything but what we have is much cheaper!" [*No tenemos todo pero lo que hay es muchisimo más barato*!] –mislead the public. The Office of Consumer Protection agreed and promptly fined Similares. Several branches of Similares were closed down (only to reopen), while representatives of the transnational pharmaceutical industry threatened to pull investments out of Mexico, as the opening of a generics market more broadly was portrayed as a violation of the intellectual property rights of these companies --even though Similares and other distributors and manufacturers of these products were very explicitly *not* in the business of breaking patents. (More on this below).

It must be noted that a fight with the transnational drug companies was and remains something that González Torres and those working with him have taken up with a certain gusto. In fact the *Similares* project was launched in 1997 precisely as a battle against the

foreign companies who have "the health of the Mexican population" (at least in the form of pharmaceuticals – an importantly narrow definition of 'health' [see Nichter]) in their hands. This is a situation that, they suggest, does not work in the best interests of the nation's health or the national economy. [GRAPHIC: Defiende tu economia!] Farmacias Similares thus pitched themselves from the start as much more than a distribution chain: they describe themselves as an engine for the promotion of national interest and self-sufficiency, the health of the Mexican population, and most importantly, as the defenders of "those who have the least" – not an insignificant demographic in a country in which, according to recent figures, unemployment is now higher than it has been in seven years. Cheaper medicines, produced by *national* companies, available (at a low price) to all: this has been the health care revolution promised by Farmacias Similares.

And in fact Similares *have* also taken the fight with transnational firms into even more contentious territory, attempting in 2002 and 2003 to enter or at least gesture to the compulsory licensing fray. For, a serious shortcoming to a health care revolution based on respecting patents is that one can only stock medicines that have been on the Mexican market for at least 20 years. A stunning number of products fit the bill, to be sure; Cyclosporin, Advil, Clarityn, Aspirin, and hundreds more. But in domains where novel and even experimental therapies are of enormous importance, such as cancer and HIV/AIDS, the "Similares" revolution runs into a significant block. Hence an attempt in 2002 and 2003 to mobilize AIDS and cancer activists, legislators, and various other allies (most pointedly, the Green Party of Mexico, founded by Victor González's brother and then headed by his nephew, the scandal-ridden "*niño verde*") in a struggle to change

Mexico's patent law. The legislative proposal that made it to the Camara de Diputados was to cut patents in half, to 10 years, in the case of "essential medicines." The proposal failed to clear the Camara –but only by only 5 votes-- in the summer of 2003.

Take 2. Quality: or, the technics and politics of the similar

Te curaste o te sientes similar?

"Are you better … or do you feel similar?"

--Pharmaceutical industry anti-Similares campaign slogan[6]

The question of market share is a clear point of contention in the TNC-Similares wars. But unlike in high profile international battles over the pricing of patented antiretrovirals, the fight over generics Mexico is *not* primarily being waged over the prospect of patent "infringement." As noted above, the accusation of piracy—the industry's big stick--hovers persistently in industry objections to the "unfair advantage" leveraged by generics companies which piggy-back onto existing products and existing demand, and which bear none of the research and development costs shouldered by the big companies that patent new drugs. But this is of course precisely what is *supposed* to happen at the end of the patent. Indeed, as we might surmise from their choice of name, the folks at Similares happily cede the work and the trope of innovation to the bigger companies and insist that such labor, for which larger transnationals are uniquely suited, is sorely needed.

[6] Cite to la Licenciada.

This is, to be sure, not the only way to frame an enterprise based on freely copied material. Unlike Linux developers, or even the Brazilian manufacturers of (unlicensed) copies of Apple computers who insisted that it actually takes a great deal of innovative labor to reverse-engineer a Macintosh (da Costa Marques 2004), Similares associates are not prompting us to re-orient our notions of *who* can claim dominion over the prized category of innovation.[7] Theirs is a more modest effort, it would seem: to convince Mexicans (and their political representatives) that it is possible for a national enterprise to manufacture quality medicines at prices that place "health" – again, in the specific form of pharmaceutical products --in the reach of a broad and increasingly impoverished public. In *this* formulation, the crucial point of entry and contest is not "innovation" per se, but the closely related trope --and hotly contested biochemical fact –of "quality." In pharmaceutical industry efforts to discredit and block the move towards a broader market in generics, quality has been used to redefine and restrict the *licitness* of copies that are, after all, *legal*.[8] Quality has become the technical-political tool for chipping into the amorphous category of the copy and creating ever more "refined" technics for differentiating generics from themselves – and thus, as ever and as always, from their patented counterparts.

[7] Brazilian science studies scholar Ivan da Costa Marques has written about the manufacture, by a Brazilian firm, of (unlicensed) copies of Apple Macintosh computers in the 1980s. Apple, accusing the company of piracy, sought a legal injunction and damages. The Brazilians countered that indeed it took at lot of ingenuity to reverse engineer these computers, and that this innovative labor should be recognized and validated.

[8] See Janet Roitman's work on contraband and trafficking in the Chad Basin for a brilliant exploration of what can be at stake in drawing lines between the (il)licit and the (il)legal (Roitman 2003).

Not all generics are *similar*

> ‘There is no such thing as a *medicamento similar* in the health regulations. The category of the similar ***does not exist***.” --Chief chemist, Laboratorios Best/Farmacias Similares, Mexico City, interview, 2004

> “As of right now (1997) there is not one product in this country that we can call generic in the terms established by the new law.” --UNAM Pharmacology professor Fermín Valenzuela, consultant for the Secretary of Health on the General Health Law of 1997

When the Mexican Secretary of Health started to foment a new policy on “generics” in 1997, definitions were very much at issue. They remain so: in the relevent regulations and norms, and in my conversations with physicians, people in the pharmaceutical industry, and the chemists in charge of producing these products, a rather fragmented and ever-proliferating classificatory universe has started to take shape. It is not just that there are a number of different names for the same thing: the generic, or to use a less freighted term, the copy, has become a fractured thing indeed.

Among the conditions imposed by the Secretary of Health in the 1997 law regarding the prescription of generic medicines was a list of conditions that a copied drug must meet in order to be registered and thus authorized for sale as a generic in Mexico. Initially, regulatory provisions spoke of *medicamentos genéricos* (those packaged for the public sector and labeled only with the name of the active substance) and *genéricos de marca*

(branded generics: those labeled with a generics' company's own brand name, for sale to the wider public, through pharmacy chains). But with industry pressures running high, yet another category stepped in: interchangeable generic (*genérico intercambiable, or GI*): that which meets strict tests for "bioequivalence." *This* moniker for "the same" requires not only that the drug contain the same active substance and at the same concentration as its patented counterpart, but that it be absorbed by human bodies in the same way, and at the same rate (this absorption rate signals its "bioavailability"). Bioequivalence is expensive to prove, requiring clinical trials in patients (at least 24 healthy patients over 3 months), whereas simple *medicamentos genéricos* do not require this level of testing. Where accusations of piracy do not stick (or at least, not for long), bioequivalence and its categorical ally, the *genérico intercambiable*, has stepped in as a key weapon in the ongoing generics wars. (Again, definitions continue to spin here: a researcher who works in a field servicing the pharmaceutical industry told me that "*intercambiables* don't even need to be called generics. They are the same, and that's that. Below this level, *then* you can start talking about generics." (pers comm)).

The chief chemist of Laboratorios Best (again, the lab from which sprang Farmacias Similares) told me of her company's objections to bioequivalence and the *genérico intercambiable* as a new standard of proof:

> But listen: you know that this medicine has been sold [to the public sector] for fifty years. It's not just in one clinic: it's millions of people to whom absolutely nothing [bad] has happened. And why are you [Mexican regulators with, she

> suggested, the transnational firms behind them] asking me, now, for this proof of what you call 'quality'? Because you know it's very expensive, and you suppose that the national laboratories don't have the economic power to carry them out. But surprise! The national labs are doing it and they are demonstrating to the transnationals that they meet the proof perfectly well. So there can't be any doubt, anymore.

But presumably, and this is the point for those insisting on the *GI* designation, there remains the potential for doubt, as long as there is a category of "interchangeable generic" on the menu—a label which adorns only a minority of the products on the shelves of Farmacias Similares and other chains that now sell generics to the general public.

Sui-genericide

As the stratifications of legitimate and illegitimate copy-ness have become more complex, "genérico intercambiable" has surged to the expensive and elusive top of the heap, while the diffuse category of "the similar" has plunged to the bottom. This is not the best of news for the Similares enterprise. Their quest for legitimacy has indeed become more complicated now that Similar the (generic) brand has, as Grupo's director of public relations described the situation to me, become "like Kleenex." Scholars of trademark and the brand such as Celia Lury and Rosemary Coombe have drawn our attention to the phenomenon of "genericide" – the [legal] death of a brand when it becomes so well known that it loses its distinctiveness and becomes, well, "like Kleenex" – a stand-in for the entire class of products to which it refers. This is not good for the

purveyors of these brands because they can no longer enforce their exclusive claims to the use of their name in the public sphere. Similarly, the *brand* Similar has, it seems, gone generic: it has been absorbed into the public sphere and associated regularly-- in the press, by folks in the street, by doctors, by pharmaceutical company representatives -- and by many other folks, with *all* medicines that are "copies" of patented products. While this might not seem like such a dissonant or even disagreeable fate for a company that traffics in the generic, Farmacias Similares are not very different from the makers of Kleenex or of Clarityn, for that matter, in their desire to control the use and associations of the Similares trademark (see Coombe 1998). Complaining about the pirates who plague them (such as small corner pharmacies that sell "medicamentos similares", or, the independent shop I saw in a small town outside of Toluca, a few hours from Mexico City, sporting the hand-painted sign, "Farmacias Simylares"), Similares are engaged in a serious battle for control over the domain of the copy.

Similares associates might indeed find reasons to regret their initial inspiration regarding commercial names, as they now find themselves trying, at every turn, to differentiate the Similar brand from the idea of the *merely* similar, insisting in interviews and in public symposia that there is actually no such thing as a "similar" medicine. I noted to one commentator familiar with the Mexican pharmaceutical industry that it seems that the company had become trapped by their own name. "Trapped, no," he responded. "They've hung themselves with their own rope" (GB pers. comm 2004). It just might be an adequate assessment. For, while the marketing folks at Simimex (another affiliated enterprise) diffuse with extraordinary vigor the image of Dr. Simi as a purveyor of

quality goods, his namesake enterprise faces the unenviable task of insisting that the main product they sell, under an increasingly well known name, does not actually exist. It is a commercial name-- the name of their chain, to be sure-- but they do not produce "similar" medicines. "Now everyone says we sell *medicamentos similares* ... it's not true! They're branded medicines, made by national laboratories." (*Son medicamentos de marca, fabricados por laboratories nacionales*).

In fact Similares™ won't be outdone (certainly, not easily) on the question of "quality." They have their own claims to make, and their own tests to run. Just as they are (various members of the Similares enterprise tell me) constantly being monitored by the Secretary of Health and IMSS to make sure their products meet the new regulations, this pharmacy chain too pegs its own distinctiveness on its meticulous quality control. For recall that pharmacies are essentially distribution chains. Similares happen to make some of their own medicines (in 2004, 50 of the 300 or so medicines that they sold were produced by their own Laboratorios Best) but they buy the rest from other "labs of quality," national and otherwise. Similares associates told me and insist over and over again in their publicity that they regularly surveil their providers and subject them to the same standards to which the Secretary of Health subjects Laboratorios Best. Indeed, ever vigilant over their suppliers/competitors, the head of public relations for Foundation Best, the umbrella organization that includes Farmacias Similares, told me that they have succeeded in getting the Secretary of Health to close down more than one lab whose production standards malign the good name of the "serious" national pharmaceutical industry (interview, 2005). Similares are not only the regulated, but the regulator. This

is of some significance as I return now to my question about the constitution of Mexican pharmaceutical "publics" organized around generic medicines.

Take 3: A privatized nationalization?

After its rough start in the rapidly changing Mexican pharmaceutical marketplace, Farmacias Similares has become one of the fastest growing and most visible businesses in the country. It was not at all clear from the start that it would work: in 2000, newspaper articles on the ongoing struggles between the transnational pharmaceutical industry, the Ssa, and Similares could note, off-handedly, that "generics had failed." Yet we might note the significant fact that 1999 registered the first year of a drop in pharmaceutical prices in Mexico, precisely, industry analysts note, because of the introduction of a market in generics. Similares are certainly not the only players here, and I do not mean to ascribe them sole authorship of this change. But their role in this transformation has been important--as much for what they are doing through their pharmacies as for what they are doing far beyond the doors of these commercial outlets.

***Similar* social security**

While the Secretary of Health (Ssa) and Similares presented a more or less aligned front in 1997 on the question of the need for "cheaper, national brands" of drugs, this strategy of de facto solidarity and identification has now been turned on its head. IMSS and Similares are currently at war; the office of the Secretary of Health now issues public statements not in its defense against transnational companies as it did in 1997 but in its defense against the attacks of Victor González Torres, whose civil association, the National Movement against Corruption (MNA), has launched an all-out attack on "corruption" in IMSS pharmaceutical purchasing practices. Refusing, as of May 2003, to

sell any more Laboratorios Best products to the public sector, González Torres dramatically offered to sell at a further 25% discount any medicine that patients were prescribed by IMSS but could not get their hands on in the still understocked public sector pharmacies.

But price wars with the public sector are merely the tip of the proverbial –and immense--iceberg. Victor González Torres is the head of a wide-ranging movement, simultaneously political, non-profit, and highly profitable which has much more than a foot in *lo público*– the terrain of functionalities that, as Gustavo Verduzco notes in the case of Mexico, have largely been seen to be the province of "the state" (Verduzco 2003: 31). As Verduzco and countless other scholars have noted, an identifiable and viable Mexican "civil society" started to emerge in the mid-1980s[9] and it did so in the context of a history in which the corporatist state and the Catholic Church had, since the Mexican Revolution, held a virtual monopoly on electoral politics, social assistance programs, and even "social movements" themselves. But now, Verduzco notes, we might take note of a proliferation of organizations that are not reducible to either of these institutions ('state' or church) and that increasingly engage in direct political action (here, think of human rights groups), or that take charge of questions of social assistance, health care, and other matters of "public interest" (Verduzco 2003: 157). González Torres has certainly been staking direct and explicit claims in both arenas (the 'political' and the 'social'). In addition to the pharmacies, the drug company, a physicians' association, the transport and

[9] This, following a massive earthquake in Mexico City and intense grassroots organizing that took shape to deal with the catastrophe in the absence of a credible and competent state response (see Poniatowski).

packaging firms, and the anti-corruption campaign currently waging war on IMSS, he heads up a civic association, Fundación Best, which offers a wide range of public or social-assistance programs to some of Mexico's most indigent citizens and which is, according to Gonzalez Torres, funded by his ever-increasing sales from the Farmacias (critics have accused him of money-laundering and suggested more sordid explanations for the source of all this money). Dr. Simi, under the umbrella of Fundación Best but taking a cue, it would seem, from time-honored tactics of the once-ruling party, the PRI, has presided over the transfer of mountains of beans, rice, clothing, housing, and other much-needed goods to the poor, the indigenous, the alcoholic, the orphaned, and the disabled. The Foundation and Dr. Simi now hand out free rice in *fiestas populares* that they host on Sundays in city squares from Mexico City to Oaxaca and beyond. Fundación Best has also, crucially, set up health clinics adjacent to the Farmacias Similares storefronts. Staffed largely by recently graduated doctors, and located primarily in poor neighborhoods (*barrios populares*), these clinics now offer medical attention (usually accompied by prescriptions for Similares products) for a stunningly cheap 20 pesos (2 dollars) to over 1 and half million patients a year. Laboratorios Best, with the help of the Foundation, has also branched out into offering discounted diagnostic tests; the Foundation runs a call-in line for advice on medications, and another call-in line for mental health advice. In 2003, Foundation Best took the next logical step, pioneering its own Health Plan (the Sistema Similar de Seguros [SSS] or "el *Simi*Seguro" for short), for which patients pay 50-60 pesos a month and receive free medical treatment and half-price medicines. The catalogue of goods and services offered by this hybrid and hydra-like organization continues to proliferate at a stunning rate. We might note – and I will

elaborate on this below --that this movement in the name of national sovereignty and self-sufficiency is rather explicitly setting itself up as a direct competitor to the state, at least where health care and social assistance are concerned.

But the parallel quickly intersects: it may not be a surprise, given all of this, that González Torres/Dr. Simi are actively pursuing the possibility of running for President of Mexico when Vicente Fox's term expires in 2006. The corporate flag, corporate hymn, weekly press conferences, ever-increasing attacks on prominent political figures, and embattled family connections to embattled political parties give us some hints that he might be well prepared for the job. While the status of pre-candidate is an uncertain one, infinitely more certain is Dr. Simi's spread into the rest of Latin America. Guatemala is now home to several Farmacias Similares (the chain has the very visible and explicit backing of Rigoberta Menchu); the company has become active in Argentina, a country still reeling from its recent financial crisis and in the throes of its own generics-friendly public health maneuvers; and Farmacias Similares established their first storefront in Costa Rica in 2004. They hope to be in ten Latin American countries by the end of 2005. What might we make of all of this?

Take 4: Pharmaceutical nationalisms, then and now

Similares have, as we have seen, attempted to launch a major challenge to the previously existing order in the provision of medicines under the mantle of a nationalist fight against "transnational greed," and as champions of social justice and domestic self-sufficiency. In that regard, they have tapped into –but also radically transformed --a political-technical discourse which has an illustrious history in Mexico, *precisely* (though not

exclusively) where pharmaceutical development and distribution is concerned. For the most recent reference point for this kind of pharmaceutical politics, we might look to the 1970s, when president Luís Echeverría made what I call a form of "pharmaceutical nationalism" the pillar of his efforts to shore up a fracturing national body politic (Hayden 2003 and 2006; see Soto Laveaga 2003). Hoping to jump start a long-faltering domestic industry (operating in a context in which 80% of the pharmaceutical market was then, as in the late 1990s, controlled by foreign companies), Echeverría rescinded the existing patent law, thus opening the way for any drug to be legally reverse-engineered/copied, regardless of its patent status. He also effectively nationalized the industry, mandating that all companies within the country be at least 51% Mexican-owned (Sherwood). Echeverría's nationalizing efforts were quickly reversed in the succeeding administration, as pharmaceutical patents were reinstated and transnational companies invited back in. Mexican physician Xavier Lozoya, a prominent player in the changing fortunes of public sector pharmaceutical research and development in Mexico, has argued that Echeverría's short-lived efforts were part of an attempt to chart a "*tercer vía*/third way" –that is, they were a key salvo in a growing *tercer mundista* (third worldist) politics in Latin America, in which the newly denominated "third world" would chart its own path, "neither U.S. nor U.S.S.R." (Lozoya, pers comm. 2004).

We might suggest that Echeverría's *tercer vía* has been invoked and radically transformed through a rather differently configured Third Way -- that which comes to us re-packaged as the capitalism-friendly "alternative" to neoliberal development that has been articulated by British sociologist Anthony Giddens. As anthropologist John

Gledhill notes, Giddens' Third Way is/was not just the recipe book for Blair's New Labour and for the Clinton administration; Giddens has tried to make the case that his Third Way has a particular relevance to Latin America and indeed many of its tenets have found much favor in Vicente Fox's Mexico and among other Latin American politicians and intellectuals (Gledhill 2001). Insofar as *this* third way emphasizes "social citizenship," a strengthened voluntary sector, and responsible capitalism, it seems Giddens could take some lessons from González Torres on how to set these principles in motion. González Torres' social-political-health-populist movement is one in which the private sector, a growing web of "civil society" organizations *of his own making*, and the explicit reconfiguration of "citizens" as consumers – particularly, poor citizen/consumers (those without the resources to go to private doctors, and those who are excluded from IMSS by virtue of their work in the "informal" labor market)-- are very powerfully being called upon to do the work that *some* agents of "the state" still attempt to do. [10] As we might glean from this pharmaceutical magnate's self-description – "I'm Che Guevara in a Mercedes!"—the Similares movement is indisputably a businessman's revolution, executed by an enterprise laying claim to a social-nationalist (not to be confused with socialist) conscience. The distinction is clearly a difference that matters: at regular, lavish breakfasts they host in Mexico City, *Similares'* associates assure over 500 political figures and businessmen and –women that this politics of broadened access to medicines is "*not* a communist" or socialist strategy. To prove the point, González Torres's foundation exhorts at every turn: *Ayuda mucho y gana más* (Help a lot and earn more).

[10] The mayor of Mexico City, Andres Manuel Lopez Obrador and his Secretary of Health, Asa Cristina Laurel, have made a left-leaning, inclusive social and health policy a hallmark of their administration. AMLO has now left office in order to run for president.

It seems clear to a certain extent that the biggest difference between Echeverría's tercer vía and Gonzalez Torres' own brand of the third way lies in the role of "the state" and the "not-state" in ongoing battles to define the distributive agencies that shall organize the provision of healthcare and the care of "the poor," and perhaps more precisely, that shall organize a fragmented, dispersed market of disenfranchised consumer-patients (Pego, pers.comm 2005). This is a rather sizable constituency that has been created through a powerful combination of factors, including but not limited to ongoing, widespread economic hardship, the far from universal coverage offered by the public sector health services, the continued underavailability of medicines therein, and decades of accusations and resentments over presumed exclusions, elitism, and patronage that have surrounded membership in IMSS in the first place (Schwegler 2004). It is this "market" (and presumably this voting base) that the *Simi*Seguro is after.

But significantly, it is not only Dr. Simi who has explicitly sought to address and indeed to call into being *this* excluded pharmaceutical public. Vicente Fox's Secretary of Health, Julio Frenk Mora, helped design and implement the government's own answer to this problem of a disenfranchised pharmaceutical/biomedical public, with the *Seguro Popular* – a new plan which calls upon families and individuals to pay into a publicly administered insurance plan, the remaining costs of which would be met by significant contributions on the part of state governments. While critics note that the *Seguro Popular* asks people to pay into a set of services to which they already, technically speaking, have access for free, the Fox administration and *Seguro Popular* defenders make a strong bid for the importance of government-individual (or family) "co-

responsibility." While "the state" launches the Seguro Popular in the name of individual (and a *decentralized* governmental) responsibility, Dr. Simi – often flanked by his buxom SimiChicas (popular actresses/singers who have signed on as "spokespeople" for Similares)– routinely and loudly predicts its certain failure. And he does so while making his own bid for how to guarantee the 'well-being' of the Mexican population. Denying accusations that he seeks to compete with the public sector, Víctor González Torres promises a viable "complement", while he busily builds an alternative and highly lucrative health care system fused with a populist public assistance "model" that together now extend far beyond national borders.

Open-ness is a complicated thing

This is, to be sure, far from the last word on the multiple dimensions of the Similares enterprise, its leader's political aspirations, and its relation to the question of social security, health, and social assistance in Mexico and across Latin America. But let me offer a few thoughts to wrap this up for the moment.

One of the things this generic-ization is not is a shift towards "open-ness" in the public patent or open source sense. The Similares move to set pharmaceuticals in broad circulation outside of the confines of the patent and the (transnational) brand name is not in any easy sense a booster shot for the public sector but rather a populist privatization which requires and fosters a boom in private consumption, particularly among the poor. This development adds another layer to the pointed thoughts of a colleague of mine who heads an IMSS research unit on plant-based pharmaceutical development. When I talked to him about efforts to apply the notion of open source to biotechnology and

pharmaceutical research and development, he (respectfully) shot the idea down with one swift blow: it is a sueño guajiro – a futile dream, certainly, but more than that too: a sad joke. The open-ness at work in Mexico and to which he is forced respond, he insisted, is a different one: that of coyuntura, open markets. In fact, in Mexico, generics or at least Similares are, arguably, far from a "challenge" to neoliberal trade regimes, but seem to be part of an ongoing privatization of health care, in which the burden of medication costs shifts ever further towards individual consumers. The implications of this are not at all clear: for as many of my most trusted interlocutors insist, grudgingly, Dr. Simi is undeniably intervening in an important way, speaking directly to those 'excluded' by/from the machinery of IMSS and the rest of the social security system.

We might reiterate the question, then: what lies "outside" or beyond the pharmaceutical patent in Mexico? The spatiality presumed by this question (that the patent has an inside and an outside) is not one I will hold onto for very much longer (Timothy Mitchell, for one, has done a beautiful job showing just how much we need to ethnographize the presumed lines between the insides and outsides of capitalism's cherished economic forms) but it is the one that propelled me into the present inquiry and its utility lies, perhaps, in its very inadequacy. For we know from a great deal of critical work on intellectual property and post-Habermasian publics that the public and private are by definition permeable to each other in many complicated ways.[11] The lively career of the Similar in Mexico tells us something perhaps more challenging, which is that we need to broaden our vocabularies and theoretical reference points in thinking about a) what is

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[11] For example, Habermas' public sphere is of course a bourgeois public sphere enabled by private property rights; open source folks have to copyright software in order to keep it in the right/left/public hands; the Institute of One World Health similarly licenses patented molecules in order to then prosecute its efforts to do non-profit drug discovery. None of this is a scandal. It does however provoke us to think as ever about what public-ness is made of.

other to “the patent” and b) more broadly, how pharmaceutical politics are a key nexus for re-thinking the relationship among *lo público*, nationalism, and populism in contemporary Mexico. For in the generics/Simi wars we see a powerful battle afoot not just or even primarily between “transnational” (private?) and “national” (public?) interests, but alongside and mixed up therein, over the relationship between the state and an increasingly powerful populist consumerism. With Echeverría’s 1970s Mexico and post 1996 Brazil in mind, we should not be surprised that core questions about distributive agency and ‘the state’ should be waged through the politics of the pharmaceutical; but as Victor González Torres shows us all too vividly, we would do well not to assume too much about the shape that *this* politics of the copy might take.