



Drug Patent Expirations and the “Patent Cliff”

Beginning in 2010, the pharmaceutical industry faced one of the biggest waves of drug patent expirations in history, a phenomenon referred to as the “patent cliff.” A significant number of top-selling drugs in the history of the pharmaceutical industry will experience patent expirations over the next 5 years, paving the way for lower-priced generics. In November 2011 alone, four major drugs—Lipitor (atorvastatin), Caduet (amlodipine/atorvastatin), Combivir (lamivudine/zidovudine), and Solodyn (minocycline extended release tablet)—lost

patent protection. Combined, these four drugs accounted for more than \$7 billion in sales.¹⁻⁵ In total, patents on drugs worth \$12 billion expired by the end of 2011, and in 2012 that figure is expected to increase to more than \$30 billion in annual sales. Furthermore, it is estimated that generic competition will have eroded \$67 billion from top drug companies’ annual sales in the United States between 2007 and 2012 alone, as more than three dozen drugs lose patent protection during this time.⁶ That figure represents approximately 50% of the companies’ combined U.S. sales in 2007. With patents on many so-called blockbuster drugs about to expire, an estimated \$250 billion in sales is at risk between now and 2015.¹⁻⁵ Selected drugs whose patents have expired or will expire over the next several years are shown in **TABLE 1**.⁶

Once drugs lose patent protection, lower-price generics quickly siphon off

as much as 90% of their sales.^{2,3} For consumers, the savings from generics can be substantial. Drugs are granted 20 years of patent protection, although companies often do not get a product to market before as much as half of that period has already elapsed. Once a drug enters the market, however, patent protection can result in high profits, with gross profit margins exceeding 90%.²⁻³ When patents expire, generic makers offer the products at prices reported to average about 30% of the price of the brand-name originals.²⁻³ Although the generic industry will benefit in the short term, it will also see a slowdown in revenue growth after 2015 because fewer branded blockbusters will be coming off patent after this time.

As of 2010, patents had expired on a number of widely used drugs, including Advair (fluticasone propionate and salmeterol), Levaquin (levofloxacin), Cozaar (losartan), and Taxotere (docetaxel). In addition to the drugs mentioned above, in 2011 Bristol-Myers/Sanofi-Aventis lost exclusivity for Avapro (irbesartan), an angiotensin II receptor antagonist for treatment of hypertension, and Pfizer lost the glaucoma drug Xalatan (latanoprost ophthalmic solution). Other patents expiring in 2011 included 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 (folitropin beta injection, Organon); and the HIV/AIDS drug Viremune (nevirapine, Boehringer Ingelheim).¹⁻⁶

Among drugs scheduled to come off patent in 2012 is AstraZeneca’s cholesterol-lowering drug Crestor (rosuvastatin) and its asthma drug Symbicort (budesonide/formoterol). Merck loses its top-selling asthma drug, Singulair (montelukast), as well as its migraine medication, Maxalt (rizatriptan), in 2012. GlaxoSmithKline’s (GSK) patent on the diabetes drug Avandia (rosiglitazone) and Forest Laboratories’ patent on the antidepressant Lexapro (escitalopram) also expire in 2012. Novartis’s Zometa (zoledronic acid), its bisphos-

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