EDITOR’S MESSAGE

The inaugural edition of the Maryland IP Law Electronic Newsletter this summer was a success. We received many subscription inquiries for our free service, and welcome new requests anytime. To be placed on our electronic circulation list, please send the appropriate e-mail address information to Professor Lawrence Sung at lsung@law.umaryland.edu.

FEATURE ARTICLE

On July 31, 2002, the U.S. Senate passed S. 812, entitled “A bill to amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals.” Also known as the Schumer-McCain Generic Drug Bill, this legislation awaits action in the House of Representatives and by the President. As amended, the bill, inter alia: (1) eliminates the possibility of “stacked” 30-month stays of approval of generic drug applications by the U.S. Food & Drug Administration (FDA); (2) requires the generic drug company that first challenges a drug patent to forfeit the 180-day market exclusivity it receives against other generic drugs for being first, if it settles the infringement suit with the brand name drug company or otherwise delays in marketing the generic drug; and (3) increases the accuracy of the patent listings in the FDA Orange Book by requiring brand name drug companies to certify the correctness of listings, and by allowing generic drug companies to bring suits solely to challenge the appropriateness of Orange Book listings. Our feature article is adapted from a paper presented during Spring Semester 2002 in the course, Biotechnology & Law Seminar. In that paper, the author provided a critical analysis of the original version of the Schumer-McCain bill, which contained several provisions since stricken from the legislation. The author’s introduction to the statutory scheme and her excerpted commentary follows.

FAIR GENERIC DRUG COMPETITION IN THE U.S. PHARMACEUTICAL MARKET

by Allison K. Young, J.D. – Class of ‘02
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The cost of prescription drugs in the United States is rising dramatically, by 14% to 18% each year, according to some private sector estimates. In 2001, U.S. retail sales of generic prescription drugs totaled $11.1 billion, in contrast to brand name prescription drug sales of $121 billion. In that same year, generic drugs were dispensed in 45% of all prescriptions filled, but accounted for only about 8.4% of all drug retail sales. The consumer benefit of generic drugs lies with their cost, typically half of that of the brand name counterparts. Moreover, the entry of a generic drug into the market often results in the lowering of the brand name drug price.

In 1984, Congress passed the Hatch-Waxman Act attempting to strike a careful balance in the pharmaceutical industry. The purpose of the law was to encourage the expedition of generic drug products into the marketplace in an effort to lower the sky-high prices of prescription medication. But Congress also wanted to maintain the integrity and strength of the patent system and continue to provide incentives to brand name drug manufacturers to innovate and discover new medications.

The Hatch-Waxman Act established the Abbreviated New Drug Application (ANDA) as a way for a generic manufacturer to avoid repeating the costly studies associated with approval of new drugs. The ANDA applicant merely has to show that the generic drug is “bioequivalent” to the approved pioneer drug, and thus may obtain FDA approval without having to replicate the safety and efficacy studies already done with regard to the brand name drug.
Virtually all brand name drugs are patented. To facilitate the earliest entry of a
generic drug into the market, the Hatch-Waxman Act exempted from patent infringement
liability any activity by a generic drug company performed before the expiration of
the drug patent, so long as such activity is reasonably related to the drug approval process.
Accordingly, a generic drug company could secure timely FDA approval to allow retail
sales of the generic drug to begin the day the drug patent expired.

As part of the balanced statutory scheme, the Hatch-Waxman Act provided drug
patent holders with specific recourses. An ANDA filer is required to make certain
certifications regarding the generic drug with respect to any patent listed in the FDA’s
Orange Book that pertains to the brand name drug. One such certification, known as a
Paragraph IV certification, may allege that the claims of a particular drug patent are
invalid, unenforceable or will not be infringed by the generic drug. Filing a paragraph IV
certification in an ANDA alone may be the basis for a patent infringement suit by the
drug patent holder. If suit is filed against the ANDA filer within 45 days of receiving
notice of the Paragraph IV certification, the FDA will impose an automatic 30-month stay
of FDA grant of the ANDA unless the patent expires or a final adjudication occurs first.

Thus, the primacy of an Orange Book patent listing is evident, dictating the trigger of
the 30-month FDA approval stay as well as the 180-day market exclusivity to which the
first paragraph IV ANDA filer is entitled. However, the FDA lists patents in the Orange
Book upon request by the brand name drug company, without independent review. One
aspect of the Schumer-McCain bill is to address the inequities that can arise given the
absence of any procedure to ensure the accuracy of Orange Book patent listings. Indeed,
the U.S. Court of Appeals for the Federal Circuit, in Mylan Pharm., Inc. v. Thompson,
Andrx Pharm., Inc. v. Biovail Corp., and 3M v. Barr Labs., Inc., held that no private
cause of action existed for delisting a patent from the FDA Orange Book. A drug patent
holder could improperly list a patent in the Orange Book, but still draw the generic drug
company into litigation while stalling the FDA approval of the ANDA for 30 months.
Furthermore, by listing patents in the Orange Book successively, the drug patent owner
can prolong market exclusivity by “stacking” 30-month stays, triggered each time a new
Paragraph IV certification is filed, even well after the initial submission of the ANDA.

U.S. Senators Charles Schumer (D-N.Y.) and John McCain (R-Ariz.) have attempted
in their sponsored legislation to close the loopholes that exist in the Hatch-Waxman Act.
However well intentioned, the bill [as originally drafted] is silent on many problems, has
internal inconsistencies, and may create more ambiguities than it resolves. The bill
[approved by the Senate still] fails to address the fundamental underlying problem of
foisting policing responsibilities upon the FDA that lie outside of the agency’s field of
expertise. To promote fair generic drug competition in the U.S. pharmaceutical industry,
legislators need to divorce considerations of intellectual property protection under the
patent laws from those of drug safety and efficacy, and place the responsibility for each
in the hands of the respective federal agencies that are best equipped to deal with them.

Perhaps elimination of the stay and market exclusivity provisions of the Hatch-
Waxman Act, coupled with more vigorous enforcement of existing laws, is a better
resolution. Drug patent holders can sue for infringement and obtain injunctive relief as
appropriate. Generic drug companies can seek declarations that their products do not
infringe a drug patent to the extent they meet the requirements of the Federal Declaratory
Judgment Act. Orange Book patent listings can continue to serve as notice for purposes
of money damages in infringement litigation, but should be divested of their impact on
FDA approval and market exclusivity to eliminate any potential reward for manipulating
the listings or obtaining de facto patent extensions as a result of gaming the system or
engaging in anticompetitive behavior. Moreover, the FDA can avoid distraction with the
unintended consequences of its decisions on patent protection, and remain focused on its
primary mission of assuring consumers that new drug products are safe and effective for
their stated use.
ALUMNUS SPOTLIGHT

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by Krista L. Lynch – Class of ‘03

The biotechnology revolution has come to the fore with the promise of breakthrough advancements in medicine, agriculture, and nutrition. Exploiting these scientific breakthroughs to obtain commercial success requires sound intellectual property advice and guidance from experts in the industry, such as alumnus, Dr. Michelle Marks.

Dr. Marks received her B.A. in Biology and Art from Pitzer College in 1978. After earning a Ph.D in Cellular Biology from Tufts University in 1987, Dr. Marks was an Arthritis Foundation postdoctoral fellow at the National Institute of Health. The biotechnology patent boom of the 1990s, however, offered scientists promising career opportunities in law. Already an accomplished scientist and eager for a new challenge, Dr. Marks decided to attend the University of Maryland School of Law and embark on a whole new direction in her career.

During law school, Dr. Marks worked as a patent examiner at the U.S. Patent & Trademark Office, reviewing patent applications in biotechnology. The Food and Drug Law Institute named Dr. Marks a Vincent A. Kleinfeld Food and Drug Law Scholar in 1996. Graduating from law school with honors in 1996, Dr. Marks began her legal career as an associate with Foley & Lardner in its Washington, DC, offices. Dr. Marks later worked as a patent attorney for Human Genome Sciences, Inc., a biopharmaceutical company in Rockville, Maryland that develops genomic-based drugs.

Opting to return to law firm practice, Dr. Marks is now a patent attorney with the Life Science Practice Group of Shaw Pittman in its Washington, DC, offices. Drawing on her extensive experience in the biotechnology industry, she develops and implements competitive intelligence programs for biotechnology and pharmaceutical companies. Through competitive intelligence, a company can analyze information about its competitors, its markets and its customers and anticipate changes in the industry to make the right strategic decisions. Competitive intelligence ensures that companies make decisions with their eyes wide open. For example, Dr. Marks points out, “often it is not beneficial for a company to continue to invest R&D dollars in an area where their competitors have deeper pockets or already have a head start.”

Dr. Marks recommends that all companies, from small start-ups to large publicly held multinational corporations, implement competitive intelligence programs, and monitor the intellectual property landscape. Armed with a complete picture of the intellectual property landscape, a company can maximize its freedom to innovate and expand the commercial market for their technology. In the phenomenally fast growing business of biotechnology, Dr. Marks stresses that keeping up to date with the explosion of nucleic acid and amino acid sequence patents is critical to scientific as well as commercial success.
MedImmune is a leading vertically integrated biotechnology company focused on researching, developing and commercializing products to prevent or treat infectious disease, autoimmune disease and cancer. MedImmune actively markets three products, Synagis® (palivizumab), Ethylol® (amifostine) and CytoGam® (cytomegalovirus immune globulin intravenous (human)), and has 11 products in clinical testing. MedImmune employs approximately 1,600 people, is headquartered in Gaithersburg, Maryland, and has additional operations in Frederick, Maryland, as well as Pennsylvania, California, the United Kingdom and the Netherlands.

MedImmune’s success is based on more than outstanding research and development. The company also has an exceptional marketing, sales, and customer support organization. This team has developed and implemented a broad range of programs and services that add significant value to MedImmune products. MedImmune is committed to providing customers and patients with the programs they need to use the company’s products appropriately and cost-effectively.

With all the great new products MedImmune is working on bringing to market, the company recognized the importance of having in-house counsel focused on intellectual property. Jonathan Klein-Evans joined MedImmune in February 2002 as Director, Intellectual Property. After several years of graduate research training in molecular biology at Stanford, Jonathan obtained a law degree at Georgetown in the evening division. During law school, Jonathan pursued a career in patent law while working at Pennie & Edmonds LLP, where he continued after graduation as an associate for another year and a half. Then, Jonathan worked at Human Genome Sciences as an in-house patent attorney for two years, before joining MedImmune. Jonathan comments that evening students are a special group who face special challenges, but don’t give up – it’s worth it. “For those students pursuing a career in a technical field of law, the key challenge, and the greatest reward, is to become a good lawyer who also knows the technology, and not just another technical person with a law degree.”

The great thing about MedImmune as an employer is that every employee’s input is valued in all aspects of the organization’s decision-making. Three employees, Mike Wasicko, Tricia Ryti, and Maria Apostolaros, are all third year evening students at the University of Maryland School of Law. Mike entered law school initially with the intent to practice IP/Patent Law. However, after taking so many great law classes, he is now interested in finding a career that combines health law and criminal law. At MedImmune, law school helps Mike deal with FDA regulations, the Code of Federal Regulations and other aspects of regulatory law. Tricia was able to put her first semester at law school to great use by joining MedImmune as a member of the Legal Department focused on Contract Law and some Intellectual Property law. Maria is in Medical Affairs Oncology. Like Mike, Maria also deals with FDA regulations, the Code of Federal Regulations and other aspects of regulatory law. With Maria the story is different, in that after taking one great course in Patent Law with Professor Sung, she is now interested in pursuing projects that will provide more experience in the intellectual property area.
NEWS & EVENTS

BIOINFORMATICS CONFERENCE

On October 21, 2002, the law school will host a conference entitled, “At the Crossroads – Public/Private Priorities Concerning Access to Genetic Information,” at the USM Shady Grove campus in Rockville, MD. The program will include presentations by leading research scientists, legal scholars, bioethicists, and biotechnology industry members. The conference will also feature a luncheon address by Dr. Francis Collins, Director of the National Human Genome Research Institute. Further information and registration materials can be found at http://www.law.umaryland.edu/conferences.asp.

RECENT IP CASES

Mattel, Inc. v. MCA Records, Inc.
296 F.3d 894 (9th Cir. 2002).

“The parties are advised to chill.”

On July 24, 2002, the 9th Circuit affirmed the district court’s summary judgment that MCA neither infringed Mattel’s Barbie trademark under the Lanham Act (15 U.S.C. § 1125 et seq.), nor diluted the Barbie trademark in violation of the Federal Trademark Dilution Act. MCA distributed the hit 1997 song, Barbie Girl, performed by Danish pop group, Aqua. Although the 9th Circuit noted that “MCA used Barbie’s name to sell copies of the song,” the use was noncommercial because the song was social commentary on Barbie’s image and the cultural values she represents, and thus, fell under a constitutionally protected exception to dilution liability. In addition, the parties’ litigation conduct garnered the court’s admonishment quoted above.


“[R]eference in the specification to a deposit in a public depository, which makes its contents accessible to the public when it is not otherwise available in written form, constitutes an adequate description of the deposited material sufficient to comply with the written description requirement of § 112, ¶ 1.”

For a more detailed summary of the Enzo opinion (as well as the opinions in all precedential patent cases decided by the Federal Circuit), please refer to the following website at http://www.law.umaryland.edu/fac_fsmung_decision.asp.

NEW IP PROGRAM MATERIALS

The law school returned this summer to its former location at 500 West Baltimore Street, Baltimore, MD. The IP Program will benefit greatly from the new technology available in this state-of-the-art facility. In addition, the IP Program has launched a dedicated website, which contains the respective listings of the program course offerings, extracurricular program opportunities, the IP faculty and our distinguished Board of Advisors, and informative IP career links. For additional information, please visit the website at http://www.law.umaryland.edu/iplaw/.

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