



**Brand Name Drug Patent  
Expirations Create a Perfect  
Storm for Litigation**



The *Wall Street Journal* recently reported that on November 30, 2011, a generic manufacturer will release an unbranded version of Pfizer's cholesterol-controlling Lipitor, which is currently the top-selling drug in the world.<sup>1</sup> Eli Lilly's antipsychotic drug, Zyprexa, will suffer the same fate this fall. Both medications generated billions of dollars in 2010 and their numbers are expected to drop exponentially when the patents expire. In 2012, several other important medications will follow suit, including Plavix, an anti-clotting drug from Bristol-Myers Squibb and Sanofi-Aventis, Seroquel, an antipsychotic prescription from AstraZeneca, and Singulair, an asthma medication from Merck.

The loss of patent exclusivity is mandated by law and a predictable element of the pharmaceutical industry, but the unprecedented number of expirations of the world's most popular drugs is fueling an array of litigation due, in part, to the 1984 Hatch-Waxman Act.

Because Hatch-Waxman allows companies interested in marketing the generic version of a previously patented drug to file an Abbreviated New Drug Application (ANDA) and secure approval of its product by the Food & Drug Administration, this creates a system that effectively guarantees expensive and lengthy litigation. This environment underscores the need for an effective jury consulting and presentation strategy for trial.

TrialGraphix offers a potent combination of jury research and graphics expertise that makes us uniquely suited to support this barrage of activity. Our research team features experts with Ph.D.s in key social science disciplines and an unrivaled depth of experience, while our design team and presentation technology consultants garner an outstanding level of loyalty throughout the legal community.

## **Factors Fueling Pharmaceutical Patent Litigation**

This regulatory structure and two primary factors have created a perfect storm for patent proceedings.

First, the recession and insurance company requirements have fueled an increased use of generic drugs in the past few years. While research conducted by TrialGraphix and other industry experts once showed that most jurors preferred brand names to generics, thought they were of superior quality, and regarded generic manufacturers as interlopers trying to ride the wake of the brand name's success, more of them now use generic products because of their lower cost and equivalent quality. In fact, many mock jurors rated generic drug manufacturers more positively than those producing branded products, due in part to the skyrocketing costs of health care.

Second, Hatch-Waxman enables generic manufacturers to characterize a relevant dispute as a simple business matter about extending the life of a patent, rather than protecting the intellectual product of a creative mind. Although research studies tend to endorse the commonly held perception that jurors strongly support patents, the recognition accorded inventors, the authority of the U.S. Patent & Trademark Office, and the rights of patent holders to protect their intellectual property, they increasingly view these disputes as pure business maneuvering to block new production of the drugs at issue. "TrialGraphix gives a client the clearest sense of what jurors in particular venues think of these cases and companies," says Robert Minick, Ph.D., Senior Jury Consultant for

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<sup>1</sup>Peter Loftus, Big Pharma Patent Expirations To Sock 2012 US Drug Sales, *The Wall Street Journal*, February 15, 2011.



TrialGraphix. Throughout his career, Dr. Minick has been the lead consultant on more than 600 cases, including a wide variety of those involving name brand drug manufacturers, several have been cited as outstanding wins by *The National Law Journal*.

TrialGraphix helps clients identify the factors that are likely to impact each case most significantly and navigate through the complexity with greater success. “The various areas that we assess will have an impact on how these jurors will ultimately decide the case,” says Dr. Minick.

### **Research Reaps Rewards**

In many disputes over the protection of a name brand drug on the market, the differences of opinion in how jurors view that manufacturer, whether they support government regulations of food products and refute the claims of monopolistic or anticompetitive practices of the name brand drug maker will directly influence the outcome. Advanced research techniques can support the strategic direction at different points in the trial process and can provide varying levels of insight. They include:

**Focus Groups:** This is an exploratory process in which the team of experts at TrialGraphix tests key themes, strategies, witnesses, documents, and evidence to determine their impact and effectiveness.

**Mock Trials:** Similar to a scrimmage between the parties, this technique applies refined themes to a trial setting to gauge outcome variables, which helps name brand litigants evaluate potential results.

**Witness Preparation:** In pharmaceutical litigation, senior executives, as well as those responsible for a drug’s primary research and development, offer critical testimony. TrialGraphix prepares these individuals to help them overcome anxiety, communicate effectively, and convey the proper message.

**Jury Selection:** In an effort to find those jurors who are sympathetic to the claims of a name brand manufacturer, the seasoned jury consultants at TrialGraphix leverage decades of experience to profile prospective jurors and craft voir dire questions that enable counsel to rank members of the jury pool. The consultants will often provide immediate feedback in the courtroom during the selection process.

### **The Visual Advantage**

In any setting before a judge or jury, strong visual aids can bridge the gap between clarity and confusion. For instance, in pre-trial claim construction hearings concerning the formation of a drug, its production, and the medical condition it treats, judges routinely request tutorials. These lessons often serve as a mini-documentary in which chemists, doctors, and other experts explain the science in a practical fashion.

The concentration of experience in creating these highly influential presentations by leading graphic specialists at TrialGraphix is unmatched. In a case for a well-known manufacturer concerning a rheumatoid arthritis drug, TrialGraphix experts prepared sophisticated animations with voiceover tutorials to help the trial team explain complicated recombinant DNA technology. And, in a dispute involving a drug-eluting stent, the animation that TrialGraphix prepared detailing the impact of its use in a procedure

on the coronary artery offered far more persuasive advocacy than oral argument. This strategy is essential because a 3-D image of drug compositions and patent applications, for instance, can significantly influence the decision-making process.

At trial, visually highlighting an argument frequently offers counsel the best chance for effectively explaining the specific patents at issue and the reasons supporting or refuting their validity. Timelines are also useful for demonstrating the drug's development from conception to patent, including its various filing milestones and sometimes even competition details between two companies. "We have the experience to take convoluted information and transform it into a powerful visual aid that influences judges and jurors," says Matthew Quigley, a Managing Director of TrialGraphix, who in his 17 years with the consulting firm has worked on cases supporting numerous brand name manufacturers.

The sophisticated team at TrialGraphix is skilled at synthesizing complicated information using storyboards and a host of visual technology tools for a range of audiences. With experience preparing hundreds of graphics in pharmaceutical matters and evaluating the perceptions of countless jurors in venues nationwide, TrialGraphix has the creativity and knowledge to support the coming storm of litigation.

## Biographies



**Robert Minick, Ph.D.** is a Washington, D.C.-based senior jury consultant for TrialGraphix. He has served as the lead consultant on more than 600 cases, including many related to pharmaceutical and biomedical issues, throughout his career. Dr. Minick has been helping companies win for over two decades by leveraging his expertise in the design and implementation of social science research, the analysis of group dynamics and persuasion, and the evaluation of juror reactions to case facts, witnesses, and trial strategies. In addition, he has provided commentary on high-profile matters for *The Wall Street Journal*, CNN, BBC, ABC, BET, *The Associated Press*, and *Businessweek*.

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**Matthew Quigley** is a Miami-based managing director for TrialGraphix. Quigley has almost two decades of experience in leveraging cutting-edge technology to conceptualize and depict themes specifically related to patent litigation, including coronary artery animations to demonstrate the impact of a drug-eluting stent, interactive 3-D modeling of drug compositions, and digital timelines that explain developments in drug therapy. In his

17 years with TrialGraphix, he has worked on a variety of pharmaceutical disputes over Paxil and Flomax, among other drugs.

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## The Diversity of Pharmaceutical Litigation Claims

Beyond standard patent invalidity claims by generic drug manufacturers, consumers, wholesalers, pharmacies, and state or municipal governments have creatively introduced a variety of legal challenges to permit a cheaper form of a popular medication into the market. Several current examples include:

### 1. Unlawful Monopolization

A series of retail pharmacies and distributors sued Abbott Laboratories for allegedly abusing its monopoly position as the sole provider of Norvir, a drug used in protease inhibitor cocktails that offer promising new HIV/AIDS therapies, by raising its price by 400% and significantly increasing the cost of Abbott's other drugs related to this treatment. In an uncommon move, GlaxoSmithKline, the maker of similar HIV/AIDS therapies, joined the plaintiffs in their legal action.

### 2. Antitrust

In ongoing litigation, Warner-Lambert Company (acquired by Pfizer Inc.) sued a number of generic drug manufacturers following notice of their ANDAs to produce generic versions of Neurontin, an anticonvulsant medication. Subsequently, a number of interested parties filed suit against Pfizer and Warner-Lambert alleging that their opposition to the ANDAs amounted to sham litigation. They claimed that Pfizer and Warner-Lambert violated antitrust laws by preventing generic items from entering the market, delaying prosecution of a related patent, and wrongfully listing certain drugs in the FDA's official Orange Book of approved products.

### 3. Unfair Trade

A current class action lawsuit alleges that GlaxoSmithKline filed citizen petitions, which are letters that address issues of the safety and efficacy of a drug under review by the FDA, to prevent the sale of generic versions of Flonase, a nasal allergy inhalant. The plaintiffs claimed that GlaxoSmithKline's petitions violated federal and state antitrust laws, as well as state unfair trade practices restrictions.

