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## HOW WILL *EBAY V. MERCEXCHANGE* AFFECT PHARMACEUTICAL AND BIOTECHNOLOGY PATENT OWNERS?

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**According to a recent decision by the United States Supreme Court, patent owners may no longer be able automatically to obtain permanent injunctive relief after showing that their valid patents have been infringed. Historically, courts issued permanent injunctions – which effectively stop the infringing activity – once the subject patent was found to be both valid and infringed. In *eBay v. MercExchange, L.L.C.*, 547 U.S. \_\_\_\_, 126 S. Ct. 1837 (2006), however, the Supreme Court made clear that permanent injunctions are not to be granted automatically in patent infringement cases.**

Rather, the Court held, a permanent injunction is an equitable remedy that may only be imposed in patent cases where – as in all other types of cases – the remedy is appropriate in light of equitable principles and evaluated under a traditional four-factor test. In the words of the Supreme Court, there is no “‘general rule,’ unique to patent cases, that a permanent injunction will issue once infringement and validity has been adjudged.”

The new uncertainty introduced by the Supreme Court’s holding in *eBay*, and the lack of specific guidance as to how the traditional four-factor test will be applied consistent with equitable principles, means that patent owners – including those in the pharmaceutical and biotechnology industries<sup>1</sup> – should be concerned about whether and when permanent injunctive relief may be obtained.

But some guidance does exist. And pharmaceutical and biotechnology patent owners should familiarize themselves with the factors and considerations to help better position themselves to obtain permanent injunctive relief when their patents are infringed.

### What Is the Traditional Four-Factor Test?

Under the traditional four-factor test, a patent owner seeking permanent injunctive relief is required to show: (1) that the patent owner will suffer irreparable injury; (2) that remedies available at law, such as an award of monetary damages, are inadequate to compensate for the injury; (3) that equitable remedies, including perma-

nent injunctive relief, are warranted in light of the balance of hardships between the patent owner and the infringer; and (4) that the public interest would not be disserved by the granting of a permanent injunction.

### Has the Traditional Four-Factor Test Been Applied Before in Patent Cases?

Yes. Although many had come to view permanent injunctions as a matter of course once a valid patent was found to be infringed, courts have always had discretion to either grant or deny injunctive relief in patent cases based on that exercise of discretion.<sup>2</sup> Furthermore, courts, including the United States Court of Appeals for the Federal Circuit,<sup>3</sup> have applied the four-factor test in cases involving patents.<sup>4</sup> Those findings, in turn, provide some guidance to patent owners who are or may be attempting to show that they are entitled to injunctive relief under the traditional four-factor test.

<sup>1</sup>The pharmaceutical industry involves the innovation of new chemical entities and incremental innovation thereof for the development of small molecule drug products, whereas the biotechnology industry generally focuses on innovation of macromolecules for therapeutic use. See Fed. Trade Comm’n, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* 3, 4, 15-16 (Oct. 2003) [hereinafter “FTC Report”]. The importance of permanent injunctions to infringed pharmaceutical or biotechnology patent owners stems, in large part, from the fact that only a handful of patents usually cover a commercial pharmaceutical or biotechnology product, unlike products of other industries. *Id.* at 14, 16-17; see also John W. Walsh & Ashish Arora, *Patents in the Knowledge Base Economy: Effects of Research Tool Patents and Licensing on Biomedical Innovation*, 5 Nat’l Acad. Sci. 285, 322 (2003) (finding that the number of relevant patents covering a research tool technology is often twelve or less). <sup>2</sup>35 U.S.C. § 283 (2005). “The several courts having jurisdiction of cases under this title [35 U.S.C. § 1 et seq.] may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable.” *Id.* “The Federal Circuit is the federal appellate court for patent cases, among other specialized cases.” See e.g., *Bell & Howell Document Mgmt. Prod. Co. v. Altek Sys.*, 132 F.3d 701 (Fed. Cir. 1997); *Bio-Tech. Gen. Corp. v. Genentech, Inc.*, 80 F.3d 1553 (Fed. Cir. 1996); *Hybritech Inc. v. Abbott Labs.*, 849 F.2d 1446 (Fed. Cir. 1988); *eSpeed, Inc. v. BrokerTec USA, L.L.C.*, 342 F. Supp. 2d 244 (D. Del. 2004); *Glaxo Group, Ltd. v. Apotex, Inc.*, No. 02-1492 (Fed. Cir. Apr. 22, 2003) (not selected for publication), available at [www.jurisnotes.com/Cases/glaxogroup.htm](http://www.jurisnotes.com/Cases/glaxogroup.htm) (last accessed, May 29, 2006); *Arthrex, Inc. v. dj Orthopedics LLC*, No. 02-67, 2002 U.S. Dist. LEXIS 7634 (D. Del. Apr. 20, 2003); *Am. Cyanamid Co. v. U.S. Surgical Corp.*, 833 F. Supp. 92 (D. Conn. 1992), *appeal dismissed without op.*, 9 F.3d 977 (Fed. Cir. 1993).

## How Will Courts Analyze the Four-Factors of the Traditional Test:

### Are All Factors Created Equal?

Historically, the first factor of the four-factor test – whether the patent owner will suffer irreparable injury – is often the most important consideration. If patent owners cannot establish that they will suffer irreparable harm in the absence of injunctive relief, then courts will likely find it unnecessary to give much consideration or weight to the other three factors.<sup>5</sup> Indeed, as Chief Justice Roberts implied in his concurring opinion in *eBay*, the other factors are often engulfed by the irreparable-harm factor. Therefore, pharmaceutical and biotechnology patent owners should devote considerable thought to, and truly focus on, evidence of irreparable harm that can be established if their patents are infringed.

### Factor One: How Can Patent Owners Establish Irreparable Harm?

Courts will consider a number of criteria when deciding whether patent owners can demonstrate that they will suffer irreparable harm.<sup>6</sup> Because this portion of the test is so important, patent owners should carefully evaluate each of these items and assert them, if applicable.

### 1. Whether the field of technology covered by the infringed patent is new.

Although biotechnology is a relatively young field compared to pharmaceuticals, both industries are closely related, and both innovate in new areas of technology that are encompassed by their main fields of technology – namely, biology and chemistry, respectively. When courts consider the age of a patented technology, they consider whether it is mature or emerging; however, this consideration is not done in a vacuum. For example, courts have considered different segments of a market in deciding whether the field is new or not – and have found that new segments exist even in established fields. Accordingly, patent owners should show, if possible, that the field of technology is new or, even if the field is mature, that the area or segment covered by the patent is new.

### 2. Whether the field of technology has a substantial amount of competition.

Since 1965, competition in the pharmaceutical industry has been increasing, mainly because the period of market exclusivity has been shrinking. The Hatch-Waxman Act, in particular, has contributed to this increase, allowing generic competitors to capture almost half of the industry's market, representing a 150% market share increase in less than twenty-five years. The biotechnology industry is similarly competitive. Competition especially increases for a biotechnology company

once it successfully introduces a product, as “much bigger and better funded competitors enter the market.”<sup>7</sup>

Pharmaceutical or biotechnology patent owners therefore should attempt to show that given the intensively competitive nature of the field, they will be assaulted with copycat infringers if a permanent injunction is denied. One way to do this is by informing the court about the competitive landscape, including information not only about direct competitors, but also about related competitors who may be encouraged to copy the infringed product or enter and compete in its market in the absence of a permanent injunction.

### 3. Whether the infringer has a “very large” presence in this technology field.

Courts have found that when the patent owner is a large company and sales of the patented product produce a relatively small percentage of overall revenues – unlike an infringer whose sales of the product may comprise a much greater percentage of its overall revenues – then the patent owner may not suffer irreparable harm to its market share. However, courts have also recognized that small parties have no special right to infringe patents simply because they are small. In any event, courts are not permitted to rely exclusively on the size of the parties in determining the equities between them.

<sup>5</sup>U.S. Int'l Trade Comm'n, USITC Pub. 2764 (Mar. 1994), 1994 ITC LEXIS 726, \*13 (citing Roper Corp. v. Litton Sys., Inc., 757 F.2d 1266, 1271 (Fed. Cir. 1985)).

<sup>6</sup>In what appears to be one of the first post-*eBay* decisions where a court has denied permanent injunctive relief after a valid patent was found to have been infringed, the United States District Court for the Eastern District of Texas rejected the patent owner's claim that there was a rebuttable presumption of irreparable harm to the patent owner. *z4 Techs., Inc. v. Microsoft*, \_\_\_ F. Supp. 2d \_\_\_, No. 6:06-CV-142 (E.D. Tex. June 14, 2006). Analyzing the traditional four-factor test, the district court held that the patent owner, *z4*, which did not create any products, had not shown that it would suffer lost profits, the loss of brand name recognition, or the loss of market share – thus it could be compensated for the harm it suffered, and it had not demonstrated irreparable harm. The district court also analyzed the other factors and found the balance of the hardships and consideration of the public interest weighed in favor of the infringer.

<sup>7</sup>FTC Report, *supra*, at 17.

Because pharmaceutical companies are often challenged by smaller rivals, while biotechnology entities are comparatively small, this consideration must be evaluated closely. Although a large pharmaceutical company may not be able to show that the infringement will affect its overall business or market share, it may nonetheless show that the infringement will have a significant effect on a particular line of business. Meanwhile, a smaller, less diversified biotechnology company may show that it will suffer irreparably by losing its market lead to an infringer. For example, a biotechnology firm participating in a single market may be able to show that it will become insolvent if unable to stop the infringing activity. To substantiate this claim, a biotechnology patent owner may be able to demonstrate, among other things, that an infringing rival previously had little or no interest or presence, but has had an escalating level of interest or presence since the patented product found a market and now presents a lucrative opportunity. Thus, to the extent that infringing rivals may be larger and have more resources than the biotechnology company, the biotechnology company can assert that fact to substantiate its claim that the infringing activity will likely harm it irreparably through loss of market share or solvency.

**4. Whether the technology in this field changes rapidly; whether the patented product has a short life cycle; and whether the status of**



**the market for the patented product has changed or may change rapidly, so that the infringed patent may have no value when the litigation has finished.**

In deciding whether irreparable harm may result, courts have considered the speed with which technology in a given field changes, the life cycle of the product at issue, and the status of the market. For example, where the market for a patented product is in decline, courts may consider whether the passage of time during litigation may inflict irreparable harm to the patent owner because the patent owner was not allowed to exclude the infringing competitor during that period, even if non-infringing competitors were also taking away its market share. Along the same line, pharmaceutical and biotechnology patent owners should consider the length of

time spent to obtain regulatory approval of their patented product because the approval process also may have shortened the term of their patent covering the product. Delays encountered in the regulatory approval process, in addition to delays resulting from litigation, can be significant in supporting the finding that the market value of patented inventions has been shortened or eliminated. Accordingly, patent owners should assert, where applicable, that delays encountered have shortened the life of patent protection, thereby increasing the showing of irreparable harm.

**5. Whether there is “a lot” of research being performed in this field.**

Courts consider the amount of research performed in a field when assessing irreparable harm. In the pharmaceutical industry, companies



often innovate in the same therapeutic areas and may compete in the same therapeutic classes of drugs. Meanwhile, biotechnology entities often focus on similar areas of technology in which to innovate.<sup>8</sup> As a result, pharmaceutical or biotechnology patent owners should marshal and offer proofs with regard to both innovators that are direct competitors and innovators in related fields – because the patent owners’ markets, affected by infringing products, also may be affected by non-infringing products from related innovators. In this situation, patent owners will be more likely to show irreparable harm if they cannot otherwise salvage a declining market position from infringers.

**6. Whether the infringed patent may assist the patent owner in establishing market position and creating business relationships in the market.**

For biotechnology entities, patents are often their primary asset, which allows them to form relationships with investors and collaborators and, thus, to be able to enter markets with products that often have no rivals. Biotechnology is one of the most research-and-development-intensive and capital-focused industries, with most research and investment coming from private investors. Biotechnology patent owners should therefore consider whether they will lose investors and investment dollars, or their ability to attract investors and funding, without obtaining a permanent injunction. Patents are also important assets for pharmaceutical companies, often impacting the companies’ ability to form relationships or to create investor interest. Thus, patent owners who can show a loss of investors, a loss of investors’ dollars, or severed negotia-

tions with investors for the infringed patented inventions, along with those of other patents that had interest from investors, will be in a much better position to show irreparable harm. Additionally, patent owners should show any harm to the long-term value relationships that may have previously been developed, but are now injured or severed as a result of the infringement.

**7. Whether the injury to the patent owner is predictable or not.**

The injury to pharmaceutical or biotechnology patent owners is often predictable because of the nature of the innovations and of their industries – and pharmaceutical and biotechnology patent owners should focus great attention on this point. The costly nature of pharmaceutical and biotechnology innovations substantially supports the irreparable harm that patent owners will suffer if not permitted to exclusively attempt to recoup those costs through lawfully excluding others. Research and development spending by the biotechnology industry is more than double the average of the pharmaceutical industry, and the research and development spending of the pharmaceutical industry is many times more intensive than other industries.<sup>9</sup> Costs also include the high-risk nature and the long development time of the products in these industries. For example, only about one in 5,000 biopharmaceutical products achieves FDA approval, and only one-third of these approved biopharmaceuticals cover the

<sup>8</sup>Examples include therapeutics and diagnostics, high-throughput screening tools, micro-array technologies, antisense and RNA interference technologies, bioinformatics, genomics, and proteomics.

<sup>9</sup>FTC Report, *supra* note 1, at 16. Also, for example, pharmaceutical research and development costs average hundreds of millions of dollars per product while generics can be developed at much lower costs, because generic manufacturers can obtain FDA approval to market the generics without having to conduct expensive clinical trials.

development costs expended (let alone turn a significant profit), and most take at least a decade to reach the market. Similarly, the drug development plan of a pharmaceutical drug can take up to fifteen years, beginning with the identification of a candidate from hundreds of thousands of potentials.

The ease of reverse engineering patented inventions also supports that patent owners will be irreparably injured without permanent injunctive relief. Infringers who easily can design around patented inventions should not be given a free ride at the expense of the patent owners and their lawfully gained right to exclude others from their patented invention. Specifically, pharmaceutical inventions are more susceptible to reverse engineering than biotechnology products because pharmaceutical innovations are more discrete and incremental. Nonetheless, pharmaceutical and biotechnology patent owners who are able to make the connection between development costs and other irreparable harm factors will be much better positioned to obtain injunctive relief.

#### **8. Whether other potential infringers may be encouraged to infringe in the absence of an injunction.**

Because most drugs and biological therapeutics are high-commodity products, an infringer has a high likelihood of substantial returns on a relatively small investment, even if not the first market entrant. Thus, pharmaceutical

and biotechnology patent owners should track the activities of those who infringe by offering to sell, by selling or importing, or by contributing to infringement. For pharmaceutical drugs, especially, in the realm of gray goods (the preferred term in the United States) and parallel imports (the preferred term in Europe), patent owners' products may be redirected without consent, potentially giving rise to these other forms of infringement.<sup>10</sup> Pharmaceutical or biotechnology patent owners should use the information gathered to monitor unauthorized distribution of, and counterfeit activity concerning, their patented product both to show the scope of the potential infringing activity and to highlight that such infringement may be exacerbated in the absence of a permanent injunction.

#### **9. Whether the price of the patented product and profits of the patent owner may be negatively affected by a loss in market share.**

A loss of market share alone is generally insufficient to support a finding of irreparable harm, and speculative loss of sales or of market share also is insufficient to support such a finding. But patent owners who may go out of business because of the entry by infringers into the market likely will be deemed to have demonstrated irreparable injury. Further, patent owners who face a permanent loss of users of their patented products and reduced patent value may demonstrate harm that is not adequately redressed through an award of monetary damages.

These considerations likely will not be very helpful for emerging biotechnology



<sup>10</sup>Margaret M. Buck, *Understanding How the Principle of Exhaustion Affects Your IP* The Metropolitan Corporate Counsel, Feb. 2005.



entities, which typically are small, with no marketable product or operating income. However, for pharmaceutical or biotechnology patent owners with a marketed product, they should – if they can – show more than just lost sales and market share (which are generally monetarily compensable) to establish irreparable harm.

#### **10. Whether the patent owner has lost sales of related non-patented products as a result of sales of infringing products.**

Pharmaceutical or biotechnology patent owners who can establish lost sales of related non-patented products resulting from the sales of infringing products will advance their claims of irreparable harm. Similarly, patent owners should consider demonstrating, if possible, a loss of goodwill –

which may be a significant factor in demonstrating irreparable harm.

#### **11. Whether the patent owner licensed the infringed patent.**

It has long been the case that licensing activity of patent owners has been held to affect negatively the owners' right to exclude by, among other things, demonstrating that their injuries suffered can be compensated monetarily. Patent owners who license some of their patents may be precluded from exercising exclusivity over non-licensed – but infringed – patents.

But in *eBay*, the Supreme Court expressly found that licensing activity of patent owners and their lack of using their patents cannot be used to “categorically den[y]” them the chance to satisfy the four-factor test for permanent injunctive relief. Put

another way, patent owners do not have to use their patents to have the right to obtain injunctions. Such patent owners, however, may face difficulties in presenting sufficient facts to demonstrate that they are entitled to injunctive relief. Irreparable harm may be more difficult to demonstrate if, for example, the infringing activity does not affect the patent owners' ability to market, sell, or license their patented technology to other entities in the market, or if the patent owners can be compensated monetarily for the damages caused by the infringement.

For smaller pharmaceutical companies and biotechnology entities, as well as their technology transfer spin-offs, the Supreme Court's pronouncement bodes well. Such patent owners often do not have the means to commercialize their patented inventions, but instead license their patents to see the products reach market. In the aftermath of *eBay*, courts should no longer consider this licensing activity antithetical to irreparable harm, and pharmaceutical and biotechnology patent owners should be prepared to remind the court that licensing is not dispositive.

#### **12. Whether the patent owner delayed in seeking the injunction.**

A showing of delay does not preclude, as a matter of law, a determination of irreparable harm. But it is one factor the court must consider. Thus, it is advantageous to not delay unduly in seeking permanent injunctive relief. If there is a delay in seeking such relief,

patent owners should be prepared to demonstrate that the delay was for good cause, such as first seeking relief from another infringer or securing a granted patent.

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### **Factor Two: Monetary Damages Are Inadequate.**

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This factor is really the flip-side of the first factor. To the extent that patent owners can demonstrate irreparable harm absent the grant of injunctive relief, they almost certainly have demonstrated that no monetary award will sufficiently compensate them or make them whole. Conversely, if patent owners may be adequately compensated by monetary damages, then this weighs against the grant of permanent injunctive relief.

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### **Factor Three: Balancing the Equities Between the Patent Owner and the Infringer.**

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This factor requires examination of the relative hardships between the patent owners, on the one hand, and the infringers, on the other. Patent owners should marshal evidence demonstrating and highlighting the severity of the burdens that will be imposed if the permanent injunctive relief is not granted, and showing that the grant of permanent injunctive relief will not impose undue burdens on infringers. For example, an infringer who has not yet begun manufacturing a product will face little hardship from being enjoined against bringing the infringing

product to market. Conversely, a patent owner who faces reclassification from a preferred brand to a non-preferred brand may be able to show significant hardship.

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### **Factor Four: Will the Public Interest Be Disserved by Granting an Injunction?**

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Courts have temporarily stayed or denied permanent injunctions where they have found an important public interest would be disserved by granting or enforcing the injunction. But it is only under exceptional circumstances that the interest of the public for pharmaceutical or biotechnology patented inventions outweighs the other three factors of the test. And on those rare occasions where the public-health-and-safety interest trumps the other

factors, the result is usually only a short delay of imposition of the injunction. Often such circumstances involve minimizing or precluding any disruptive effect or negative impact on medical users, such as surgeons and institutions, of the infringing product.

The question then arises: Will courts continue to find that the public's interest in health and safety should give way to pharmaceutical or biotechnology patent owner's right of exclusivity to its invention after *eBay*? In light of the tremendous public discussion and focus on the need for more affordable medicines and therapies, as well as the purported promise of generics to achieve this aim,<sup>11</sup> some have speculated that *eBay* – and in particular the Supreme Court's finding that all four factors must be evaluated in deciding whether to grant a permanent injunc-



<sup>11</sup>See e.g., Richard G. Stefanacci, *Generic Drugs...Just What the MMA Ordered*, Pharmacy & Therapeutic, Aug. 2005, at 462-464, available at <http://www.ptcommunity.com/ptjournal/fulltext/30/8/PTJ3008462.pdf> (last visited June 26, 2006) (discussing the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) that created the new drug benefit of Medicare - "Part D" - and Title XI (Access to Affordable Pharmaceuticals) of the MMA, which modified the Hatch-Waxman Act provisions of the Food, Drug and Cosmetic Act, and the likely increase in the use of generic agents over branded products); see also, e.g., *Bill Would Allow Generic Versions of Patented Drugs for Export*, 72 Pat. Trademark & Copyright J. (BNA), No. 1772, at 111 (June 6, 2006) (reporting on legislation (S. 3175) introduced May 25, 2006 by Senator Patrick Leahy for compulsory licensing of exported generics of patented pharmaceutical products to needy nations without consent of the patent owner, as well as other compulsory licensing legislation for health-related patented products).

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tion – appears to favor a shift towards denying permanent injunctive relief in order to enable patented products to become more available at a lower cost. The answer to this question will turn, in part, on whether or not *eBay* extends to enforcement of patents under the Hatch-Waxman Act.<sup>12</sup> The Hatch-Waxman Act specifically precludes, unless certain conditions are met, the Food and Drug Administration from granting marketing approval to a generic competitor before the expiration date of the patent.<sup>13</sup> It may well be that district courts will have no discretion to deny the Hatch-Waxman remedy following a successful Paragraph 4 litigation, which acts like a permanent injunction in favor of the pharmaceutical patent owner.<sup>14</sup> However, it is also likely that the generic companies will use *eBay* to obtain a second opportunity to challenge the patent owners' ability to obtain injunctions on "public interest" grounds.

On the other hand, there is no established pathway for biogenerics to enter the marketplace based upon bio-equivalence as provided for in the Hatch-Waxman Act. And with biogenerics being viewed as "an extraordinary opportunity" and "the future" by the generics industry,<sup>15</sup> generic companies may well determine they are willing to assume the risk of

infringing patents directed to biogenerics and hedging that "public interest in affordable medicines" outweighs the other factors that must be shown to obtain permanent injunctive relief. In addition, the costs of infringing may not be so prohibitive to generic companies because they likely would be able to place lucrative biogenerics on the market more quickly than if permanently enjoined.

Most likely, however, courts will still find it is the rare circumstance when the public's interest in health and safety outweighs a patent owners' right to stop infringers. In fact, Chief Justice Roberts' concurring opinion in *eBay* cautioned courts to be guided by historical practice when exercising their equitable discretion in applying the traditional four-factor test. There is, however, one notable exception where the "public interest" has been found to be significant enough to deny injunctive relief – where an infringing healthcare product is removed from the market and no alternative product exists. That situation does not happen routinely, in any case, because it is likely the patented biologic will be on the market thereby providing an alternative. In the unlikely event that a patented biologic is not on the market, courts should consider whether the public's interest is best served by

denying the permanent injunction or by honoring the patent owners' Constitutional right to exclude.

## Conclusion

Pharmaceutical and biotechnology patent owners who are considering patent infringement litigation need to focus early and keenly on the factors that must be demonstrated to obtain permanent injunctive relief against the infringing product. In all of their submissions and arguments to the court, patent owners should strive to address all four factors of the traditional test – providing as much substantiation and corroboration as possible. Patent owners should focus, in particular, on demonstrating harm, which will greatly increase the chance that permanent injunctive relief will be awarded.

<sup>12</sup>21 U.S.C. § 355 (2005); 35 U.S.C. § 271(e) (2005). The Hatch-Waxman Act established a generic drug approval procedure whereby a generic applicant can obtain FDA approval to market a generic drug by providing data showing that the generic drug is bioequivalent to a patented drug that previously has been determined to be safe and effective.

<sup>13</sup>21 U.S.C. § 355(j)(2)(A)(iv), (j)(5)(A); 21 U.S.C. § 271(e)(4)(A).

<sup>14</sup>Brief of Amicus Curiae Pharmaceutical Research and Manufacturing of America in Support of Respondent, *eBay v. MercExchange LLC*, 547 U.S. \_\_\_, 126 S. Ct. 1837 (2006) (No. 05-130), 2006 WL 622122, at \*20.

<sup>15</sup>Aaron Lorenzo, *Follow-On Biologics Spur Much Dialogue At Generic Policy Event*, *BioWorld Today*, Sept. 26, 2005, at 1, 4. It is estimated that biogenerics represent ten to fifteen percent of the world's pharmaceutical market, and that eighteen biogenerics with about \$10-\$15 billion in annual sales have gone off patent or will do so over the next several years.

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