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# Non-Price Competition in “Substitute” Drugs: The FTC's Blind Spot

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# *N*onprice competition in “substitute” drugs: *The FTC’s blind spot*

BY GREGORY DOLIN, M.D.\*

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As the recent case of *United States v. Lundbeck* illustrates, the Federal Trade Commission’s lack of knowledge in medical and pharmacological sciences affects its evaluation of transactions between medical and pharmaceutical companies that involve transfers of rights to manufacture or sell drugs, causing the agency to object to such transactions without solid basis for doing so. This article argues that in order to properly define a pharmaceutical market, one must not just consider the condition that competing drugs are meant to treat, but also take into account whether there are “off-label” drugs that are used to treat a relevant condition, whether drugs actually compete with each other on price or whether they are selected based on their side-effects (or lack thereof), mechanism of action, physician knowledge, and other noneconomic considerations, and finally whether the drugs in question enjoy any patent or nonpatent-based exclusivity that prevents generic manufacturers from entering the market.

KEY WORDS: *FTC, antitrust, pharmaceutical, off-label, FDA, patent, exclusivity*

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## I. INTRODUCTION

The Federal Trade Commission (the FTC or the Commission) has been instrumental in enforcing America's antitrust laws for the last century across all industries—and with remarkable success. But while the FTC wields extensive expertise in law and economics, it lacks solid grounding in the medical and pharmacological sciences. This lack of knowledge, however, affects the FTC's evaluation of proposed transactions between various medical and pharmaceutical companies that involve transfers of rights to manufacture or sell drugs, causing the agency to object to such transactions without solid basis for doing so.

This article will focus on the fundamental errors in the FTC's analysis in *FTC v. Lundbeck*,<sup>1</sup> a case in which the Commission attempted to dissolve the acquisition by one company of rights covering two drugs that treating the same condition.<sup>2</sup> The *Lundbeck* case is illustrative because the FTC took the position that the relevant market is defined by the condition being treated,<sup>3</sup> without considering other medical issues relevant to the drug used to treat that condition. After an introduction to the case in section II, section III rejects the position that the drugs competed, explains why the FTC rightfully lost its case in *Lundbeck*, and suggests an alternative approach to evaluating rights transactions in the pharmaceutical market. I will offer concluding observations in section IV.

## II. THE LUNDBECK CASE

In 2005, Lundbeck, then named Ovation Pharmaceuticals, purchased the rights to Indocin IV (Indocin),<sup>4</sup> an off-patent drug, from Merck & Co. Indocin is used to treat a neonatal condition known as

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<sup>1</sup> 650 F.3d 1236 (8th Cir. 2011).

<sup>2</sup> See Complaint for Permanent Injunction and Other Equitable Relief, Including Disgorgement of Unlawful Monopoly Profits, *FTC v. Ovation Pharm.*, No. 08-6379, 2010 WL 3810015 (D.Minn. Aug. 31, 2010), available at [http://www.ftc.gov/sites/default/files/documents/cases/2008/12/081216\\_ovationcmpt.pdf](http://www.ftc.gov/sites/default/files/documents/cases/2008/12/081216_ovationcmpt.pdf).

<sup>3</sup> See *id.* at 5.

<sup>4</sup> See *FTC v. Ovation Pharm.*, No. 08-6379, 2010 WL 3810015, at \* 1 (D. Minn. Aug. 31, 2010).

patent ductus arteriosus (PDA) in which the duct that shunts blood to bypass the lungs of a neonate (a physiological necessity prebirth) fails to close after birth.<sup>5</sup> The condition can be treated either medically or surgically, with the medical method being preferred as its risks are lower. Interestingly, simple ibuprofen can be used to treat the condition and cause the duct to close.<sup>6</sup>

In the meantime, another pharmaceutical company—Abbott Laboratories—developed an alternative treatment for PDA. That drug, called NeoProfen, was a salt of ibuprofen that could be administered intravenously.<sup>7</sup> Abbott began the final Food and Drug Administration (FDA) approval process in late 2005, with approval coming in April 2006.<sup>8</sup> While Abbott was in the midst of the FDA process, Lundbeck approached it with an offer to acquire the rights to the drug.<sup>9</sup> In early 2006, Lundbeck acquired the rights to NeoProfen.<sup>10</sup> Thus, Lundbeck

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<sup>5</sup> See NAT’L HEART, LUNG, & BLOOD INST., WHAT IS PATENT DUCTUS ARTERIOSUS?, <http://www.nhlbi.nih.gov/health/health-topics/topics/pda/> (last visited Jan. 28, 2014).

<sup>6</sup> See, e.g., Sh. Pourarian, et al., *Comparison of Oral Ibuprofen and Indomethacin on Closure of Patent Ductus Arteriosus in Preterm Infants*, 14 E. MEDITERRANEAN HEALTH J. 360, 364 (2008) (concluding that “oral preparations of these drugs may have a similar efficacy to the intravenous preparations for ductal closure in preterm infants in developing countries where supplies of intravenous drugs are unavailable,” and are “a safer alternative.”); Eli Heyman, et al., *Closure of Patent Ductus Arteriosus With Oral Ibuprofen Suspension in Premature Newborns: A Pilot Study*, 112 PEDIATRICS e354, e355 (2003) (reporting 95.5% effectiveness of oral suspension of ibuprofen in closing PDA); Sau Supapannachart, et al., *Oral Ibuprofen and Indomethacin for Treatment of Patent Ductus Arteriosus in Premature Infants: A Randomized Trial at Ramathibodi Hospital*, 85 J. MED. ASSOC. THAI. S1252, S1258 (2002) (concluding that “[o]ral ibuprofen therapy is as effective as indomethacin for the treatment of PDA in premature infants and seems to have fewer renal side effects.”).

<sup>7</sup> *Ovation*, 2010 WL 3810015, at \*5.

<sup>8</sup> See *id.*; Food & Drug Admin., Label and Approval History for Neoprofen, [http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label\\_ApprovalHistory#apphist](http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label_ApprovalHistory#apphist) (last visited Jan. 28, 2014).

<sup>9</sup> *Ovation*, 2010 WL 3810015, at \*5-6.

<sup>10</sup> *Id.*

became the owner of both drugs approved by the FDA for the treatment of PDA.

Prior to completing the acquisition of NeoProfen, Lundbeck drastically raised the price on Indocin over the price charged by Indocin's previous owner, Merck).<sup>11</sup> The price rose from just under \$80 to \$1,500 for a course of treatment. Once Lundbeck acquired NeoProfen, it priced it slightly lower than Indocin, but in the same general range.<sup>12</sup>

The FTC challenged Lundbeck's acquisition of the rights to NeoProfen and lost. The courts concluded that though Indocin and NeoProfen are meant to treat the same disease, they are not in the same "market" because "treatment decisions are based solely on perceived clinical advantages/disadvantages of" each drug rather than on any price differences between the two.<sup>13</sup> Although the courts agreed that either drug *could* be used to treat PDA, they concluded that in reality, neonatologists choose a specific drug based on their own clinical experience.<sup>14</sup> In other words, the individuals choosing the drug are basically price insensitive,<sup>15</sup> thus undermining FTC's claim that it was Lundbeck's co-ownership of both FDA-approved drugs allowed it to drastically raise prices.

The neonatologists' insensitivity to price changes is actually not that surprising. Studies consistently show that doctors generally do not know the cost of drugs or procedures that they themselves prescribe.<sup>16</sup> Patients are equally price insensitive because for a vast majority of them, insurance covers medical costs (often after some sort of co-pay that doesn't significantly vary with the treatment).<sup>17</sup> All of this may present a potentially intractable problem when it comes to con-

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<sup>11</sup> FTC v. Lundbeck, 650 F.3d 1236, 1238 (8th Cir. 2011).

<sup>12</sup> *Id.*

<sup>13</sup> *Id.* at 1240.

<sup>14</sup> *Ovation*, 2010 WL 3810015, at \*17-18.

<sup>15</sup> *See Lundbeck*, 650 F.3d at 1241.

<sup>16</sup> *See, e.g.*, Carl E. Schneider & Mark A. Hall, *The Patient Life: Can Consumers Direct Health Care?*, 35 AM. J.L. & MED. 7, 29 (2009); Steve D. Shadowen, Keith B. Leffler, & Joseph T. Lukens, *Anticompetitive Product Changes in the Pharmaceutical Industry*, 41 RUTGERS L.J. 1, 11 n.33 (2009).

<sup>17</sup> Christopher Robertson, *The Split Benefit: The Painless Way to Put Skin Back in the Health Care Game*, 98 CORNELL L. REV. 921, 939 (2013).

trolling the spiraling costs of medical care,<sup>18</sup> but it does shed light on what constitutes a “market” for a particular pharmaceutical compound. It is to that question that I now turn.

### III. DEFINING THE MARKET IN PHARMACEUTICAL CASES

It is a truism that in any merger case defining the relevant market is the first and, perhaps, the most important step.<sup>19</sup> It is here that the FTC’s lack of depth in medical and pharmacological sciences caused its antitrust analysis to falter. The problem with FTC’s approach is that it ignores or at least heavily discounts three fundamental institutional realities of pharmacological markets. The courts in *Lundbeck* picked up on that failure, but they too did not address the full scope of issues that should be considered when defining pharmaceutical markets. Instead of looking at the prescribing physicians’ behavior alone, the Commission and the courts should consider three separate, but interrelated issues before determining the boundaries of the relevant market.

First, in determining the market for a given drug it is important to understand the FDA approval process. In order for any drug to be legally sold in the United States (whether by prescription or over-the-counter) it must undergo rigorous testing and, ultimately, approval by the FDA.<sup>20</sup> Prior to granting such approval, the FDA must be satisfied that the drug is both safe and efficacious for the condition meant to be treated.<sup>21</sup> After satisfying itself that the drug is safe and effective, the FDA grants approval for the chemical compound to enter the market.<sup>22</sup> The FDA also approves a label for the new drug.<sup>23</sup> In other

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<sup>18</sup> CONG. BUDGET OFFICE, THE LONG-TERM OUTLOOK FOR HEALTH CARE SPENDING 6 (2007).

<sup>19</sup> See, e.g. *Funeral Consumers Alliance, Inc. v. Serv. Corp. Int’l*, 695 F.3d 330, 348 (5th Cir. 2012); *City of New York v. Group Health Inc.*, 649 F.3d 151, 155 (2d Cir. 2011).

<sup>20</sup> 21 U.S.C. § 355(a) (2014).

<sup>21</sup> *Id.* § 355(a), (b), (j).

<sup>22</sup> *Id.* § 355(c)(1)(A).

<sup>23</sup> *Id.* § 355(a), (c), (d). See Martin A. Ramey, Conte v. Wyeth: *Caveat Innovator and the Case for Perpetual Liability in Drug Labeling*, 4 PITT. J. ENVTL PUB. HEALTH L. 73, at n.127 (2010) (That label “includes drug indications, contraindications, instructions for use, warnings and similar information.”); and Labeling Requirements for Prescription Drugs and/or Insulin, 21 C.F.R. § 201.56–.57 (2005).

words, technically speaking, the FDA approves the compound and the specific uses of that compound, which are then described on the compound's label.<sup>24</sup> The drug manufacturer is always responsible for updating the label with any additional warnings or potential side effects,<sup>25</sup> but it is not required, and, in fact, not permitted to add any additional indications for use absent a separate FDA approval.<sup>26</sup> Nor is the manufacturer permitted to advertise that his drug can be used to treat an "off-label" condition.<sup>27</sup>

These prohibitions on label alterations and off-label advertising, however, do not translate to prohibition on off-label *use*.<sup>28</sup> Indeed, once the chemical compound itself is approved for sale, a prescribing physician can prescribe the medication for whatever condition or ailment he deems appropriate.<sup>29</sup> In fact, off-label use is prevalent in almost all areas of medical practice.<sup>30</sup> Sometimes the off-label use is similar to the FDA-approved use, as is the case with Actiq (oral transmucosal fentanyl citrate), which is approved for breakthrough pain in

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<sup>24</sup> See Jacqueline Fox, *The Hidden Role of Cost: Medicare Decisions, Transparency and Public Trust*, 79 U. CIN. L. REV. 1, 17 (2010).

<sup>25</sup> See 21 C.F.R. § 201.57(c)(6)(i).

<sup>26</sup> See 21 U.S.C. § 551(b)(1)(A); Applications for FDA Approval to Market a New Drug, 21 C.F.R. § 314.70(a) (2014).

<sup>27</sup> Prescription Drug Advertising, 21 C.F.R. § 202.1(e)(4) (2013). Firms, however, often violate these prohibitions. See Marc A. Rodwin, *Rooting Out Institutional Corruption to Manage Inappropriate Off-Label Drug Use*, 41 J.L. MED. & ETHICS 654, 657 (2013).

<sup>28</sup> Michael Friedman, Deputy Comm'r for Operations, FDA, Prepared Statement Before the Subcommittee on Human Resources and Intergovernmental Relations of the House Committee on Government Reform and Oversight (Sept. 12, 1996), available at <http://www.hhs.gov/asl/testify/t960912a.html>.

<sup>29</sup> See Artie Berns, *Dementia and Antipsychotics: A Prescription for Problems*, 33 J. LEGAL MED. 553, 562 (2012); Michelle L. Mello, *Psychotropic Medication and Foster Care Children: A Prescription for State Oversight*, 85 S. CAL. L. REV. 395, 407-08 (2012).

<sup>30</sup> Ryan Abbott, *Big Data and Pharmacovigilance: Using Health Information Exchanges to Revolutionize Drug Safety*, 99 IOWA L. REV. 225, 264 (2013) ("[O]ff-label use is common and legal; it accounts for around one-fifth of all prescriptions.").

cancer patients, but is often used to treat moderate-to-severe chronic, nonmalignant pain.<sup>31</sup> Other times though, the prescribed use differs radically from the FDA-approved indication. For example, Zoloft (sertraline) is often used to treat premature ejaculation while being approved only as an anti-depressant.<sup>32</sup>

One might wonder why the drug companies would not move to expand their labels to include new indications; after all, the more indications a drug could be marketed for, the higher the likely profit for the company. In reality, however, the calculation is not that simple. The FDA approval process for a new use is both costly and time consuming. The cost of submitting a “supplemental” application is in the millions of dollars,<sup>33</sup> while the approval time may actually exceed the time spent approving the initial application.<sup>34</sup> What’s more, the new studies may bring previously unknown problems to the fore<sup>35</sup>—a useful outcome for the patients, but a risky one for the pharmaceutical company. Finally, while the company is conducting these additional studies and the FDA is conducting its review, the clock continues ticking on any patent-based exclusive rights that the company may have in the underlying chemical compound.<sup>36</sup> Thus, by the time the company receives the FDA approval to list an additional indication on the label, the patent rights may have expired or be close to expiration, thus allowing a generic company to enter the market and reap the benefits

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<sup>31</sup> See John Carreyrou, *Potent Product: Narcotic “Lollipop” Becomes Big Seller Despite FDA Curbs—Actiq Is Only for Cancer Pain But Cephalon Pitches It to Many Types of Doctors—“Like the Most Delicious Candy,”* WALL ST. J., Nov. 3, 2006, at A1.

<sup>32</sup> See Chris Adams, *Off-label Drug Use Concern*, SAN JOSE MERCURY NEWS, May 9, 2005, at A5.

<sup>33</sup> See Leah Brannon, *Regulating Drug Promotion on the Internet*, 54 FOOD & DRUG L.J. 599, 618 n.151 (1999) (noting that a supplemental application for a new use could cost over \$300 million (in 1997 dollars)).

<sup>34</sup> See Mitchell Oates, *Facilitating Informed Medical Treatment through Production and Disclosure of Research into Off-Label Uses of Pharmaceuticals*, 80 N.Y.U. L. REV. 1272, 1285 n.66 (2005).

<sup>35</sup> Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 377 (2007).

<sup>36</sup> See Oates, *supra* note 34, at 1285.



of these additional studies.<sup>37</sup> Although the generic's label won't be able to list the new indication due to the FDA-based three-year exclusivity provision and any additional patents claiming the use of the drug rather than the chemical composition,<sup>38</sup> once a physician prescribes a brand-name drug, for whatever indication, a pharmacist is generally free to fill the prescription with a generic substitute.<sup>39</sup>

The bottom line is that drugs that are FDA-approved to treat a medical condition may not be the only drugs actually used to treat that condition. This means that in defining the relevant market, it is erroneous to look only at what FDA has approved. Instead, the market consists of both on-label and off-label medications. Such a market definition would reflect the reality of medicinal practice in this country. Had the FTC looked beyond merely FDA-approved medications to treat PDA, it would have recognized that clinical studies showed that a simple (and rather inexpensive) oral suspension of ibuprofen (rather than intravenously administered Indocin or Neo-Profen) can be used to treat the condition.<sup>40</sup> Ibuprofen, of course, has long been available in generic form and could have been used as a substitute for the other two drugs. It is an open question whether oral suspension of ibuprofen is actually used by neonatologists to treat PDA. If neonatologists eschew this option, then perhaps in *Lundbeck* there were no competing off-label drugs in the relevant market.<sup>41</sup> In either case, the fundamental point remains—in deter-

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<sup>37</sup> *Id.*

<sup>38</sup> 21 U.S.C. § 355(j)(D)(iv) (2014).

<sup>39</sup> Indeed, the law may require pharmacists to fill a prescription with a generic substitute, unless explicitly directed otherwise by the physician. See generally Michael A. Carrier, *A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product Hopping*, 62 FLA. L. REV. 1009, 1017 (2010).

<sup>40</sup> See Heyman, *supra* note 6, and accompanying text.

<sup>41</sup> Despite the fact that some studies reported the efficacy of oral suspension for the closure of PDA as early as 2002, see Supapannachart, *supra* note 6, this choice remains unpopular in the United States. There may be several explanations for this. Doctors may simply be more comfortable with the drugs they know, and given the potential for things to go wrong should the PDA not close, may be unwilling to switch (as they did in fact testify at trial).

mining the scope of the relevant market for treating a medical condition it is important to consider not just therapies specifically approved for the treatment of that condition but also other therapies that are actually being used in the field despite the absence of a label recommending such use.

The second error that the FTC made in defining the market in *Lundbeck* was focusing almost exclusively on the condition to be treated. Although looking at the ailment is a reasonable point of departure when attempting to define a market, it is important to recognize that different drugs with different mechanisms of actions can be used to treat the same overriding condition. For example, in treating hypertension a physician can choose among: diuretics, beta-blockers, ACE inhibitors, calcium channel blockers, angiotensin II receptor blockers, and a number of others.<sup>42</sup> There are multitudes of drugs within each category.<sup>43</sup> When prescribing a drug to treat hypertension, a physician doesn't consider only the patient's blood pressure, but also drug interactions, potential side effects, age, comorbidities, and even race.<sup>44</sup> Thus, for some group of patients a beta-blocker would be

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FTC v. Lundbeck, 650 F.3d 1236, 1241 (8th Cir. 2011). Additionally, the early reports were small group studies, which may not be viewed as sufficiently robust to justify switching from a proven therapy. Finally, all of the early reports are from studies conducted abroad (for example, in Iran, Israel, and Thailand) and thus may be viewed somewhat skeptically by American physicians. None of this is to say that the studies are incorrect or that oral ibuprofen is in reality less effective than intravenous ibuprofen or indomethacin. Rather, this is to explain why Lundbeck thought that its pricing strategy would work (and did indeed work). See *infra* note 61 and accompanying text.

<sup>42</sup> See, e.g., John D. Bisognano, et al., *Calcium Channel Blockers, Angiotensin Receptor Blockers, and Angiotensin-Converting Enzyme Inhibitors: Effectiveness in Combination with Diuretics or  $\beta$ -blockers for Treating Hypertension*, 3 VASCULAR HEALTH RISK MGMT. 579 (2007).

<sup>43</sup> See AM. HEART ASS'N, *Types of Blood Pressure Medications*, available at [http://www.heart.org/HEARTORG/Conditions/HighBloodPressure/PreventionTreatmentofHighBloodPressure/Types-of-Blood-Pressure-Medications\\_UCM\\_303247\\_Article.jsp](http://www.heart.org/HEARTORG/Conditions/HighBloodPressure/PreventionTreatmentofHighBloodPressure/Types-of-Blood-Pressure-Medications_UCM_303247_Article.jsp) (last visited Feb. 7, 2014).

<sup>44</sup> See John A. Rizzo, *Advertising and Competition in the Ethical Pharmaceutical Industry: The Case of Antihypertensive Drugs*, 42 J.L. & ECON. 89, 94 (1999).

preferred while for others it would be a diuretic.<sup>45</sup> The two categories of drugs, though both capable of and used for treating hypertension, are not in the same market because in fact they are not used on the same population. If one were to focus simply on the ailment being treated—hypertension—one would miss this important patient-consumer differentiation.

This is what the courts in *Lundbeck* recognized when they held that NeoProfen and Indocin were not in the same market because the choice of drugs depended not on price but on physicians' evaluation of the risk of side effects and general comfort with the drug.<sup>46</sup> Admittedly, in *Lundbeck*, this conclusion did not rest on particularly strong grounds, as it seems that the two drugs have the same mode of action and similar side effects (with NeoProfen being somewhat less likely to cause these effects).<sup>47</sup> However, the court was correct in recognizing that it is not sufficient merely to identify the condition which the pharmaceutical compound is intended to treat; rather, one must look deeper and consider any comorbidities and the side effects of the drug that may differentially affect different patient subpopulations.<sup>48</sup> In other words, I think that the *Lundbeck* court relied too much on mere preferences by neonatologists, but was ultimately focused on the right issue because those preferences are most often driven by biologic and pharmacologic considerations. These considerations must always be taken into account when attempting to define a proper market for drugs and medical devices.

Finally, in defining the market, it is important to consider the presence or absence of exclusivity regimes that the drug may enjoy. In the pharmaceutical world, the exclusivity regimes come in two varieties:

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<sup>45</sup> See JOINT NAT'L COMM. ON DETECTION, EVALUATION, AND TREATMENT OF HIGH BLOOD PRESSURE, *The 1984 Report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure*, 144 ARCHIVES INTERNAL MED. 1045, 1057 (1985) (noting that ACE inhibitors are less effective in African-Americans than in whites).

<sup>46</sup> *Lundbeck*, 650 F.3d at 1240.

<sup>47</sup> See, e.g., Grace Poon, *Ibuprofen Lysine (NeoProfen) for the Treatment of Patent Ductus Arteriosus*, 20 BAYLOR UNIV. MED. CTR. PROCEEDINGS 83 (2007).

<sup>48</sup> See *Lundbeck*, 650 F.3d at 1240.

patent-based and FDA-based.<sup>49</sup> When there is a valid, unexpired patent on the underlying chemical compound or on all of those uses of the compound approved by the FDA, a generic company is unable to enter the market and compete with the brand-name product.<sup>50</sup> However, once the patents expire, even if new patents are issued on additional uses, a generic company can enter the market with its own version of the drug<sup>51</sup> (though it will not be permitted to market that version for purposes that are still under patent.)<sup>52</sup> A generic company can enter the market at much lower costs and within a much shorter period than a pioneer company, because a generic company needs merely to show that its product is bioequivalent to the already approved brand name.<sup>53</sup> Moreover, a generic need not wait until the brand name’s patents actually expire to submit its application to the FDA. It can file long before the expiration date and simply request that the approval go into effect immediately following the patent expiration date.<sup>54</sup>

The FDA-based regime is somewhat different, but its basic features track the patent regime. Again, once the FDA-based exclusivity on the chemical compound expires, a generic drug manufacturer can seek approval to enter the market even if there are additional FDA-based exclusivities on use of the brand-name drug.<sup>55</sup> As with the patent regime, the generic would not be permitted to list on its label the indications for which FDA-based exclusivity has not yet expired.<sup>56</sup> However, as previ-

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<sup>49</sup> See generally, Gregory Dolin, *Exclusivity Without Patents: The New Frontier of FDA Regulation for Genetic Materials*, 98 IOWA L. REV. 1399, 1448–54 (2013).

<sup>50</sup> See Laura J. Grebe, *Generic Entry in a Rough Economy—Proposed Legislation May Ease Health Care Costs*, 14 MARQ. INTELL. PROP. L. REV. 167, 187 (2010).

<sup>51</sup> See 21 U.S.C. § 355(j)(2)(A)(viii) (2014); *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1672 (2012).

<sup>52</sup> See *Caraco Pharm.*, 132 S. Ct. at 1672; 21 C.F.R. § 314.94(a)(8)(iv) (2014).

<sup>53</sup> 21 U.S.C. § 355(j)(2)(A)(ii), (iv).

<sup>54</sup> *Id.* § 355(j)(2)(A)(vii)(III).

<sup>55</sup> See Elizabeth Stotland Weiswasser & Scott D. Danzis, *The Hatch-Waxman Act: History, Structure, and Legacy*, 71 ANTITRUST L.J. 585, 592–93 (2003).

<sup>56</sup> 21 U.S.C. § 355(j)(5)(F)(iii).

ously discussed, the lack of the specific indication on the generic's label is not a bar to substituting the generic for the prescribed brand name.<sup>57</sup>

The lack of any exclusivity barriers to market entry and the comparatively low cost of such entry should be considered in defining the market for pharmaceuticals, because the presence of these conditions exerts a strong check on the ability of the brand-name manufacturer to raise prices.

By the time the FTC lodged its complaint in *Lundbeck*, patents on Indocin had long expired.<sup>58</sup> Thus, in theory, it should have been easy and advantageous for generics to seek approval to produce a generic version of the drug. The FTC recognized in its complaint that no patents bar the entry of generics,<sup>59</sup> but argued that entry barriers are high because it takes time to win approval and that given the small population suffering from PDA the payoff for such generic companies may be rather small.<sup>60</sup> What the FTC was missing, however, is that the payoff was small precisely because the brand-name Indocin was underpriced, making the drug an unattractive investment for a generic firm. Indeed, Lundbeck's entire strategy was premised on raising the price of Indocin so as to attract more generic companies, increase competition for that drug, and then position itself as a sole provider of what it viewed as a better alternative—NeoProfen.<sup>61</sup>

Whether the FTC was right or wrong on the barrier issue in Indocin, its recognition that the presence or absence of a patent on a drug is a key consideration in defining the market for that drug was correct and should continue to be applied in future cases.

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<sup>57</sup> See *supra* note 39 and the accompanying text. The Federal Circuit has held that a generic company does not infringe use patents merely because its drug is likely to be prescribed for patented uses, so long as at least one approved use is off-patent. See *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348 (Fed. Cir. 2003).

<sup>58</sup> See Complaint, *supra* note 2, at 5.

<sup>59</sup> *Id.*

<sup>60</sup> *Id.* at 7.

<sup>61</sup> See *FTC v. Ovation Pharm.*, No. 08-6379, 2010 WL 3810015, at \* 6-7 (D. Minn. Aug. 31, 2010).

#### IV. CONCLUSION

In deciding whether to challenge the sale or transfer of patents or wholesale merger of pharmaceutical companies, the FTC should apply traditional antitrust law and economic principles. But the Commission should apply those principles to the realities of medical practice. In doing so the Commission ought to recognize that certain pharmaceuticals or medical devices can be substitutes product even if not formally approved by the FDA for that specific purpose. Additionally, in defining the market the Commission must realize that although those multiple drugs could treat the same major medical condition, the drugs are not necessarily competitors with each other if physicians select drugs (and prefer one to another) based on considerations besides the underlying medical condition. Finally, the FTC should remember that with the expiration of patents for the active ingredient and at least one FDA-approved indication, any number of generics can and will enter the market if the drug itself is profitable. Only once such factors are taken into account should the FTC exercise its powers. It is precisely because the Commission failed to do so that it lost in *Lundbeck*, and rightly so.