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## Going, going, gone

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### *Patents set to expire soon on many brand-name drugs*

Time is running out on the U.S. patents for many of the most popular brand-name drugs. Unless original exclusivity dates are somehow extended, over the next several years generic versions of many well-known best-selling drugs will become available.

Pharmacists will need to stay abreast of these changes as consumers struggling to cope with the high cost of prescription medications turn to them with the question "Is there a generic for that?" Increasingly, over the next several years, the answer will be yes.

#### **Off patent in 2009 and 2010**

(Courtesy Getty Images/Glowimages)

Patents have already expired or are soon to expire in 2009 for several brand-name drugs. From GlaxoSmithKline (GSK), the blockbuster **Valtrex** (valacyclovir hydrochloride) for the treatment of genital herpes and cold sores goes off patent this year. Teva has received tentative approval from the Food and Drug Administration (FDA) to begin marketing its generic version in December.<sup>1</sup> Also going off patent is **Mepron** (atovaquone), GSK's antiprotozoal used for the treatment of pneumonia in patients with compromised immune systems. Mepron is also used to treat Lyme disease.

**Prevacid** (lansoprazole), Takeda's blockbuster heartburn and acid reflux medication, will see its patent expire in 2009 and will be marketed in an over-the-counter version by Novartis, which has acquired the rights.<sup>2</sup>

Three big-name drugs for the treatment of migraine — Ortho-McNeill's **Topamax** (topiramate); Novartis' **Migranal** (dihydroergotamine); and GSK's **Imitrex** (sumatriptan) — are going off patent this year. A generic version of Topamax already has been approved by FDA.<sup>3</sup> GSK is evaluating in trials a spinoff Imitrex-plus-naproxen combination drug, Trexima, which it hopes to launch to replace lost sales.<sup>4,5</sup>

Generic formulations of **Lamictal** (lamotrigine), GSK's treatment for bipolar disorder and epilepsy, which has lost its patent protection, have been approved by FDA. GSK obtained FDA approval in June, however, to market its **Lamictal XR** (extended release) epilepsy drug, again in the hope of replacing sales expected to be lost to the generic.<sup>6</sup>

Patents for many blockbuster brand-name drugs begin expiring at a rapid pace in 2010 and will continue for the next few years. Facing increased competition from generics, drug companies are busy developing

new pipeline drugs and devising strategies to try to hold onto sales for their drugs facing patent expiration.

**Lipitor** (atorvastatin) — Pfizer's blockbuster cholesterol pill goes off patent in March 2010. Lipitor is the best-selling drug in the world, with nearly \$13 billion in sales.<sup>7</sup> Pfizer has struck a deal with Ranbaxy Laboratories that will enable release of the generic form outside the United States before patents run out, but delays U.S. release until November 2011.<sup>8</sup>

**Arimidex** (anastrozole) — AstraZeneca's after-surgery treatment for postmenopausal women with early breast cancer was set to expire in December 2009, but an extension was granted so that pediatric studies could be made. It now looks as if June 2010 is the earliest a generic version could become available.<sup>9</sup>

**Aricept** (donepezil) — Pfizer/Eisai is to lose patent protection in 2010 on this treatment for symptoms of early Alzheimer's. Teva has gained tentative FDA approval to market its generic version; however, Eisai and Teva are locked in a patent challenge, keeping the generic off the market for now.<sup>10</sup>

**Cozaar** (losartan) — In April 2010, Merck loses U.S. market exclusivity for Cozaar, its widely prescribed best-selling treatment for high blood pressure and diabetes. Cozaar is expected to earn at least \$3.4 billion in 2009, but generic competition from Teva is likely to quickly chip away at these revenues.<sup>11</sup>

**Levaquin** (levofloxacin) — The patent for Johnson & Johnson's broad-spectrum antibiotic Levaquin was due to expire in December 2010, but a pediatric study extended the expiration date to June 2011. The drug ultimately won approval for use in children exposed to anthrax.<sup>12</sup>

**Flomax** (tamsulosin) — Boehringer Ingelheim/Astell's popular prescription for the treatment of complications of an enlarged prostate was originally scheduled to go off patent in 2009, but delays will make a generic version unavailable until March 2010. Ranbaxy acquired exclusive rights to sell the generic, still under the brand name Flomax, for two months before the patent officially expires.<sup>13</sup>

Also set to expire in 2010 are Wyeth's blockbuster heartburn medicine, **Protonix** (pantoprazole); GSK's cancer drug **Hycamtin** (topotecan); Bayer's **Climara** (estradiol) hormone-replacement therapy; Roche's **Invirase** (saquinavir), used with ritonavir to treat HIV infection; and UCB's **Keppra** (levetiracetam) for the treatment of epilepsy.

## 2011 and beyond

**Advair** (fluticasone/salmeterol) — GSK lost some patent protection on its best-selling asthma drug Advair (also known as **Seretide**), in 2009, but additional indications make it more likely for generic versions to be released in 2011.

**Plavix** (clopidogrel) — Bristol-Myers/Sanofi-Aventis' blockbuster blood-thinning agent for patients with MI, stroke, and PAD goes off patent in 2011. Sales of Plavix were nearly \$5 billion in 2008.<sup>14</sup> After much legal wrangling, Apotex should begin marketing the generic version by the end of the year.<sup>15</sup>

Several best-selling antipsychotic and antidepressant drugs are expected to go off patent this year, among them AstraZeneca's second-largest seller, **Seroquel** (quetiapine), the 16th-best-selling drug and an antipsychotic used to treat schizophrenia; **Zyprexa** (olanzapine; Eli Lilly), the eighth-best-selling drug, also used to treat schizophrenia; and the antidepressant **Effexor XR** (venlafaxine). Wyeth's best-selling drug for treatment of depression and panic disorder, Effexor is the subject of a legal struggle between

Wyeth and Teva. Teva can begin selling its generic formulation in 2010.<sup>16</sup>

Bristol-Myers/Sanofi-Aventis will lose exclusivity for **Aprovel** (irbesartan), an angiotensin II receptor antagonist for treatment of hypertension, in 2011. Pfizer will lose the glaucoma drug **Xalatan** (latanoprost ophthalmic solution).

In addition, patents are scheduled to expire in 2011 for **Astelin** (azelastine, Wallace) antihistamine nasal spray; **Synarel** (nafarelin, Roche) nasal spray for precocious puberty and endometriosis; **Actos** (pioglitazone, Takeda) for type 2 diabetes; the fertility drug **Follistim** (follitropin beta, Organon); and **Viramune** (nevirapine, Boehringer Ingelheim), an anti-HIV drug.

Among drugs scheduled to come off patent in 2012 is AstraZeneca's cholesterol-lowering drug **Crestor** (rosuvastatin). The company also loses its patent on the asthma drug **Symbicort** (budesonide/formoterol) the same year.

Merck loses its top-selling asthma drug, **Singulair** (montelukast), as well as its migraine medication, **Maxalt** (rizatriptan), in 2012. Merck is working at developing a new migraine medication, but is having difficulty bringing it to market.<sup>17</sup>

GSK's patent on the diabetes drug **Avandia** (rosiglitazone) expires in 2012; Novartis' **Zometa** (zoledronic acid) bisphosphonate cancer drug and its **Diovan** (valsartan) antihypertensive both expire in 2012; and Forest Laboratories loses its patent on the antidepressant **Lexapro**, also known as **Cipralex** (escitalopram), in 2012.

Also in 2012, first patent protection disappears for Pfizer's **Viagra** (sildenafil).

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