
Distinctively Similar: A Generic Problem

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INTRODUCTION: PARITY SITUATIONS¹

This Essay examines a paradox that is becoming increasingly visible in the world of pharmaceutical making and marketing: the emergence of sameness and similarity as generative forms of distinction and value. Whether we consider the rise of the powerful pharmacy chain *Farmacias Similares* in Mexico or the relatively new category of biosimilars in Europe and the United States, generic drugs can no longer be described as merely the undifferentiated commodity counterpart to distinctive brand-name drugs. Working within and across some of the pharmaceutical landscapes that have given rise to such terms and things as *similares*, biosimilars, *copias*,

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¹ WILLIAM MAZZARELLA, SHOVELING SMOKE: ADVERTISING AND GLOBALIZATION IN CONTEMPORARY INDIA 254 (2003).

interchangeables, biobetters, and supergenerics, this Paper asks: (1) What are the conditions of possibility for pharmaceutical equivalence to function as a kind of distinction? And (2) If generic sameness can become a valued *kind* of distinction, even a proper noun, what are the consequences for our understanding of how brands, trademark, and value work?

What happens when a patented pharmaceutical reverts to the public domain? When a drug patent expires, “the product becomes a commodity.”² In political economic terms, it becomes fungible: the market in which some of us live treats commodities as equivalent and interchangeable with each other, no matter what laboratory, factory, or farmer may have produced them. Marx famously made the point through the example of wheat-as-commodity (*terroir* be damned): “From the taste of wheat it is not possible to tell who produced it, a Russian serf, a French peasant or an English capitalist.”³ The definition of a commodity — different producer, same interchangeable product — also happens to be the World Health Organization’s (“WHO”) definition of a generic drug. The WHO defines a generic drug as a “a multisource pharmaceutical product [i.e., *one that can be made by laboratories other than the original patent-holder*] which is intended to be interchangeable with the comparator product.”⁴ Different producer, same thing: as objects that are meant to be interchangeable regardless of the laboratory that makes them, and as undifferentiated versions of once- (and still-?) distinctive things, generic drugs are dynamic materials through which to consider the increasingly odd relationship between the mere generic commodity and the distinctive pharmaceutical brand.

In the United States, the “innovator” pharmaceutical industry has certainly long had a hand in selling generic drugs, but its focus until recently has been directed towards “novel,” brand-name drugs, largely ceding the market for generic medicines to smaller laboratories.⁵ In

² Stephen A. Charles, *SuperGenerics: A Better Alternative for Biogenerics*, 10 DRUG DISCOVERY TODAY 533, 533 (2005).

³ KARL MARX, *A Contribution to the Critique of Political Economy*, in KARL MARX, FREDERICK ENGELS: COLLECTED WORKS, VOL. 29, at 257, 270 (1987). For Marx, of course, the erasure of the specific conditions of labor and production was precisely the problem with the commodity form. See generally *id.* (deconstructing the commodity as an objectification of labor).

⁴ Rein Pähkla, World Health Org. [WHO], *Multisource (Generic) Pharmaceutical Products: Guidelines on Registration Requirements to Establish Interchangeability*, at 7, WHO Doc. QAS/04.093 (2005).

⁵ See generally DOMINIQUE A. TOBBELL, *PILLS, POWER, AND POLICY: THE STRUGGLE FOR DRUG REFORM IN COLD WAR AMERICA AND ITS CONSEQUENCES* 163-92 (2012)

fact, pharmaceutical economists argued in the early 1990s that the leading-brand and generic markets in the United States were essentially separate.⁶ But this situation has changed in a number of ways. The oft-decried innovation failures, waves of patent expiration, and dry pipelines confronting the pharmaceutical industry since the 1990s are undeniably at play in this shift, and bigger companies are finding generics quite interesting after all. Generics are being rediscovered as raw material for research and development, as discovery firms resurrect quaint forms of recombination — combining the active chemical principles in two off-patent generics to see if some novel effect might be achieved.⁷ Major transnational drug companies are setting up new departments of “established products” (i.e., generics divisions).⁸ The rise of cost-cutting pressures in the United States and Europe is also contributing to the growing dominance of generics, both in terms of “volume” and “value”: for example, generics accounted for 78% of the prescriptions dispensed in the United States in 2010.⁹

But to a certain extent the action lies on a broader, more differentiated global stage. Campaigns for access to essential medicines

(discussing the dynamics in the U.S. industry).

⁶ See Richard G. Frank & David S. Salkever, *Generic Entry and the Pricing of Pharmaceuticals*, 6 J. ECON. & MGMT. STRATEGY 75, 90 (1992). Studies have extensively examined the relation between generics and brand-name market share in the United States. Along with the arguably predictable effects of generic entry into the market (market share shifts to the cheaper generic), we also see an unexpected effect: the strength of “consumer loyalty” often prompts firms to raise the price of the leading brand, in part to help offset losses due to generic competition. Daniel Maceira, *Entry and Price Response in Markets Without Patent Protection 2* (Apr. 11, 2011) (unpublished manuscript) (on file with author), available at <http://www.danielmaceira.com.ar/pdfs/Maceira-LeaderPrice-PharmaArg.PDF>; see also Frank & Salkever, *supra*, at 82-83, 89. But see Henry G. Grabowski & John M. Vernon, *Brand Loyalty, Entry, and Price Competition in Pharmaceuticals After the 1984 Drug Act*, 35 J.L. & ECON. 331, 345 (1992) (noting that normally the firm with the lowest prices has the largest market share, but suggesting other factors that cause market share not to shift to the cheapest generics).

⁷ See Andrew Pollack, *Old Drugs In, New Ones Out*, N.Y. TIMES (June 30, 2007), http://www.nytimes.com/2007/06/30/business/30combo.html?pagewanted=all&_r=0; Pamela Sankar & Jonathan Kahn, *BiDil: Race Medicine or Race Marketing?*, HEALTH AFF. W5-455, 456 (Oct. 2005), <http://content.healthaffairs.org/content/early/2005/10/11/hlthaff.w5.455.full.pdf+html>.

⁸ See Natasha Singer, *Drug Firms Apply Brand to Generics*, N.Y. TIMES (Feb. 15, 2010), <http://www.nytimes.com/2010/02/16/business/16generic.html>.

⁹ IMS INST. FOR HEALTHCARE INFORMATICS, *THE USE OF MEDICINES IN THE UNITED STATES: REVIEW OF 2011*, at 26 (2012), available at http://www.imshealth.com/ims/Global/Content/Insights/IMS%20Institute%20for%20Healthcare%20Informatics/IHII_Medicines_in_U.S_Report_2011.pdf.

have made generics a pillar of treatment activism, and the “patent cliff” is in many respects a global, if not uniform, phenomenon. Growing tides of business intelligence reports note that in “emerging markets” generics are where much of the growth will occur.¹⁰ In Latin America, where my research is concentrated, generic drugs have become new and important features of national pharmaceutical landscapes. Generics sales in Brazil increased by 53% from 2010 to 2011, and the category “unbranded generics” is the fastest growing pharmaceutical niche in both Mexico and Brazil.¹¹

With these considerations in mind, we might make the simultaneously obvious and strange argument that the pharmaceutical market is becoming commodified; that is, it is being genericized. This development raises a second question. What happens in commercial landscapes saturated by sameness? In William Mazzarella’s trenchant account of the Indian advertising industry in the late 1990s, an industry brochure gave a succinct appraisal of the commodity terrain which both conditions and requires the labors of branding and advertising: “parity situations” were becoming the order of the day.¹² The consumer landscape into which India’s ad agencies were striving to make their mark (on behalf of their clients) seemed saturated with substantive likeness — the things, images, services that needed to be sold were really not all that different from each other.¹³ As we know so well, it is upon and against the terrain of substantive likeness that branding and advertising are meant to do their magic, as they strive to create distinction in the eyes of consumers and, often, the law. Similarity, likeness, and fungibility are raw material for, but also obstacles to, the labor of making — and keeping — distinct.

But genericized pharmaceutical landscapes — shaped simultaneously by (international) intellectual property regimes, trade

¹⁰ See, e.g., Kim Ribbink, *Olá Brazil: Latin America’s Biggest Market Accelerates*, PHARMAVOICE, Jan. 2011, at 50 (noting that interested companies need to partner with local companies to create market access through branded generics); *Modernizing Pharma Markets in Brazil and Mexico*, BOURNE PARTNERS (June 1, 2012, 3:40 AM), <http://bournepartners.wordpress.com/2012/06/01/modernizing-pharma-markets-in-brazil-and-mexico/> (discussing how reforms in Brazil and Mexico are “phasing out” similares).

¹¹ *Brazil: Generic Drugs Boom*, LATIN BUS. CHRON. (Apr. 26, 2011), <http://www.latinbusinesschronicle.com/app/article.aspx?id=4871>.

¹² Mazzarella noted in that context that “[b]randing as an exercise assumes that markets have been saturated to an extent where there are few discernible material differences between competing products within a particular category.” MAZZARELLA, *supra* note 1, at 254.

¹³ See *id.*

agreements, national regulatory projects, and commercial and popular vernaculars — bring another dynamic to our attention. In Mexico, Brazil, the United States, and Europe, similarity and sameness are not simply playing their expected role as the opposites of distinction. Rather, the notions of the equivalent, the same, and the similar are becoming sources of distinction in themselves. Examples might include, in Mexico, the rise of the powerful pharmacy chain *Farmacias Similares* and the emergent commercial vernacular of “equivalents” and “interchangeables”; or, in European and U.S. regulatory debates, the recent invention of “biosimilars” as a new kind of kind. Moreover, “the generic” is a rapidly expanding and differentiating category; this space of presumed indistinction is actually coming to hold within it and generate surprising potential for heterogeneity and stratification. Branded generics, long familiar to many readers in the form of a pharmacy’s own-brand drug (e.g., Walgreen’s ibuprofen, “Walprofen”) now join (the idea of) SuperGenerics, BioBettters, and Interchangeables in this field. The generic is, it seems, shedding its status as (mere) commodity. This Essay asks how, and with what effects, generic-ness has come to be the site and source of such exuberant proliferation and distinction.

Let me offer a brief initial word on distinction. Distinction is the “hinge”¹⁴ around which formal trademark law revolves and the force that animates brands — as well as consumers’ relations to them. That is precisely why I find these generic developments so provocative. The discussion offered here is focused less on legal parameters of distinctiveness (source, relational, economic)¹⁵ than on broader pharmaceutical-vernacular reconfigurations of the idiom. When I call similarity or equivalence a source or site of distinction, or invoke the notion of a proper noun, I do so with the understanding that the things or names discussed here often do not fit the strict definition of brands or trademarks; in particular, they are not always officially registered as such. Nonetheless, they are doing some of the work that these forms do. (And, in the case of “branded generics,” we can dispense with these caveats altogether). The larger point I would like to make is that *generic kinds* might now, counterintuitively, be

¹⁴ Barton Beebe, *The Semiotic Analysis of Trademark Law*, 51 UCLA L. REV. 621, 625 (2004); P. Sean Morris, *The Economics of Distinctiveness: The Road to Monopolization in Trade Mark Law*, 33 LOY. L.A. INT’L & COMP. L. REV. 321, 342 (2011).

¹⁵ See generally Morris, *supra* note 14, at 342-43 (addressing the legal parameters of distinctiveness).

considered an instance of what Mario Biagioli has called “intellectual property without intellectual property,” or IP without IP.¹⁶

The Essay works in three sections. I begin by locating this analysis first in the notable proliferation of generic and similar kinds in Latin America. Second, I offer some brief reflections on the complex dynamic by which “similarity” in the pharmaceutical sector is simultaneously a source of value (even for transnational “innovator” firms) and a threat: that is, a target for disciplinary regimes in which similarity suggests deception, the not-quite proper, or danger. Third, I take up the trajectory of “similarity” in the biopharmaceutical sector. Here, simultaneous to the policing of similarity discussed in Section II, a newly invented kind of similar is the engine for yet another expanding market niche. In light of these developments, what, we must ask, has become of the undifferentiated commodity form?

I. DIFFERENT KINDS OF SAMENESS

One of the constitutive factors in the construction of generics as commodities is the contested nature of pharmaceutical equivalence and interchangeability. Generics are products whose regulatory legitimacy, and hence identity, depends to a certain degree on their proven equivalence to something else. The history of generic drugs in the United States, as in Latin America, India, and elsewhere, is in part a history of political-technical struggles over definitions of equivalence and the technical thresholds deemed adequate thereto (it is also a history of intellectual property regimes, as the definition of a generic is relative to patent status as much as it is relative to relations to a “reference” drug).¹⁷ The U.S. definition of a generic today did not exist before 1984, for example, and thus the question of what we call copied drugs circulating before then can be glossed nicely with statements like this: “generic-like things might have been happening earlier than 1984.”¹⁸ Similarly, many pharmaceuticals legally sold as generics in Mexico in 2001 no longer qualified as such in 2010, as the goalposts

¹⁶ Mario Biagioli & Rochelle Dreyfuss, Remarks at the “IP Without IP” Workshop of the Radcliffe Institute for Advanced Study (May 3, 2008).

¹⁷ See generally Cori Hayden, *No Patent, No Generic: Pharmaceutical Access and the Politics of the Copy*, [hereinafter *No Patent, No Generic*] in MAKING AND UNMAKING INTELLECTUAL PROPERTY 285 (Mario Biagioli et al. eds., 2011) (recounting the history of generic drugs in countries including Argentina and Mexico).

¹⁸ U.S. FOOD & DRUG ADMIN., FDA/DIA SCIENTIFIC WORKSHOP ON FOLLOW-ON PROTEIN PHARMACEUTICALS: PLENARY SESSION 41 (2009), available at <http://www.fda.gov/downloads/Drugs/ScienceResearch/UCM180470.pdf>.

for proper measures of equivalence have shifted.¹⁹ “The generic” is thus heterogeneous across geopolitical boundaries and across time, and this rather simple point has strong reverberations for the question of how distinction comes to materialize under the signs of sameness and similarity today.

In the United States there have been several shifts over the twentieth century that reverberate in contemporary debates over the global harmonization of standards for pharmaceutical equivalence (see Section II). An early requirement of chemical equivalence (same active compound, same dosage — e.g., the presumption that 25 mg of fluoxetine equals 25 mg of fluoxetine) — was supplanted in the 1970s by the current standard of bioequivalence, a statistical measure based on similarity in the absorption rates of the drugs under comparison into human bloodstreams, or “bioavailability.”²⁰ The 1984 Hatch-Waxman Act created expedited pathways for generics to enter the U.S. market, effectively declaring that, as long as the generic copy met the bioequivalence threshold, then it could lay claim to the safety and efficacy data provided by the original manufacturer.²¹

Not all countries define generics the way that the United States does currently, nor in the way that the WHO does. These differences may have as much to do with divergences in patent regimes as with different standards of equivalence. In Argentina, to confound our idioms from the start, “originals” have no standing as such, given that pharmaceutical patent enforcement has been roundly resisted by the powerful domestic drug industry. Thus, domestic copies (“*copias*”) are, in many cases, the leading brands and they are in fact relatively expensive.²² Generics must be described in part in Argentina as cheaper copies of these leading-brand *copias*.²³ In Brazil, where pharmaceutical patents are enforced, generics and *similares* are both

¹⁹ A 2005 reform to Article 376 of Mexico’s General Health Law set in motion a new five-year limit for drug registrations, effectively requiring all previously-registered generic drugs to be re-submitted for review under new thresholds for what would count as proper equivalence. Decreto por el que se Reforma el Artículo 376 Ley General de Salud [Decree To Reform Article 376 General Law for Health], Diario Oficial de la Federación [DO], 24 de Febrero de 2005 (Mex.).

²⁰ Daniel Carpenter & Dominique A. Tobbell, *Bioequivalence: The Regulatory Career of a Pharmaceutical Concept*, 85 BULL. HIST. MED. 93, 118 (2011).

²¹ Prior to the Hatch-Waxman Act, generic manufacturers were required to submit a New Drug Application (NDA) to the Food and Drug Administration in order to gain regulatory approval for selling a drug no longer under patent protection. This requirement in many cases entailed conducting new clinical trials, which were both costly and time-consuming. See *id.* at 94, 98-99.

²² See Hayden, *No Patent, No Generic*, *supra* note 17, at 293-94.

²³ See *id.* at 297.

regulated forms of copied drugs. The difference lies in both their brand status, and the kind of equivalence that each can claim: “[A]ll generic medicines must be commercialized with no brand and they are the only group of medicines which are considered interchangeable [bioequivalent] with the originator brand; ‘*similares*’ are all the other brand medicines available on the market.”²⁴ In Mexico, two different kinds of generics sit alongside each other: generics and interchangeable generics (“GI”), while *similares* is a rousingly popular commercial term, though it is not a recognized regulatory kind as such.²⁵

In an illuminating 2005 report meant to compare generic (“multisource”) regulatory regimes across ten Latin American countries, anthropologists N ria Homedes and Antonio Ugalde found this heterogeneity both widespread and vexing.²⁶ Fungibility proved elusive, and comparison, impossible. “Our study documented high levels of confusion among our respondents (all of whom were working in regulatory agencies or were pharmaceutical experts),” they wrote.²⁷ “Generic” not only had different meanings from country to country, but its meaning could vary “within a country depending on the context”²⁸ Generic is not the only term of art with which they had to contend: as we have seen, *copia*, *similar*, and interchangeable (“*intercambiable*”) help populate this terrain. As I have argued elsewhere, “confusion” is certainly an understandable term to use here, but there is quite a bit of dynamic order behind the seeming chaos, reflecting the specific and shifting legal, trade, and regulatory histories that have helped generate these categories.²⁹

For the present purposes, we might simply ask, what do these heterogeneities have to do with questions of brand, trademark, or distinction? There is, after all, meant to be a firewall between regulatory kinds and the work of distinction carried out through

²⁴ Andr a D. Bertoldi et al., *Evolution of the Generic Medicines Market in Brazil, 1998–2010: Antihypertensives, Antidiabetics, and Antibiotics*, ICIUM 3 (2011), http://www.inrud.org/ICIUM/ConferenceMaterials/998-bertoldi_a.pdf (emphasis added).

²⁵ Cori Hayden, *A Generic Solution?: Pharmaceuticals and the Politics of the Similar in Mexico*, 48 CURRENT ANTHROPOLOGY 475, 482 (2007) [hereinafter *A Generic Solution?*].

²⁶ N ria Homedes & Antonio Ugalde, *Multisource Drug Policies in Latin America: Survey of 10 Countries*, 83 BULL. WORLD HEALTH ORG. 64, 66-67 (2005).

²⁷ *Id.* at 67.

²⁸ *Id.* at 65.

²⁹ See generally Hayden, *A Generic Solution?*, *supra* note 25 (presenting some of the contradictory processes forming on behalf of copied pharmaceuticals in Mexico).

names, trademarks, and brands.³⁰ Where pharmaceutical marks are concerned, the difference between kind and brand³¹ (to use Donna Haraway's productive gloss) should be straightforward. As the Indian pharmaceutical portal Pharmabiz explains to its audience, chemical or generic names are understood to be "general" or descriptive terms; they are kinds, and hence cannot be brands or marks.³² Much like "products of nature" in some patent law and public domain content in some copyright law, the generic name has thus been the *constitutive outside* of claims to exclusivity in pharmaceutical trademarks. Thus, for example, one of the defining features of generics in some of the contexts mentioned above, as in Brazil, is that they cannot have brand names. Brazilian generics must be commercialized only under the name of the active molecule (e.g. "ibuprofen" or "fluoxetine").³³

Specific drug names aside, there is another relation between kind and brand at work here. A number of Latin American pharmaceutical commercial landscapes have become saturated with, and animated by, distinctions at what we might call a meta-generic level. The equivalent, the generic, and the similar themselves are kinds that have come to do the work of distinction, itself. The differences between these kinds are both reflected and produced in the commercial vernaculars and consumer practices that are so crucial to the making of distinction.³⁴

In Mexico, where I have done the bulk of my ethnographic work on the shifting landscapes of *lo genérico* as a (multiple) kind, one finds a compelling and in some senses singular illustration of this phenomenon. Unlike in Argentina, where the laboratories that produce leading-brand copied drugs have marketing budgets and advertise their drugs widely, in Mexico, it is pharmacy chains — not drug manufacturers — that are carving out new landscapes of generic distinction. The generics market, which emerged in the late 1990s and early 2000s, is organized around a particular commercial topography. There are pharmacies that sell expensive, brand-name drugs, and there

³⁰ See also Jeremy A. Greene, *What's in a Name?: Generics and the Persistence of the Pharmaceutical Brand in American Medicine*, 66 J. HIST. MED. & ALLIED SCI. 468, 475-80 (2011).

³¹ DONNA J. HARAWAY, *MODEST_WITNESS@SECOND_MILLENNIUM.FEMALEMAN@_MEETS_ONCOMOUSE™: FEMINISM AND TECHNOSCIENCE* 64-66 (1997).

³² Feroz Ali K, *Chemical Names as Pharmaceutical Trademarks*, PHARMABIZ.COM (Dec. 30, 2004), <http://saffron.pharmabiz.com/article/detnews.asp?articleid=25499§ionid=46>.

³³ See Bertoldi et al., *supra* note 24, at 3.

³⁴ See CELIA LURY, *BRANDS: THE LOGOS OF THE GLOBAL ECONOMY* 8 (2004) [hereinafter *BRANDS: LOGOS*].

are now myriad chains and smaller, one-off enterprises dedicated solely to selling generics, or cheaper copies.³⁵ Rarely are these inventories found in the same shop. One of the commercial actors that has had a strong hand, if not always a well-regarded one, in enlivening this new topography and creating a spectacular niche for cheaper, copied drugs is the proprietor of a franchise-based pharmacy chain called *Farmacias Similares* (or “Simi”), about whom and which I have written often.³⁶ *Similares* has powerfully shaped the argument animating this Essay, for reasons that should quickly become clear.

Farmacias Similares emerged as part of a rapid shift in Mexico’s dynamic of pharmaceutical access. The late 1990s saw a move from a situation of “scarcity” — the market was dominated by expensive brand-name drugs that were out of reach for many — to “abundance” — in the form of a proliferation of generic kinds and pharmacies dedicated to selling them. This proliferation was sparked by government regulatory efforts to foment both supply and demand for generics, or, drugs with the same active substance as the leading brand, at a fraction of the price.³⁷ Simi’s peculiar genius has been its ability to make a distinctive mark, even to assert a certain amount of semiotic dominance, in the market for these new and unfamiliar pharmaceutical kinds.³⁸

One of the major critical interventions in theories of the brand has been the recognition that, as communicative acts, brands and trademarks are not the exclusive products of corporations. As Coombe, Desai, Lury, and others have argued persuasively, consumers have a fundamental role in mobilizing brands, giving meaning to

³⁵ See Hayden, *A Generic Solution?*, *supra* note 25, at 478-79; Hayden, *No Patent, No Generic*, *supra* note 17, at 291-92.

³⁶ See generally Hayden, *A Generic Solution?*, *supra* note 25 (discussing the “saga” of *Farmacias Similares*); Hayden, *No Patent, No Generic*, *supra* note 17, at 292 (noting the cheap competition *Farmacias Similares* provides against transnational companies in Mexico).

³⁷ NORMA OFICIAL MEXICANA, NOM-164-SSA1-1998, BUENAS PRACTICAS DE FABRICACIÓN PARA FÁRMACOS (2000), available at <http://www.salud.gob.mx/unidades/cdi/nom/164ssa18.html>; NORMA OFICIAL MEXICANA, NOM-177-SSA1-1998, QUE ESTABLECE LAS PRUEBAS Y PROCEDIMIENTOS PARA DEMOSTRAR QUE UN MEDICAMENTO ES INTERCAMBIABLE: REQUISITOS A QUE DEBEN SUJETARSE LOS TERCEROS AUTORIZADOS QUE REALICEN LAS PRUEBAS (1999), available at <http://www.salud.gob.mx/unidades/cdi/nom/177ssa18.html>.

³⁸ See Hayden, *A Generic Solution?*, *supra* note 25, at 478 (noting that pharmacies did not previously offer generics as an object of consumer choice. Consumers either obtained free medicines via the increasingly stressed public health infrastructure, or bought expensive brand name drugs in private pharmacies).

them, and hence generating their value.³⁹ Marxist theorist of post-industrial capitalism Adam Arvidsson makes the point this way: “By thus making productive communication unfold on the plateau of brands, the enhanced ability of the contemporary multitude to produce a common social world is exploited as a source of surplus value.”⁴⁰ Brands are thus a kind of crowd-sourced value. This argument has been one of the major critical interventions in brand and, now, trademark theory, as in Desai’s proposal for a “brand theory of trademark,” which must take into account the productive force of the consumer or the “non-corporate stakeholder,” or what Ritzer calls the “prosumer.”⁴¹ There is something quite pointed about this critique or orientation where generics and similares are concerned in Mexico.

Simi was one of the first chains to emerge in Mexico selling only generics (sanctioned copies of off-patent drugs). The chain’s slogan captured the spirit of generic substitution brilliantly: *The same, but cheaper!* (*Lo mismo, pero más barato!*). It is, in every respect, a perfectly generic marketing slogan. Pithy, and nonspecific, the phrase could presumably be deployed for any commodity differentiated only by price, leading one to wonder, why didn’t anyone think of this before? But no one did, and the phrase has become proper to Simi. And it has done so, as proper names do, partly by being copied widely, and rather cheerfully, across Mexico. In the explosion of smaller and bigger pharmacy outlets that came to join Simi in this new niche in the first decade of the 2000s, the name *Similares* and the slogan (*lo mismo, pero. . . !*) came to serve as a “reference product,” if I may take a poetic liberty. Countless small pharmacies, the size and feel of a small corner candy shop, called themselves “Similares,” “Simylares,” or, hedging their bets, “Similares y Genéricos.” The Simi-slogan itself went viral, with myriad iterations. For example, Simi’s “the same, but cheaper” became, in a competing pharmacy chain, “the same substance, but more economical!”

³⁹ Cf. LURY, BRANDS: LOGOS, *supra* note 34, at 100 (arguing that distinctiveness is “achieved in usage”). See generally ROSEMARY J. COOMBE, THE CULTURAL LIFE OF INTELLECTUAL PROPERTIES: AUTHORSHIP, APPROPRIATION, AND THE LAW (1998); CELIA LURY, CULTURAL RIGHTS: TECHNOLOGY, LEGALITY AND PERSONALITY (1993) (contending that cultural reproduction varies depending on the relationship between producers and the audience); Deven R. Desai, *From Trademarks to Brands*, 64 FLA. L. REV. 981, 983-85 (2012) (arguing that consumers share and create information that affects the image and meaning of the brand).

⁴⁰ Adam Arvidsson, *Brands: A Critical Perspective*, 5 J. CONSUMER CULTURE 235, 235 (2005).

⁴¹ Desai, *supra* note 39, at 986; George Ritzer & Nathan Jurgenson, *Production, Consumption, Prosumption*, 10 J. CONSUMER CULTURE 13, 17 (2010).

But the Simi brand was never simply, or only, a way to distinguish medicines as same, but cheaper. The auratic personality of the chain, its mascot (the cartoonish “Dr. Simi”) and its proprietor are outsized, far exceeding generic medicines themselves. The enterprise itself is the brand, the primary locus of distinction.⁴² *Similares* has been defined largely by its proprietor, Victor González Torres, whose ambitions involve but are not limited to selling cheaper medicines.⁴³ González Torres has ensured his own identification with the chain’s cartoon mascot, Dr. Simi,⁴⁴ and his massive media presence, dancing Dr. Simi mascots, sexy “SimiChicas” (models and “spokespersons”),⁴⁵ and penchant for inciting political scandal have ensured his place in the mass-mediated popular public sphere in Mexico.⁴⁶ So too have his efforts to create something like a low-cost, private health system, parallel to and competing with the state health institutions and expensive private care.⁴⁷ The *Similares* project is an expansive one, to say the least.

With this massive presence, to which I give lengthier consideration elsewhere,⁴⁸ no one mistakes this Similarity for any other. Indeed, while other low-cost generics pharmacies have imitated aspects of Simi’s wide-ranging enterprise (notably, by following Simi’s model of offering low-cost consultations with physicians in clinics next to their pharmacies), the broader package is in many ways singular.

Thus, even in the midst of its massive popular proliferation as a term, *similares* did not thereby become generic. Such a fate, which trademark law has come to describe as “genericide,”⁴⁹ can meet a

⁴² This point resonates with the longer history of commercial marks, in which the emergence of corporate brands-as-personalities effectively supplanted the “local shopkeeper as the interface between consumer and product.” Such efforts to cut into the relation between consumers and retailers soon generated “the emergence of retail outlets as brands themselves.” LURY, BRANDS: LOGOS, *supra* note 34, at 19. Characteristically, Simi manages to work both sides of that dynamic.

⁴³ See *El Poder del Doctor Simi*, ETCÉTERA (Aug. 1, 2004), <http://www.etcetera.com.mx/articulo.php?articulo=337>.

⁴⁴ See *id.*

⁴⁵ See David Luhnaw, *In Mexico, Maker of Generics Adds Spice to Drug Business*, WALL ST. J. (Feb. 14, 2005), <http://online.wsj.com/article/SB110833733909653530.html>.

⁴⁶ See *Simiseguro, Ya Es Un Hecho*, ANUNCIACIÓN (Apr. 27, 2005), <http://www.anunciacion.com.mx/historial/noticias/noticia.php?ID=1096>

⁴⁷ See *id.*; cf. Hayden, *No Patent, No Generic*, *supra* note 17, at 292.

⁴⁸ See, e.g., Hayden, *A Generic Solution?*, *supra* note 25, at 479-86 (characterizing *Farmacias Similares* as one of the “fastest-growing” and “most visible” businesses in Mexico); Hayden, *No Patent, No Generic*, *supra* note 17, at 292 (describing *Farmacias Similares* as an “emergent” pharmacy chain across Latin America).

⁴⁹ Saul Lefkowitz & Barry W. Graham, *Court Rules that “Monopoly” Has Suffered*

brand or trademark when it becomes so dominant that it becomes synonymous with its entire kind. Brand here reverts to kind: like Aspirin, now aspirin, or Kleenex, now kleenex, the specific brand is said to have “died.”⁵⁰ This has not been the trajectory of Simi’s distinction. To the contrary, many consumers I have interviewed maintain a strong distinction between *Similares* (which they also call Simi, after the mascot, Dr. Simi) and the legions of other pharmacies selling generics that may even call themselves “similares,” and/or “genéricos,” or “equivalentes”; those pharmacies are usually referred to as *genéricos*.

Completing the circle here, though traveling in a perhaps unexpected direction, the personality of the *Similares* brand carries such weight, that the drugs for sale therein — and only therein — have become known to the faithful as *similares*. To wit: “I am going to Simi to buy a *similar*.” This may sound like a branding victory, but the power with which the name of the pharmacy has magnetized to the drugs it sells has caused great consternation for the Simi enterprise, since similars are not a proper regulatory kind in Mexico. Thus Simi officials and pharmacists have found themselves arguing — counter to many of their loyal consumers — that “*similares* is [only] the commercial name of the pharmacy; it does not refer to the products it sells.”⁵¹ Meanwhile, just as consumers will say they are going to Simi to buy a similar, the construction holds for other pharmacies and hence for the drugs they sell: “I am going to the *genéricos* to buy a *genérico*.” This is a problem for the Simi enterprise, which, despite the infectious success of their chain’s name, has come to regret having distinguished itself with a term that lacks regulatory legitimacy. In an effort to attach themselves to the proper kind of copies, Simi’s pharmacists and publicists have been at great pains to tell their customers that they do not sell *similares*.⁵² Indeed, they say over and over again, *similares* do not exist; it is (only) the commercial name of the pharmacies! They only sell “drugs of quality” (*genéricos* and *genéricos intercambiables*).⁵³ But in an intriguing twist on the

Genericide, LEGAL TIMES, Mar. 7, 1983, at 1; see also John Brooks, *Save the Mark*, NEW YORKER, July 2, 1955, at 16.

⁵⁰ And thus, the mark’s owner loses the legal capacity to control the use of the term. See *Bayer Co. v. United Drug Co.*, 272 F. 505, 512 (S.D.N.Y. 1921).

⁵¹ See Nurit Martínez, *Dr. Simi Venderá Medicinas “Similares” Hasta 2010*, Reta, EL UNIVERSAL (Feb. 5, 2008), <http://www.eluniversal.com.mx/nacion/157397.html>; Vicente Monroy, *Guerra Sucia de la Secretaría de Salud*, ANUNCIACIÓN (Feb. 1, 2008), <http://www.anunciacion.com.mx/historial/noticias/noticia.php?ID=3112>.

⁵² Monroy, *supra* note 51.

⁵³ Cf. Hayden, *A Generic Solution?*, *supra* note 25, at 483-84.

consumer-corporate dynamics of distinction, consumers seem to have won, insisting still on going to Simi to buy their *similares*.

It is in these somewhat counterintuitive senses, I would suggest, that Simi has managed to make both sameness (*lo mismo!*) and similarity (*similares*) its own marks of distinction. The meme-like slogan, “the same, but cheaper,” is impossible to separate from Simi, whether it is used as parody (“the same, but more idiotic!” [about politicians]), or as imitation in the service of competition. My experience is that it is almost impossible now to utter the simple, nonspecific phrase, *es lo mismo* (it’s the same) in Mexico, no matter what the topic, without having to wink in the direction of Dr. Simi. At the same time, similars have become a vernacular (though not a generic) kind in Mexico precisely because of consumer attachments to the chain’s name. The fact that Simi tries and fails to un-do this act of distinction only adds to our sense of how durable this vernacular kind has become. Simi and its consumers have arguably turned the dynamic of sameness and distinction inside out. *Lo mismo* and *lo similar* have become, in this sense, proper to Simi.

II. THE THREAT AND PROMISE OF SIMILARITY

Lo similar’s capacity to serve as a form of distinction is striking given the centrality of similarity — as a technical and contested term — in the policing of trademarks and brands in Mexico and globally. In trademark law, similarity is the constitutive threat to the identifying and distinguishing capacities of particular marks.⁵⁴ Invoking the term thus has the capacity in many legal and regulatory arenas to unleash a consequential and ideologically charged chain of associations: from “confusion” (which, *pace* Homedes and Ugalde, readers may have already experienced in the foregoing discussion), to accusations of deception, to infringement, to counterfeit, fraud, and piracy. There is nothing inevitable about this progression. It is the symptom, rather, of the conceptual and ideological commitment to proprietary exclusivity — distinction, as identity, as possession — that underlies trademark law.

In defense of the proprietary mark, trademark law holds that commercial marks should not confuse or deceive the consumer regarding the identities of, and hence differences between, particular products. In the vivid, Benjaminian phrasing of a landmark 1942 U.S. trademark case, it is a violation when a mark “poaches upon the commercial magnetism” of a symbol, or mark, created by another.⁵⁵

⁵⁴ Beebe, *supra* note 14, at 644-45.

⁵⁵ “Whatever the means employed, the aim is the same — to convey through the

Deceptively similar has become the salient phrase in this arena of IP law, suturing similarity and deceit into a powerful, though certainly not tidy or straightforward, package. But, we are left to ask, “what will qualify as deceptively similar?”⁵⁶

If this is the classic question for adjudicating alleged trademark violations, it also animates, in broader senses, a number of scenarios in which “the similar” (itself a moving target) is seen to reside dangerously close to confusion, deception, danger, and fraud. This section briefly outlines four scenarios in which the proliferation and even propriety of similarity coexists with persistent assertions of similarity as suspect. I am persuaded by anthropologist Julia Hornberger’s observation that there is a dynamic and observable relationship between the increasing circulation and value of copied drugs, which I am calling the commodification of the pharmaceutical market, and increasing efforts to name in order to police the specter of “too much similarity” in IP, security, and public health arenas.⁵⁷ Hornberger and others have commented upon a spiraling escalation that is gaining traction in the global “enforcement agenda” around copied drugs: generics are increasingly being associated, *prima facie*, with the specters of counterfeit, fraud, and threats to public health.⁵⁸ The following discussion outlines briefly a few manifestations of this constitutive, dynamic tension between the proliferation and policing of similarity.

mark, in the minds of potential consumers, the desirability of the commodity upon which it appears. Once this is attained, the trademark owner has something of value. If another poaches upon the commercial magnetism of the symbol he has created, the owner can obtain legal redress.” *Mishawaka Rubber & Woolen Mfg. Co. v. S.S. Kresge Co.*, 316 U.S. 203, 205 (1942), *quoted in* Morris, *supra* note 14, at 335.

⁵⁶ *Trade Marks for Pharmaceuticals: What Will Qualify as Being Deceptively Similar?*, DAVIES COLLISON CAVE 1 (Oct. 19, 2005), [http://www.davies.com.au/publication_pdfs/IP%20law%20ipdate%2010_05\(1\).pdf](http://www.davies.com.au/publication_pdfs/IP%20law%20ipdate%2010_05(1).pdf) [hereinafter *Trade Marks for Pharmaceuticals*].

⁵⁷ See Julia Hornberger, *From Drug Safety to Drug Security* 10-11 (Feb. 1, 2012) (unpublished manuscript), available at <http://wiser.wits.ac.za/system/files/seminar/Hornberger2012.pdf> (cited with author’s permission).

⁵⁸ See *id.* (manuscript at 7); see also Mônica Steffen Guise Rosina & Lea Shaver, *Why Are Generic Drugs Being Held Up in Transit?: Intellectual Property Rights, International Trade, and the Right to Health in Brazil and Beyond*, 40 J.L. MED. & ETHICS 197, 200 (2012).

A. *Still More Similarity: From “Deceptively Similar” to Constitutively Similar*

There are certainly many singularities to the phenomenon of Dr. Simi and *Farmacias Similares*, or to Brazil’s *similares*, but the processes charted above are not, as some might have it, signs of Latin American disorder. As we will see here and in Section III, Dr. Simi’s pharmacy chain might even be considered a global thought-leader, given the degree to which the enterprise makes explicit the capacity of similarity to gather and capture value in its name. Lest we contain our analysis to the generics sector, it bears noting that this process is also particularly evident within the workings of Big Pharma itself.

Consulting firms, trademark lawyers, and drug safety bodies have made clear that if there is one thing that currently characterizes name-brand pharmaceuticals these days, it is similarity. Trends, even saturations, in drug nomenclature; the explosion of “me-too” products (the development of yet another, statin, for example, because that is where the market is); and the proliferation of product-line extensions — slight variations used to extend patent protection for name-brand drugs facing patent expiry — all suggest that even “innovative” pharmaceuticals and their marks have become constitutively similar.⁵⁹ Among the abundant examples, we could consider the registered commercial marks for antibiotics based on the active compound ciprofloxacin (including but not limited to Alcipro, Cipro, Ciprobid, Ciprolet, and Ciprova),⁶⁰ or the competing drugs Livalo and Livial, registered in Australia for menopause-related symptoms.⁶¹ Whether drawing on the name of the active compound (as with cipro-derived drugs/names), on terms related to the condition or biological system treated (“Livalo was derived by combining the first two letters of each of the words ‘lipid,’ ‘vascular,’ and ‘lower’”),⁶² or a combination thereof, the terms drug companies invent to distinguish the products they sell have become markedly difficult to distinguish from each other (as have the products themselves, in many cases).

“Magnetism” — that which should not be poached — circulates rather freely here, in ways that seem to generate yet more similarity.

⁵⁹ See ADRIANA PETRYNA, WHEN EXPERIMENTS TRAVEL: CLINICAL TRIALS AND THE GLOBAL SEARCH FOR HUMAN SUBJECTS 67-70 (2009); Nathan Greenslit, *Pharmaceutical Branding: Identity, Individuality, and Illness*, 2 MOLECULAR INTERVENTIONS 342, 344 (2002); Song Hee Hong et al., *Product-Line Extensions and Pricing Strategies of Brand-Name Drugs Facing Patent Expiration*, 11 J. MANAGED CARE PHARMACY 746, 747 (2005)

⁶⁰ See Ali K, *supra* note 32.

⁶¹ *Trade Marks for Pharmaceuticals*, *supra* note 56, at 1.

⁶² See *id.*

The Massachusetts-based consulting firm Thomson CompuMark advertises its naming services by alerting its prospective corporate customers to the challenges of a market saturated by similarity: “With literally millions of pharmaceutical trademarks in use around the world, including marks not officially registered, finding a distinctive name or mark presents unique challenges.”⁶³ It is precisely in the name of inventing/finding distinction that such marketing firms help proliferate similarity.

Thus, as noted in Section I, one response to “parity situations” — the saturation of markets with sameness and similarity — is the invention of iterations that will pass, in particular legal contexts, as “distinction,” whether in the realm of patent or trademark. But when and for whom does such proliferation begin to slide into excess or impropriety?

B. Public Health: Too Much Similarity

According to the nonprofit standards and safety organization U.S. Pharmacopeia (“USP”), the moment of excess has already arrived in the United States, in the form of a public health threat. “Too much similarity,” announced USP’s February 2004 report on the alarming problem of medication errors due to confusion between “similar-sounding” or “similar-looking” drugs among pharmacists and prescribing physicians.⁶⁴ The problem is only multiplying. In 2008, USP’s survey of patient records yielded double the number of “similar-sounding pairs” of drugs deemed responsible for medication errors, noting that certain kinds (such as the drug enalapril) were, by that point, the basis of 10-15 similar drug names in the United States alone.⁶⁵ (In Argentina there are 28 enalapriils, but that is another story.) Similar-sounding names are, from this angle, threatening to overwhelm pharmacists’, physicians’, and consumers’ own capacities for making rather consequential distinctions.

⁶³ *Pharmaceutical Services: Specialized Industry Solutions*, THOMSON REUTERS 1, http://trademarks.thomsonreuters.com/sites/default/files/TCMTR_PharmaServices_Final_2.pdf (last visited Oct. 17, 2013).

⁶⁴ U.S. PHARMACOPEIA, USP QUALITY REVIEW: TOO MUCH SIMILARITY 1-3 (2004), available at http://www.prhi.org/docs/USP%20warns%20lookalike_3-15-2004.pdf.

⁶⁵ U.S. PHARMACOPEIA, MEDMARX DATA REPORT: A REPORT ON THE RELATIONSHIP OF DRUG NAMES AND MEDICATION ERRORS IN RESPONSE TO THE INSTITUTE OF MEDICINE’S CALL FOR ACTION 3, 168 (2008), available at <http://www.labatecpharma.com/wp-content/uploads/2012/02/2008MEDMARX-DataReport.pdf>.

C. *Harmonization: Too Much Mere Similarity*

Despite (or because of) what seems to be a hefty investment in the making of certain kinds of similarity, the transnational pharmaceutical industry, as well as national federal regulators in countries such as Brazil and Mexico, have recently made “the similar” a target for complaint and for regulatory discipline. The imperatives of harmonization, which regulate not only what will qualify as a patented pharmaceutical, but also, what will count as a proper copy thereof, in both IP and pharmacological terms,⁶⁶ have started to make their mark on generic landscapes in Latin America and beyond. Harmonization, the standardization of pharmaceutical equivalence according to what are, effectively, U.S. and European thresholds, promises the fungibility demanded by markets organized around “free trade.” Such fungibility would also make it possible, presumably, to conduct a ten country comparison of generic medicines without having to delineate ten specific generic lexicons. The axis around which generic harmonizations currently revolve is bioequivalence, which, as noted above, is the measure of “interchangeability” required of generics in the United States and Europe. It is now the gold standard for harmonization, visible in, among other sites, recent legislative and regulatory shifts in Brazil and Mexico, Latin America’s biggest pharmaceutical markets. One of the effects of these shifts has been to rule similarity out of order.

Recent legislation in Brazil, for example, has declared the proximal end of *similares* (“nonbioequivalent,” branded drugs) as a regulatory kind, declaring that they are to be phased out by 2015. Only the bioequivalent, interchangeable generic will remain as the sanctioned pharmaceutical copy.⁶⁷ Prior to the Brazilian move, in 2005, Mexican regulatory requirements had also attempted to “reduce confusion” by eliminating one of two kinds of sanctioned generics there. At the time of the 2005 mandate, two legitimate forms of generics were in circulation in Mexico: (regular) generics (*genéricos*), deemed chemically equivalent to the reference product, and bioequivalent, interchangeable generics (*genéricos intercambiables*, or GI). The 2005 mandate held that, by 2010, all drugs sold as generics must meet the threshold of bioequivalence; that is, only those initially distinguished from generics as GI’s would be allowed to circulate as generics. That is

⁶⁶ See Maurice Cassier & Marilena Correa, *Intellectual Property and Public Health: Copying of HIV/Aids Drugs by Brazilian Public and Private Pharmaceutical Laboratories*, 1 RECIIS ELEC. J. COMM. INFO. & INNOVATION HEALTH 83, 88 (2007).

⁶⁷ See *Modernizing Pharma Markets in Brazil and Mexico*, *supra* note 10.

probably worth stating again, slowly: only those drugs initially distinguished as GI's will now be allowed to circulate as generics. As in Brazil, one of the goals is to remove "nonbioequivalent" (i.e., chemically equivalent) generics from the market. Whether explicitly or implicitly, these harmonizations have helped generate consequential rhetorical gaps between the merely similar and the properly equivalent. In Brazil, *similares* will soon be out of legal bounds. And although "similar" do not exist as such in Mexico and thus cannot be similarly outlawed, the specter of the merely similar vividly haunts Dr. Simi and *Farmacias Similares* (*We don't sell similares! We only sell drugs of quality!*).

D. *The Enforcement Agenda: "Tending Toward Being Close to Counterfeits"*

The slippage between the merely similar and the "not properly equivalent" can yield, with yet another not-so-subtle turn, the suggestive whiff of "deceit" and "fraud." This slippage became clear in early skirmishes in Simi's rather controversial and bumpy path to generic prominence in Mexico. Greeting the inauguration of the first Simi pharmacies in 1999 was a formal accusation of deceit submitted to the Consumer Protection agency, issued by the transnational pharmaceutical industry, members of which are well represented in Mexico.⁶⁸ On what grounds might they issue such a complaint? The chain was not calling its drugs "Viagra," "Advil," or other recognized commercial names. Nor could it credibly be accused of piracy in terms of patent infringement; the drugs sold in Mexico as generics are inarguably off-patent (that is, the patents on these drugs, valid in Mexico, have expired).

The target was thus not specific trademarks nor patents, but the commercial slogan promising the same. The complaint held that the chain's claim — the same, but cheaper — deceived and confused consumers. The drugs, they argued, were not really the same at all.⁶⁹ The complaint was upheld, but only briefly (with fines and temporary

⁶⁸ See Angeles Cruz, *Farmacias Similares Apela Demande de Impi y Profeco*, LA JORNADA (May 2, 2002), <http://www.jornada.unam.mx/2002/05/30/049n2soc.php?origen=soc-jus.html>; Angeles Cruz, *Firmarán AMIF y Farmacias de Similares Pacto de No Agresión: Promoverán También el Uso de Medicamentos Genéricos*, LA JORNADA (July 2, 2002), <http://www.jornada.unam.mx/2000/07/02/soc3.html>; see also *Alertan Farmacéuticos vs Medicamentos 'Similares'*, TERRA (June 19, 2000), <http://www.terra.com.mx/Noticias/nota/20000719/104754.htm>.

⁶⁹ See sources cited *supra* note 68.

closures of eight storefronts),⁷⁰ and the slogan, as we have seen, has since vaulted into stardom. In terms of its ultimate effect, then, the complaint was a somewhat inconsequential test of the limits of Simi's viability. But it was an indicative test of the traction that trademark's idioms and the specter of the "bad copy" might have in early attempts to police Dr. Simi's similarity. The accusation that the drugs were not properly equivalent was leveraged in trademark law's terms in the complaint, as if Simi was, by definition, "deceptively *Similar*."

Like Mexico and Brazil's moves toward generic harmonization, this moment also resonates with (and anticipates) global trends in pharmaceutical governance that have picked up steam in the latter half of the aughts. The final nodal point I want to mention briefly here, in the simultaneous proliferation and control of pharmaceutical similarity, is the emergence of the "enforcement agenda" against pharmaceutical counterfeiting, an initiative of the WHO, formalized in the 2006 Declaration of Rome.⁷¹ As Julia Hornberger has noted, this novel direction in the regulation and policing of pharmaceutical copies has created new, and at first glance, odd alliances between health and safety regulators in countries of the global south, police and security agencies such as Interpol, and the IP enforcement mechanisms of such bodies as the WTO.⁷²

One of the effects of the enforcement agenda has been the increasing tendency to treat generic drugs, *prima facie*, as skirting the edges of (il)legality. That is, they are constitutively under suspicion of violating patents or trademarks, or of being counterfeits.⁷³ Thus, in 2008 and 2009, several shipments of generic medicines were seized — and some destroyed — by Dutch authorities as the drugs were en route from India to Africa and Latin America. The drugs were seized "on *suspicion* of patent or trademark violation."⁷⁴ The logic undergirding this suspicion was, as Guise Rosina and Shaver imply, rather tortured: though these were generic versions of drugs no longer under patent

⁷⁰ See sources cited *supra* note 68.

⁷¹ WHO, *Declaration of Rome: Conclusions and Recommendations of the WHO International Conference on Combating Counte[r]feit Medicines*, at 1 (Feb. 18, 2006), available at <http://www.who.int/medicines/services/counterfeit/RomeDeclaration.pdf>; see also Pähkla, *supra* note 4, at 7; Rosina & Shaver, *supra* note 58, at 201; Hornberger, *supra* note 57 (manuscript at 5).

⁷² See Hornberger, *supra* note 57 (manuscript at 5).

⁷³ See Rosina & Shaver, *supra* note 58, at 200.

⁷⁴ "The shipments contained generic versions of drugs originally developed by large pharmaceutical companies, such as Pfizer and Novartis, who still held patent rights in the European Union. These drugs were not protected by patent in India, however, nor in any of the destination countries for which they were bound." *Id.* at 197.

protection in India (where they were manufactured) or in the countries to which they were destined, Dutch authorities seized them because they were suspected of violating patent laws in the European Union.⁷⁵ Guise Rosina and Shaver note that this particular understanding of the boundaries of IP claims under the mantle of fighting piracy or counterfeits is a relatively novel development, and a worrying one from the point of view of access to medicines in poorer countries.⁷⁶

If, in the climate of the enforcement agenda, generics might as well be considered in potential violation of patent or trademark, “similar” inhabit a purgatorial space that we might have to call counterfeit-ishness. In a WIPO/OECD workshop in 2006, Harvey Bale, of the International Federation of Pharmaceutical Manufacturers and Associations (“IFPMA”), and President of the Pharmaceutical Security Institute, sounded an alarm against the dangers of similarity. His concern was not just outright counterfeits — which he glossed colloquially as “totally deceptive and not regulated at all” — but also the hazy category of “non-bioequivalent” drugs, or “Similar,” “prevalent in Latin America, Turkey, etc,” and which he described as “tending toward being close to counterfeits.”⁷⁷ It bears noting that the WHO’s definition of a counterfeit medicine is as follows: one that is deliberately and fraudulently mislabeled with respect to identity and/or source.⁷⁸ The mere fact that chemically equivalent generics have existed in particular contexts (in the United States in 1969, in Mexico 2005, in Brazil 2012) would arguably have little to do with counterfeiting, instead falling into the category of regulatory and political negotiations over agreed-upon thresholds for pharmaceutical equivalence. But we are seeing, alongside the generification of the pharmaceutical market globally, a global enforcement agenda that has extended the reach of suspicion — “tending to be close to” illegal — over similar and generic kinds.

How, then, do these developments (the contours of which are sketched just briefly here) relate to the proliferation of similar and same as forms of distinction, as outlined in section I? Certainly the emergence of similarity as a mark of distinction is not a static development, frozen in time. Just as it emerged, it can also recede.

⁷⁵ *See id.*

⁷⁶ *See id.* at 201-02.

⁷⁷ Harvey Bale, *Pharmaceutical Counterfeiting: Issues, Trends, Measurement*, WORLD INTELL. PROP. ORG. & ORG. ECON. COOPERATION & DEV. WORKSHOP 2 (2005), available at <http://www.oecd.org/dataoecd/42/30/35650404.pdf>.

⁷⁸ *Id.* at 1.

Between harmonization and the enforcement agenda, we might be forgiven for thinking that “similarity’s” days are numbered. Indeed, in Mexico, as the 2010 horizon for interchangeable generics approached, many of the smaller pharmacies mentioned in Section I began to hedge their bets (again), painting over the term *similares* on their awnings and signs, and replacing it with *equivalentes*, *intercambiables*, or GI (and sometimes all three).⁷⁹ Nonetheless, we should hesitate before pronouncing that the liberal forces of regularization are stamping out the “merely similar,” making way for the “properly equivalent.” Anticipating the argument in Section III, I would argue that, whether via policing and securitization, or harmonization of standards, liberal efforts to regularize generics markets and guarantee fungibility are not opposed to the proliferation of multiple kinds of sameness and similarity. Rather, they are productive of it.

III. BIOSIMILARSUPERGENERIC

The opening discussion in this Essay proposed an argument that may seem both obvious and strange. Globally, the pharmaceutical market is becoming commodified, by which I mean that it is, arguably, becoming saturated with “sameness.” The commodification of their products is something that “innovator” pharmaceutical companies have famously and consistently tried to forestall, from 1970s industry critiques of prevailing standards of generic equivalence in the United States⁸⁰ to current practices of product-line extensions,⁸¹ and a host of other modes of extending the periods of exclusivity granted by pharmaceutical patents. The arguments against commodification (or in favor of delaying the end of patent-protected exclusivity), have consistently hewed to familiar lines of argument: notably, the appeal to “innovation” (exclusivity is necessary to recoup innovators’ investments and thus to continue to innovate), and to “quality” (other laboratories cannot possibly make a copy of the same quality as the original; copies must be, by definition, diminished copies).⁸²

⁷⁹ If these literal acts of resignification suggest that similarity might be losing its caché, the GI designation (and its proliferating synonyms — *equivalentes!* *intercambiables!*) is becoming yet another kind that makes its mark in the commercial landscape; it is a source of meaningful difference within the still busy field of generics, themselves.

⁸⁰ See Carpenter & Tobbell, *supra* note 20, at 94-95, 97.

⁸¹ See Greenslit, *supra* note 59, at 344; Hong et al., *supra* note 59, at 746; see also Amy Kapczynski, *Engineered in India — Patent Law 2.0*, NEW ENG. J. MED. 2 (July 2013), available at http://www.law.yale.edu/documents/pdf/Faculty/Kapczynski_Novartis.pdf.

⁸² See TOBBELL, *supra* note 5, 162-92.

This story is no different for biological pharmaceuticals, a relatively new class of drugs that reached its own, first “patent cliff” in the early 2000s. As we will see, biotechnology companies’ arguments seeking to forestall the commodification of biologicals, or to declare such a thing impossible, have followed lines of argument familiar from this longer history. Yet, despite their efforts, some intriguing results have emerged. While “similares” are being legislated out of existence in Brazil, or conflated with counterfeits in global enforcement discourse, another kind of similar constitutes one of the fastest growing sector of pharmaceuticals in Europe, the United States, and globally.

A. *Resisting Commodification*

Biological drugs, or biopharmaceuticals, are sites of remarkable category proliferation, in which the practice of making new drugs and making same drugs is turning itself inside out. Some of this extravagance is rooted in something that seems, at first telling, to be materially peculiar to this kind of pharmaceutical. Biological pharmaceuticals, which the U.S. Food and Drug Administration (“FDA”) defines as “therapeutic protein products,” are different from drugs based (merely) on active chemical compounds, which are the kind of drugs discussed in Sections I and II. Biopharmaceuticals are large, macromolecules, characterized by high degrees of molecular complexity, and they are manufactured using what Genentech calls cellular “mini-factories”⁸³ — “intricate manufacturing processes that depend on living organisms.”⁸⁴ These characteristics, biotechnology companies have recently tried to argue, make it essentially impossible for their proprietary drugs to be turned into multisource, interchangeable commodities, even when the patent on the drug expires.

But why exactly would biological drugs (seem to) defy generification? In a 2006 forum in *Nature Biotechnology*, Rob Garnick, Genentech Senior Vice President, made the case that generic biological drugs are something of an impossibility:

Unlike [with] traditional pharmaceuticals, good scientific practice does not allow the direct comparison of one biotech product to another. This is because complex operational and proprietary details of the biotech manufacturing process are

⁸³ GENENTECH, <http://www.gene.com/gene/about/views/followon-biologics.html> (last visited July 1, 2013).

⁸⁴ Rob Garnick, *Counterpoint: Why Biogenerics Are a Strawman*, 24 *NATURE BIOTECHNOLOGY* 269, 269 (2006).

central to, and define the identity and unique structural characteristics of, each biotech-derived product.⁸⁵

The manufacturing process defines the identity of the drug, and thus, the argument goes, a different manufacturer will by definition produce a different drug. Other industry chroniclers put the matter a bit less starkly: biologicals “can be more sensitive to changes in manufacturing processes than medications made by other chemical processes.”⁸⁶ But of course, as Garnick makes clear, it is not just “operational complexities” that are at work here. Elaborating on the role of “proprietary” complexities to this argument, he notes:

[T]he proposed generic . . . would be manufactured using an entirely different cell line, plasmid and process, [since] these materials and information belong to the biotech company and are closely guarded proprietary materials and trade secrets.⁸⁷

This argument seamlessly folds intellectual property into the materially necessary nature of the drug: a different manufacturer must (legally) use a different process, which, given the close relationship between vector and identity of the drug, would (arguably) produce a different drug, which thus could not possibly be considered a generic.⁸⁸ It is IP itself that is in part the obstacle to commodification, even when patents expire.

These presumed constraints notwithstanding, in the early-to-mid 2000s, with the expiration of many biologicals’ patents on the horizon, European and U.S. regulators and other interested parties debated the conditions under which manufacturers other than the so-called “pioneer” company could (re)produce a biological pharmaceutical.⁸⁹ Commentators estimated that the value of the drugs on the verge of losing patent protection was on the order of \$10 billion USD; the total market for biologicals was put at \$30 billion USD.⁹⁰ Clearly a fair

⁸⁵ *Id.*

⁸⁶ Karen von Koeckritz, *Generic Drug Trends-What’s Next?*, PHARMACY TIMES (Apr. 11, 2012), <http://www.pharmacytimes.com/publications/issue/2012/April2012/Generic-Drug-Trends-Whats-Next->.

⁸⁷ Garnick, *supra* note 84, at 269.

⁸⁸ *See id.*

⁸⁹ *See generally* WENDY H. SCHACHT & JOHN R. THOMAS, CONG. RESEARCH SERV., RL33901, FOLLOW-ON BIOLOGICS: INTELLECTUAL PROPERTY AND INNOVATION ISSUES 2-11 (2008) (providing a clear outline of the issue as framed in familiar terms of the competing imperatives of cost control versus the protection of IP and innovation).

⁹⁰ Carole S. Ben-Maimon & Rob Garnick, *Biogenerics at the Crossroads*, 24 NATURE BIOTECHNOLOGY 268, 268 (2006).

amount of money is at stake, both in terms of profits for producers and costs for consumers. Biopharmaceuticals have certainly become a central front in regulatory and political battles in the United States and Europe, pitting the public health rationale of ensuring access to affordable versions of these drugs against the continued assertions by biotechnology companies that they need more, continued, exclusivity to recoup their investments. That much is familiar. But there has also been a more intriguing and perhaps unexpected offshoot here, as debates over the parameters of reproducibility have generated a lively discussion around nomenclature. For, if it is possible to make a copy of a biological, “operational and proprietary complexities” notwithstanding, what would such a thing be called? Candidates under discussion in the trade literature included generic biopharmaceuticals, follow-on protein, biogenerics, and follow-on biologics.⁹¹

Leading the way in insisting that it is, in fact, possible to make a same enough copy of a biological drug, and that there is an adequate term for such a thing, the European Medicines Agency approved a regulatory pathway for off-patent biologicals in 2005. As to name, they settled on what Dr. Simi might consider the perfect term: biosimilars.⁹² Despite much resistance by the biotechnology lobby to the prospect of the U.S. FDA following suit,⁹³ the FDA has now followed Europe’s lead and in February 2012 released preliminary, draft guidelines for biosimilar approval. Same or similar? Mere or proper? The FDA’s understanding of biosimilarity includes the provisions that “the

⁹¹ See generally Ronald A. Rader, *What Is a Generic Biopharmaceutical? Biogeneric? Follow-On Protein? Biosimilar? Follow-On Biologic?*, *BIOPROCESS INT’L* 28, 28-29 (Mar. 2007) (providing a useful overview of the definitional landscape as it was unfolding in 2006-2007).

⁹² See COMM. FOR MEDICINAL PRODS. FOR HUM. USE, EUR. MEDS. AGENCY, *GUIDELINE ON SIMILAR BIOLOGICAL MEDICINAL PRODUCTS* 2, 5 (2005).

⁹³ Much of the battleground on this front has been around the period of exclusivity that should be granted to biological pharmaceuticals (and hence, the time frame in which competitors could manufacture and market off-patent versions thereof), which eventually became entwined with the negotiations over U.S. President Barack Obama’s Affordable Care Act. A pathway for bringing off-patent biologicals to market was first set in place in the United States in the Biologics Price Competition and Innovation Act of 2009 (BPCI Act). For information on the BPCI, see U.S. FOOD & DRUG ADMIN., *IMPLEMENTATION OF THE BIOLOGICS PRICE COMPETITION AND INNOVATION ACT OF 2009*, <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/ucm215089.htm> (last updated Mar. 10, 2011). For indicative news accounts, see, for example, Meredith Wadman, *Bills Target Biosimilar Drugs: House of Representatives Divided Over Regulating Generics*, 458 *NATURE* 394, 394-95 (2009); Andrew Pollack, *Costly Drugs Known as Biologics Prompt Exclusivity Debate*, *N.Y. TIMES* (July 22, 2009), <http://www.nytimes.com/2009/07/22/business/22biogenerics.html?pagewanted=all>.

biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components” and that “there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.”⁹⁴

Despite the biotechnology industry’s continued resistance to this legitimation — manifest in continued efforts to cast doubt on the use of similarity as a valid standard for copying drugs⁹⁵ — there is of course very little that is “mere” about this similarity. It has quickly become its own (gold) standard, one that engenders new apparatuses of testing, new sciences and techniques of evaluation, and the invention of methods for characterizing the activity of molecules, in themselves and in relation to each other.⁹⁶ Biosimilar status is difficult but not impossible to achieve. It is an aspiration. Thus, makers of monoclonal antibodies debate whether they can aim to make a “true biosimilar.”⁹⁷ There are certainly reasons to aim that high. According to a recent market forecast, the biosimilar market will grow to \$2.5 billion by 2015, with particular growth in Europe, the United States, and Asia.⁹⁸ Latin America is in the mix too. Mexican regulators, for reasons that may be clear given the foregoing discussion, have steered clear of the term *biosimilares*. In Mexico, these drugs are *biocomparables*.

B. Neither Copy nor Original

The biosimilars market may indeed be on the rise. But for those in a position to shape this sector, biosimilarity might be more trouble than it is worth. The Vice President for Business Development at Nektar Therapeutics, Stephen Charles, argued in 2005 that bringing this kind of copy to market is hard work, requiring a “full-fledged development program,” not least because manufacturers “must determine the

⁹⁴ U.S. FOOD & DRUG ADMIN., FDA ISSUES DRAFT GUIDELINES ON BIOSIMILAR PRODUCT DEVELOPMENT (2012), available at <http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm291232.htm>.

⁹⁵ See Andrew Pollack, *Biotech Firms, Billions at Risk, Lobby States to Limit Generics*, N.Y. TIMES (Jan. 28, 2013), <http://www.nytimes.com/2013/01/29/business/battle-in-states-on-generic-copies-of-biotech-drugs.html?pagewanted=2>.

⁹⁶ See Christian K. Schneider & Ulrich Kalinke, *Toward Biosimilar Monoclonal Antibodies*, 26 NATURE BIOTECHNOLOGY 985, 986-87 (2008).

⁹⁷ *Id.* at 988.

⁹⁸ RNCOS INDUSTRY RES. SOLUTIONS, GLOBAL BIOSIMILARS MARKET FORECAST TO 2015 1 (2012), available at <http://www.rncos.com/Report/IM379.htm>; see also IMS HEALTH, SHAPING THE BIOSIMILARS OPPORTUNITY: A GLOBAL PERSPECTIVE ON THE EVOLVING BIOSIMILARS LANDSCAPE 1 (2011), available at http://www.imshealth.com/ims/Global/Content/Home%20Page%20Content/IMS%20News/Biosimilars_Whitepaper.pdf.

availability of active ingredient via a non-patent infringing route.”⁹⁹ This, again, is a reference to the argument that the processes for producing these proteins are often under propriety control.

I cannot help noting that this assessment sounds remarkably similar to the dynamics of postcolonial research and development, which have also been defined by having to work around or through proprietary restrictions (i.e., patents). It is, for example, what Brazilian researchers, whether in pharmaceuticals or microcomputing, have been contending with for many decades now. Researchers in these areas have long noted that “copying” in these circumstances is hardly a walk in the park: it takes quite a lot of ingenuity to reverse-engineer an anti-retroviral,¹⁰⁰ for example, or a Macintosh computer.¹⁰¹ Indeed, it takes so much ingenuity that the process of reverse engineering may well result in a new patent, as was the case when Brazilian drug researchers developed and patented a new pathway for synthesizing an anti-retroviral that produced fewer impurities than Novartis’s initial method.¹⁰²

Similarly noting the amount of work it takes to reproduce a biological drug, Charles asked, “why not bring a differentiated and better product to market with little to no increase in development cost?”¹⁰³ Rather substantially expanding, or perhaps up-ending, the very notion of the generic, he proposed calling these things “Supergenerics.” Most qualities conventionally defining the generic would not apply. Supergenerics would not be unpatentable. They would not be the site of indistinction or fungibility. “Supergenerics,” he proposed, “offer real product differentiation, patent protection, and branding opportunities for product manufacturers.”¹⁰⁴ Why, we might reasonably ask, call it a generic at all?

Others seem to have had a similar question, for, while aspirations to super-ness continue to gain traction, the term “generic” has largely dropped from view in this particular discussion. The kind of drug Charles imagined and proposed has stabilized rhetorically in the form of “Biobetters.” Reportedly coined by the major Indian pharmaceutical firm Dr. Reddy’s,¹⁰⁵ the term is circulating with enthusiasm in global

⁹⁹ Charles, *supra* note 2, at 534.

¹⁰⁰ See Cassier & Correa, *supra* note 66, at 85-87.

¹⁰¹ See Ivan da Costa Marques, *Cloning Computers: From Rights of Possession to Rights of Creation*, 14 *SCI. AS CULTURE* 139, 141-42 (2005).

¹⁰² See Cassier & Correa, *supra* note 66, at 87.

¹⁰³ Charles, *supra* note 2, at 534.

¹⁰⁴ *Id.*

¹⁰⁵ See Angelo DePalma, *Will Biobetters Beat Biologics?*, *EYEFORPHARMA* (Oct. 4,

pharma circles, despite the fact that it is not an established, regulatory category anywhere in the world (yet).¹⁰⁶ Biobetters promise to do precisely what Charles' Supergenerics would do: improve upon existing biologicals. They also are not what Supergenerics are not: "[B]iobetters are not copies and will never be considered generics. Biobetters are new molecular entities that are related to existing biologics by target or action, but they are deliberately altered to improve disposition, safety, efficacy, or manufacturing attributes."¹⁰⁷

With this point in mind, we may pose our question anew: why would one settle for making a mere copy when one can make a better copy instead? Or, as industry analyst Niall Dinwoodie states the proposition, "Why be similar, when you can be better?"¹⁰⁸ The shift to the inventive copy (like software's idioms of versioning or iterating) over the mere copy¹⁰⁹ refuses the characteristic advantage of the generic commodity. This advantage, as Dr. Simi tells us so clearly, is that the generic is the same but (and) cheaper. The biobetter is set to "compete" not on price but rather on its meaningful differences: industry commentators suggest that there would be little expectation to lower a price on something that is better;¹¹⁰ Dr. Simi might call this, *Diferente, pero caro!* (Different, but expensive). The Generics and Biosimilars Initiative ("GaBi"), an excellent online resource on these

2011), <http://social.eyeforpharma.com/forecasting/will-biobetters-beat-biologics>.

¹⁰⁶ See, e.g., *Biobetters Q&A*, BIORESEARCH ONLINE (Sept. 7, 2011), <http://www.bioresearchonline.com/doc.mvc/Biobetters-QA-0001> (providing an overview from an industry portal); *Biosimilars or Biobetters — What Does the Future Hold*, GENERICS AND BIOSIMILARS INITIATIVE (Oct. 14, 2011), [http://gabionline.net/Biosimilars/Research/Biosimilars-or-biobetters-what-does-the-future-hold/\(highlight\)/Biobetter](http://gabionline.net/Biosimilars/Research/Biosimilars-or-biobetters-what-does-the-future-hold/(highlight)/Biobetter) (same).

¹⁰⁷ *Biobetters Rather Than Biosimilars*, GENERICS & BIOSIMILARS INITIATIVE (May 6, 2011) (emphasis added), <http://gabionline.net/Biosimilars/General/Biobetters-rather-than-biosimilars>.

¹⁰⁸ Niall Dinwoodie, *Biobetters and the Future Biologics Market*, 24 *BIOPHARM INT'L* 31, 35 (2011), available at <http://www.biopharminternational.com/biopharm/article/articleDetail.jsp?id=746281&sk=&date=&pageID=4>.

¹⁰⁹ See Cori Hayden, *The Proper Copy: The Insides and Outsides of Domains Made Public*, 3 *THE JOURNAL OF CULTURAL ECONOMY* 85, 94, 99 (2010); Lawrence Liang, *Beyond Representation: The Figure of the Pirate*, in *ACCESS TO KNOWLEDGE IN THE AGE OF INTELLECTUAL PROPERTY* 353, 358-59 (Gaëlle Krikorian & Amy Kapczynski eds., 2010); Rebecca Tushnet, *Copy This Essay: How Fair Use Doctrine Harms Free Speech and How Copying Serves It*, 114 *YALE L.J.* 535, 550 (2004).

¹¹⁰ See Dinwoodie, *supra* note 108, at 34 ("While the biosimilar aims to take market share by being slightly cheaper than the originator, the biobetter has to gain market share on merit alone. Sales presentation of a newly approved biobetter will thus extol the benefits of the product rather than relying on price alone to drive business.").

questions, explains to those who may have become lost in the thicket of sames, similars, and betters, “While biosimilars promise the same effect at a reduced price, a biobetter will possess some molecular or chemical modification that constitutes an improvement over the originator drug and its biosimilar competitors.”¹¹¹

Neither copies nor originals (“deliberately altered to improve . . .”), biobetters are a third term in this landscape. They are an alternative — a “follow-on” — to both original drugs and cheaper, similar versions thereof. There is much at stake in this formula beyond market share and health care costs, neither of which is “mere,” of course. In line with the concerns animating this article, and by way of conclusion, these iterations suggest important points about the form that the commodity-pharmaceutical is taking these days, and the dynamic relation among sameness, similarity, and distinction therein.

CONCLUSION

It has been my contention in this Article that generic pharmaceuticals are generative and malleable terrain — “ground,” writing from atop a major seismic fault, seems a suitable metaphor — for unsettling some of the foundational assumptions behind theories of brand and the work of distinction. The chief casualty of genericness as I have tried to unpack it here is the enduring and legally consequential formulation of sameness and similarity as the opposites of distinction. As we have seen, in trademark law and in theories of the brand, sameness and similarity conventionally constitute obstacles to and violations of claims to distinction, even while (in fact, because) they are distinction’s raw material. This relationship has long been understood to be dynamic: distinction and sameness feed off of each other, as “products” routinely move from one qualification into another, and back again. Thus contemporary intellectual property regimes, especially in the United States, have intensified the avenues through which natural kinds can become brands;¹¹² the expiration of a drug patent means that the once-singular drug “becomes a commodity;”¹¹³ a trademark can become so powerful that it becomes generic.¹¹⁴ In these ways, we know that sameness and distinction are permeable, even vulnerable, to each other. But in current global

¹¹¹ *Biobetters Rather Than Biosimilars*, *supra* note 107 (emphasis added).

¹¹² See HARAWAY, *supra* note 31, at 66.

¹¹³ Charles, *supra* note 2, at 533.

¹¹⁴ See *Bayer Co. v. United Drug Co.*, 272 F. 505, 510-11 (S.D.N.Y. 1921).

pharmaceutical markets, I argue, this longstanding relation between sameness and distinction takes provocative form.

As noted in Section I, generics, the fungible commodity form of a leading-brand “original” drug, are coming to a certain kind of dominance in global pharmaceutical markets. In the process, I have argued, generic-ness, and the forms of equivalence, interchangeability, similarity, and “the same” that constitute it, are functioning as forms of heterogeneity in themselves.¹¹⁵ They are not just the saturated ground from which the distinguishing work of the brand must elevate “its” product; they are distinction. On the one hand, without doubt, this is a question of historically dynamic and geopolitically variable definitions of pharmaceutical equivalence. But on the other hand, generic heterogeneity is not simply a matter of unclear or different standards that one day may all become, in the liberal fantasy of harmonization and its enforcement counterpart, narrowly “the same.” I argue instead that the generic, the equivalent, and the similar present themselves to us now as generative and explicit forms of meaningful, unique difference, and certainly, then, as new opportunities for value-production. Thus, for example, the attachment of (some) Mexican consumers to the “similar” is just one of many instances through which Similarity emerges as a proper noun. In Mexico, the similar has become effectively proper to a vivid commercial personality, the magnetism of which/whom has, for consumers, reverberated back to the products it/he sells (e.g., Dr. Simi’s “*similares*”). As we saw in Section II, the power of Similarity in this context and more broadly continues to animate consequential accusations of confusion, deception, and fraud. But, the value of the specifically similar is only growing, as we might note in the emergence of “biosimilars” as a new regulatory kind and a global market opportunity.

¹¹⁵ Here the “similarity” of the mark, or the commercial slogan, exceeds our conventional usage of the term: it is, echoing Gilles Deleuze, not simply similar *to something*, but Similar for itself. In *DIFFERENCE AND REPETITION*, Deleuze worked through and beyond the platonic metaphysics that dominates liberal understandings of originals and copies, in which the copy is by definition a diminished copy — hence, identifiably “not” the original. Deleuze posed an alternative mode of engagement with matters of identity, difference, and repetition (imitation), in which he sought to displace a negative formulation of identity (if A is self-identical, then B is different because it is not A) with a more capacious understanding of the difference that resides within relations, things, or notions of “identity.” One of the enduring formulations from this exercise is the notion of difference not as different from something else, (i.e., a negation), but a notion of difference *for* itself. If drugs can be similar (to something), why not make them Similar, in themselves? See generally GILLES DELEUZE, *DIFFERENCE AND REPETITION* (Paul Patton trans., Continuum Books 2004) (1994).

The question of consequences remains. How do these observations exert pressure on our understandings of the undifferentiated commodity form? If generic-ness can become a valued kind of distinction, even a proper noun, what are the consequences for our understanding of how brands, trademark, and value work? One reading is that these developments are a purely strategic industry and marketing response to the dearth of innovation in the global pharmaceutical sector: if you can no longer make new things, why not simply rebrand the old, or mine “the same” for its possible differences? There is certainly something important in such an argument, and we might suggest that generic-ness is in fact being “colonized” ever more intensively, even more inventively, as a resource for the differentiation that, as some might say, markets require. The Frankfurt School hardly prepared us for a world in which “commodities” become scarce. But if we hew to the understanding of the commodity I have proposed in this Essay, such a world is precisely the goal of those who align themselves with so-called “innovator” industries, whose products depend on brand differentiation. If distinction must continue to prevail over mere commodification, then why not look to the commodity (e.g., the interchangeable drug, the copied biological drug) as a resource for new forms of stratification and distinction?

There is great power to this argument. At the same time, its teleological march risks foreclosing a bit too much. The preceding discussion has suggested how the generic commodity can function as a site of elasticity, difference, and contingency. If “similares,” copias, and interchangeables in Latin America suggest as much, so too does the nexus of biopharmaceuticals, biosimilars, and biobetters. In that context, the presumed difficulties of reproducing or making “exact copies” of therapeutic proteins have been transformed by biogenerics manufacturers into a resource for creating an arguably postcolonial category of copy: that which is inventively different. Insofar as the same, the similar, and the copy serve as sites of valued difference in these contexts (i.e., they are not only impugned as “diminished” forms of “originals”), there is also at work an expansion, and perhaps a subversion, of that which can credibly happen in the name of the generic, and hence in the name of the commodity, itself. Generic drugs thus provide the empirical ground for re-imagining fungible, interchangeable commodities as constitutively heterogeneous. This argument flies in the face of a great deal of received wisdom about how the commodity form works: Its power and its violence, Marx and many subsequent interlocutors have argued, has resided in large part in the ability we give it to subsume concrete differences and

specificities (as “use-value”) under the sign of equivalence.¹¹⁶ But if “equivalence” and “interchangeability” are themselves forms of concrete difference and specificity, the very basis for our understandings of the relation between sameness and distinction must be reorganized. Parity situations, no more.

¹¹⁶ See KARL MARX, *Capital: Volume I, Part I: Commodities and Money*, in THE MARX-ENGELS READER 302, 304 (Robert C. Tucker ed., 2d ed. 1978).