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A SHIFT IN THE HATCH-WAXMAN BALANCE: FDA'S PROPOSED RULE

The Hatch-Waxman Act, which created today's generic drug system, was premised on balancing two divergent interests — facilitating the approval of generic drugs, and providing adequate incentives for the development of new pioneer drugs. While FDA's related rulemaking has helped preserve this balance in certain respects, in the 18 years since the passage of the Hatch-Waxman Act there has been continuous and rancorous debate among generic and innovator drug companies, FDA, and other interested parties (e.g., Congress, FTC, government/private payors, AARP, etc.) as to which industry is benefiting more from the law and the legality of specific regulatory strategies. The result has been a series of lawsuits, many of which FDA has lost, concerning interpretations of the Hatch-Waxman Act, as well as a plethora of legislative proposals, none of which have, to date, gained significant momentum.

On October 24, 2002, FDA issued a proposed rule that would, in several respects, tip the Hatch-Waxman balance in favor of the generic drug industry. As discussed in more detail below, the proposed rule would (1) change the types of

patents that can and cannot be listed by NDA applicants/patent holders; (2) change the patent certification statement that must be submitted as part of an NDA or NDA amendment/supplement; and (3) eliminate multiple 30-month stays of the approval date for ANDAs/505(b)(2) applications.

FDA issued the proposed rule for several reasons. As explained in the preamble, the Agency sought to resolve inconsistent court decisions,

and to respond to FTC's May 16, 2001 Citizen Petition and July 2002 report on generic drug entry prior to patent expirations. Issuance of the proposed rule also advanced important political goals: it addressed issues raised in current legislative proposals (e.g., McCain/Schumer bill) and was released just prior to the November elections (to demonstrate FDA progress in controlling drug costs).

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MANAGING PRE- AND POST-ACQUISITION PHARMACEUTICAL PATENT DUE DILIGENCE

Pharmaceutical product acquisitions are not daily occurrences. Because pharmaceutical product approvals are precious, most companies are reluctant to part with approved products or even with late-stage development compounds. However, such acquisitions seem to be increasing with, *inter alia*, the desire of pharmaceutical companies to replace revenue lost as a result of blockbuster drugs going off patent and regulatory requirements to shed products caused by corporate mergers or acquisitions.

When an acquisition of an approved or late-stage pharmaceutical product does occur,

the acquirer should ensure that the intellectual assets protecting the acquired product are effectively analyzed.

Preacquisition Due Diligence

For the acquisition of a pharmaceutical product to be profitable, the acquirer must obtain the product at a reasonable price and establish, in the face of competitive products, a revenue stream that is achievable and sustainable. To meet this objective, the acquirer will need to assess the amount of intellectual asset due diligence that should be performed. The question is: How far should an acquirer go in intellectual asset due

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diligence in light of the blistering pace and auction-like atmosphere that pharmaceutical product acquisitions can assume?

The revenue for a branded pharmaceutical product will dramatically erode once there is generic competition. Upon entry of the generic, sales of the branded pharmaceutical product typically will drop by 50% or more. The introduction of chemically similar “me-too” products, i.e., branded products that have the same mechanism of action as “first-in-class” products and are indicated for the same medical conditions, can also have a significant adverse effect on sales of the branded product. For this reason, intellectual asset due diligence focuses on the extent of patent protection for the branded pharmaceutical product, including patent protection for the drug substance, product formulation, methods of use and manufacture, intermediates and enantiomers; investigation of potentially blocking patents; confirmation of chain of title; and assessment of employment obligations and duties to assign inventions.

In some cases, examining only the key patents protecting a drug substance and its approved uses may satisfy the acquirer that patent protection for the acquired product likely is adequate to protect against competition from generics and chemically similar “me-too” products. In other situations, it may be advisable to

go further. For example, the acquirer may determine that generic or me-too competition for a competitor’s product has the potential to devastate sales of the acquired product. In such a case, it may be prudent to evaluate the patent protection for competing branded products already on the market or soon to be marketed.

The acquirer may also wish to analyze the strength of the patent positions for competitors’ products to determine the date of potential generic competition for such products. It may seem counterintuitive to review the patent positions of competitors’ products to assess their strength, but solid patent positions for all products in a particular market sector can be key to maintaining and growing sales of the acquired product.

Although analysis of the patent positions of competitors’ products may greatly increase the patent due-diligence costs for a product acquisition, entry of any competitor may significantly erode the sales and market share held by each company in the market sector. Review of a competitor’s patents can typically be done without the competitor’s knowledge because most intellectual asset documents (patents and patent file histories) are publicly available.

As an example, consider the following scenario. Company A is acquiring approved pharmaceutical product BLOCKBUSTER from Company B. Company A determines that BLOCKBUSTER competes in the relevant market sector with two other patent-protected products (Product 2 and Product 3), each having a patent term similar to BLOCKBUSTER’s. In reviewing the patent position and third-party patents relating to Product 2 and Product 3, Company A learns that the main patents covering Product 3 are subject to validity challenges based on a publication of one of the inventors of Product 3.

Should a generic competitor successfully challenge the validity of the patents covering Product 3, sales of BLOCKBUSTER, Product 2 and Product 3 could all be affected many years earlier than anticipated. Such competition likely will not only erode the market share for Product 3, but also steal market share from BLOCKBUSTER and Product 2. This will most certainly affect the value of BLOCKBUSTER. Armed with this information, Company A should be able to negotiate a better sale price for the BLOCKBUSTER product, anticipate loss of revenue, and accurately predict the useful life of the related intellectual assets. In addition, the information should aid the management of Company A in accurately predicting the sustainability of revenue streams and market share for BLOCKBUSTER. As a result of its due-diligence investigation, Company A will be better able to avoid a transaction that could negatively impact the bottom line of the company, decide whether to buy a particular product and then sell it prior to the generic’s entry, anticipate the need to replace a revenue stream, and, ultimately, understand the true value of the BLOCKBUSTER product in the market sector.

Post-Acquisition Due Diligence

Following closing of a pharmaceutical product acquisition and transfer of assets, the acquirer should take maximum advantage of intelligence related to the patent position gathered during the preacquisition due diligence. For example, it may have been uncovered that the acquired product can be delivered in a sustained release or once-a-day formulation; one or both of the enantiomers of the product have properties superior to the racemic mixture of the two enantiomers; the patent covering the product is eligible for extension under the Patent Term Restoration Act; certain third-party patents should be acquired or licensed to enhance the product patent portfolio; or certain of the acquired patents are not necessary to protect the product and can be sold or licensed. Any of this information could enhance the acquirer’s patent position. What is learned about a competitor’s patent position can also be extremely valuable in facilitating the

The acquirer should take advantage of intelligence gathered during preacquisition due diligence

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creation of new intellectual assets that give the acquirer a competitive advantage.

Such due-diligence activities could prevent an acquirer from losing patent protection earlier than anticipated and, due to the public nature of most intellectual activities, force its competitors to undertake similar activities to enhance their patent protection, thereby increasing the overall patent protection for products in the relevant market sector.

Conclusion

Preacquisition due-diligence activities can be used to determine the true value of a pharmaceutical product, and post-acquisition due-diligence activities can help sustain or extend a revenue stream and maintain healthy profit margins. Although the activities discussed above may be costly, they can be used successfully to increase the chances that your next pharmaceutical product acquisition occurs at a reasonable price and increases both net sales and net income.

For more information, contact Louis W. Beardell, Philadelphia, at 215.963.5067 or lbeardell@morganlewis.com; Manya S. Deehr, Philadelphia, at 215.963.5310 or mdeehr@morganlewis.com.

PATENT REEXAMINATION STANDARDS LIBERALIZED

Legislation enacted in November 2002 liberalized the standard for instituting patent reexamination, overruling prior case law, *In re Portola Packaging*, 110 F.3d 786 (Fed. Cir. 1997), that precluded the U.S. Patent and Trademark Office ("PTO") from considering, during reexamination, prior art references that had previously been cited during the original examination of the patent. The statute states that "the existence of a substantial new question of patentability is not precluded by the fact that a patent or printed publication was previously cited by or to the office or considered by the office." Thus, a prior art reference that was of record during prosecution of the original application may be the basis of a petition for reexamination so long as the reference raises a "substantial new issue of patentability." Although how the PTO and eventually the Federal Circuit will define "substantial

new question of patentability" remains unclear, the breadth of the statutory language could allow reexamination based on previously cited patents, excluding only those instances when a review is sought of an issue that is the same as one raised by the identical piece of prior art during the original examination of the patent.

It is unlikely that the reexamination amendments will impact patent owners seeking reexamination of their own patents. Because issued patents are presumed valid under 35 U.S.C. § 282, and courts apply a higher standard to invalidate patents over cited art, a patent owner has little impetus to request reexamination based on prior art already of record. Patent owners generally seek reexamination only for possibly relevant new prior art in order to strengthen their patents for future infringement litigation.

The new patent reexamination amendments, however, may offer substantial leeway to third-party requestors who seek reexamination of a competitor's patent based on prior art cited during the original examination of the patent. In the main, the most relevant prior art is already of record in the file wrapper, having been either cited by the examiner or provided by the patent applicant. Depending on how the standard is construed, a third-party requestor may be able to merely search the patent file and reframe an issue of validity based on previously cited art to create a "substantial new question of patentability."

Patent applicants involved in the life sciences area who seek to minimize after-issuance attacks on their patents through third-party reexamination may wish to revive the formerly required practice of explaining the relevance of the prior art that they submit to the PTO. Applicants largely abandoned that practice several years ago when the PTO rules were amended to permit applicants to submit prior art without explaining its relevance. Patent applicants now may elect to state the relevance of the prior art reference and thereby possibly foreclose reexamination based on that reference, since a would-be challenger would not be able to establish a "substantial new question of patentability."

Nonetheless, applicants must present their statements with care to avoid possible prosecution history estoppel.

The legislation is effective as of November 2, 2002 but is not retroactive. It will not affect examination of patents currently undergoing reexamination.

For more information, contact Lynn E. Eccleston, Washington, D.C., at 202.739.5474 or leccleston@morganlewis.com.

MEDICAL DEVICE USER FEE AND MODERNIZATION ACT

On October 26, 2002 important new legislation was enacted that significantly affects the regulation of medical devices and combination products. While the impetus for the legislation, the Medical Device User Fee and Modernization Act (MDUFMA), was the imposition of device user fees, the MDUFMA also covers establishment of a new office of combination products, third-party inspections, and premarket review of certain reprocessed devices.

User Fees. With almost unanimous industry support, Congress reached agreement to impose device user fees. An expansion of the definition of a "small business" entitled to fee reductions and waivers (i.e., businesses with no more than \$30 million in annual gross sales or receipts) led smaller companies that had originally opposed such fees to agree to them.

As with drug user fees, FDA appropriations will be linked to certain performance goals for prompt application review (set forth in letters from Secretary Thompson), although these goals will not apply until fiscal year 2005. User fees will apply to all device premarket applications, except humanitarian device exemption applications, 510(k)s reviewed by accredited third parties, PMA or 510(k) applications for devices indicated solely for pediatric use, and further manufacturing-use supplements. The fees will be assessed retroactively for all submissions filed on or after October 1, 2002, but will not be collected until Congress passes enabling appropriations.

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FDA's proposals with respect to the types of patents that can and cannot be listed in the Orange Book are significant. Not only would FDA prohibit the listing of packaging, metabolite, and intermediate patents (because FDA asserts that these patents do not claim approved drug products), but FDA would only permit patents to be listed for drug substances that are the "same as" approved/pending NDA drug substances. The latter proposal is significant not only in its potential effects — prohibiting, for example, the listing of patents for single-isomer versions of approved/pending racemic mixtures — but also because it is based on the merging of concepts of "sameness" from Title I (which amended the FDCA) and Title II (which amended the patent laws) of the Hatch-Waxman Act. Historically, FDA and the courts have not borrowed concepts and jurisprudence developed in the context of Title I and applied them to Title II issues, or vice versa.

The proposed rule would also require NDA holders to submit additional information demonstrating that the patented drug substances proposed to be listed perform the same as approved/pending drug substances in terms of dissolution, solubility, and bioavailability.

FDA's proposals would significantly change patent listings and patent certification requirements and eliminate multiple 30-month stays

Somewhat expected, but still controversial, are the Agency's proposed changes to the patent certification requirement and the elimination of multiple 30-month stays. FDA would replace the existing simple patent certification statement with a detailed checklist that would, among other things, require companies to identify specific patent claims that meet certain listing requirements, and presumably prevent NDA applicants/patent holders from listing inappropriate patents. Inaccurate certifications would facilitate prosecutions under 18 U.S.C. § 1001 for making false statements to the government.

FDA's proposal to eliminate multiple 30-month stays — which are triggered when an applicant submits multiple paragraph IV certifications concerning a listed patent and is sued within 45 days of receipt of such notice — is not surprising in light of FTC's objection to the listing of multiple patents as allegedly anticompetitive. Similar to the patent listing proposal, however, this proposal is a wholly new interpretation of the FDCA that is at odds with 18 years of regulatory and legal precedent.

While it is possible that FDA's proposed rule will "die on the vine," it could also be finalized and/or elements of the Agency's proposals could easily be used as a blueprint for legislation likely

next year. Consequently, pharmaceutical companies may be compelled to address the challenges raised by FDA's proposals from several perspectives.

➤ **FDA Law Issues** — To the extent that there is acceptance of FDA's merging of concepts and jurisprudence from Titles I and II of the Hatch-Waxman Act, this would further complicate statutory/regulatory analysis in this area, and would likely impact product lifecycle management strategies. More practically, the proposed rule would demand more extensive collaboration between FDA and patent counsel to make informed decisions about the listability and certification of patents.

➤ **Patent Law Issues** — While pharmaceutical companies are not likely to alter their general patenting strategy markedly in light of the proposed rule, it may be advantageous for companies to seek additional patent claims that would facilitate the listing of patents under the new certification paradigm's checklist (in consultation with patent and FDA counsel). Moreover, should FDA require companies to file evidence supporting the listing of drug substance patents, patent counsel will need to work closely with FDA counsel to assess the time and costs that would be involved in developing/submitting this data and the effect of having filed such data on future patent litigation strategies.

➤ **Antitrust Law Issues** — Competition concerns and FTC's advocacy had a major role in inducing FDA's proposed rule, and may signal the beginning of a longer-term trend of close collaboration. However, neither the proposed FDA rule nor FTC's recommendations and enforcement actions over the last several years threaten the core lifecycle management strategy of seeking additional patentable improvements prior to patent expiration.

For more information, contact Kathleen M. Sanzo, Washington, D.C., at 202.739.5209 or ksanzo@morganlewis.com.

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HOUSEY PATENTS

In November, the district court in Delaware declared that patents owned by Housey Pharmaceuticals Inc. were not infringed by the defendants in the case, several large pharmaceutical companies. The Housey patents relate to screening, testing and assays that have potential use in drug development. The decision came on the heels of the district court's November 12, 2002 *Markman* order, which had construed the patents in such a manner that Housey was forced to concede that the patents were invalid.

Housey had undertaken an aggressive licensing program for its patents, and had successfully obtained license agreements from a significant number of pharmaceutical and biotechnology companies. In 2001, Housey sued

several large pharmaceutical companies that had declined to take such licenses. After the *Markman* order, which interpreted the patent claims broadly and rejected Housey's argument for a more limited scope, Housey was forced to concede that the claims, as construed by the court, were invalid. Rather than continue the fight in district court, Housey entered into a final stipulation and order to allow prompt appeal to the Court of Appeals for the Federal Circuit.

Because the Federal Circuit considers claim construction *de novo* and frequently modifies the lower court's claim construction, there will be no final resolution of the issues of patent validity and infringement until the Federal Circuit review.

For more information, contact Lynn E. Eccleston, Washington, D.C., at 202.739.5474 or leccleston@morganlewis.com.

FTC CHAIRMAN TARGETS ANTITRUST ISSUES IN HEALTHCARE

The healthcare industry will continue to be the focus of antitrust enforcement action and the subject of extensive study and research, according to Timothy Muris, Chairman of the FTC. In a speech last November, Chairman Muris outlined an expansive enforcement program that includes:

- investigations of pharmaceutical companies, which accounted for fewer than 5% of new competition investigations in 1996 but almost 25% of new investigations in 2001,
- actions against physicians who allegedly collude in dealing with payors, and the consultants that help them do so,
- the establishment of a new merger task force to develop strategies to stop hospital mergers,
- the reexamination of consummated hospital mergers, and
- Department of Justice review of anticompetitive actions by insurers.

Chairman Muris also laid out an ambitious research agenda, centered around an extended set of hearings on healthcare and competition policy, commencing in February 2003 and continuing through the year. The planned 20-plus days of hearings, an extension of a two-day workshop on September 9-10, 2002, will examine:

- hospital mergers,
- antitrust issues in the pharmaceutical industry,
- the significance of nonprofit status in evaluating the competitive effects of hospital mergers and other provider conduct,
- the effects of vertical integration (e.g., combining in one organization the provision of hospital and medical services),
- the boundaries of the state action and Noerr-Pennington doctrines, which exempt from antitrust enforcement certain actions by governments and efforts of private persons to obtain governmental action,
- monopsony power (e.g., allegations that insurance companies have too much power over physicians and other providers of healthcare services), and
- the adequacy of existing remedies for anticompetitive conduct.

The hearings will also deal with the possible role of the FTC in ensuring that consumers are adequately informed and not victimized by false or misleading information. Among the consumer protection issues that are likely to be studied are (1) the disclosure of costs, risks, and benefits by pharmaceutical and device manufacturers and (2) the advertising of professional services.

Chairman Muris' remarks are available at <http://www.ftc.gov/speeches/muris/murishealthcarespeech0211.pdf>.

For more information, contact Willard K. Tom, Washington, D.C., at 202.739.5389 or wtom@morganlewis.com.

CO-EDITORS-IN-CHIEF:

MANYA S. DEEHR 215.963.5310
mdeehr@morganlewis.com

KATHLEEN M. SANZO 202.739.5209
ksanzo@morganlewis.com

EDITORS:

ROBERT L. ABRAMOWITZ 215.963.4811
rabramowitz@morganlewis.com

KEVIN M. DONOVAN 215.963.5420
kdonovan@morganlewis.com

LYNN E. ECCLESTON 202.739.5474
leccleston@morganlewis.com

JANET B. LINN 212.309.2110
jlinn@morganlewis.com

NANCY L. ROWE 202.739.5514
nrowe@morganlewis.com

DENIS SEGOTA 609.919.6622
dsegota@morganlewis.com

WILLARD K. TOM 202.739.5389
wtom@morganlewis.com

MONA C. ZEIBERG 202.739.5847
mzeiberg@morganlewis.com

The user-fee schedule for FY 2003 is set forth in the chart below. Small businesses are entitled to a waiver of the fee for their first PMA and a reduced fee for subsequent PMAs and supplements, but not for 510(k)s.

Application Fee Type	FY 2003 Full Fee (\$)	FY 2003 Small Business Fee (\$)
PMA	154,000	58,520
Premarket Report	154,000	58,520
Panel Track Supplement	154,000	58,520
Efficacy Supplement	154,000	58,520
180-Day Supplement	33,110	12,582
Real-Time Supplement	11,088	4,213
Premarket Notification 510(k)	2,187	2,187

Office of Combination Products. On December 31, 2002, FDA announced that a new Office of Combination Products, staffed by persons with scientific and medical expertise, had been established.

This new office is intended to be an advocate for combination products and to respond to past industry concerns regarding promptness of jurisdictional assignment and reviews of combination products. It is responsible for assigning primary jurisdiction over overseeing the timeliness and effectiveness of premarket review of, and determining the postmarket regulation of, combination products. One of its most important tasks is to rewrite the Intercenter Agreements, which will guide assignments of primary jurisdiction.

Third-Party Inspections. Perhaps the most controversial provisions of the new legislation are those allowing third-party inspections. In lieu of FDA inspections of their facilities, regulated device manufacturers are given the option of paying an FDA-accredited, independent third party to inspect their facilities. Despite the protests of those who feared that third-party inspectors paid by the company being inspected would be biased, the provisions were passed because FDA has been unable to meet statutory inspectional requirements (and even internal inspectional goals) with its limited resources. Third-party inspections will provide device manufacturers with an important option

— the ability to control the timing of their inspections.

Reuse. The reuse provisions address the concerns of original equipment manufacturers about competition from unregulated third-party equipment reproducers of single-use devices (i.e., devices intended for one use, or use on a single patient during a single procedure). Pursuant to these provisions, reprocessed single-use devices will be required to bear labels identifying them as reprocessed products. Additionally, 510(k)s will be required to be filed for reprocessed single-use Class II devices and even some Class I exempt reprocessed devices (e.g., forceps), following FDA publication of a list of such devices. A new form of premarket submission, a “premarket report,” will be required for Class III reprocessed devices.

These and other MDUFMA provisions will be implemented by FDA over the course of this year. It will be important for device and combination product manufacturers to monitor these efforts in order to determine the impact on their regulated products.

For more information, contact M. Elizabeth Bierman, Washington, D.C., at 202.739.5206 or mebierman@morganlewis.com.

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SPEECHES & ARTICLES

BUSINESS AND FINANCE

Coming to Terms: A Workshop on Negotiating Bio Deals

Eric D. Kline
Pittsburgh Technology Council, Biomedical Network
December 3, 2002; Pittsburgh, PA

PHARMACEUTICALS/BIO TECHNOLOGY

Strategic Partnering with Industry in Academic Biotechnology

Eric D. Kline
University of Pittsburgh
November 21, 2002; Pittsburgh, PA

The Role of Pharmaceutical Licensing in Product Lifecycle Management: Litigation and Settlement Under the Hatch-Waxman Act [Part I]

Edward T. Lentz
Stephen Paul Mahinka
Willard K. Tom
The Licensing Journal
March 2003

INTELLECTUAL PROPERTY

What the Future Holds for Life Sciences Research and Development

Edward T. Lentz
2003 Philadelphia-Japan Health Sciences Dialogue
February 13, 2003; Philadelphia, PA

Effective Claim Construction Strategies for Improved Patent Life Cycle Management

Edward T. Lentz
Intellectual Property & Patent Life Cycle Management for Innovator Pharmaceutical Biotech Companies
February 27, 2003; Philadelphia, PA

The Effects of Proposed Hatch-Waxman Reforms on the Patent “End Game” — The Brand Name Perspective

Edward T. Lentz
American Conference Institute’s Conference on Legal Strategies for Maximizing Pharmaceutical Patent Life Cycles
March 31-April 1, 2003; New York, NY