

# MORGAN LEWIS - ON LIFE SCIENCES

A NEWSLETTER FROM THE LIFE SCIENCES GROUP ■ [www.morganlewis.com](http://www.morganlewis.com)

APRIL/MAY 2004

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## PROTECTIVE PROVISIONS IN

# PHARMACEUTICAL/BIOTECH STRATEGIC ALLIANCES

### *Protecting Your Economic Interests*

Strategic alliances continue to be an important component of the product development and commercialization process in the life sciences industry. These transactions are highly individualized and unique and, as such, can be used creatively by the parties to advance their particular needs and goals. If you are a large pharma or big biotech company looking to acquire products or intellectual property from a smaller company, one of your main objectives is to maximize your rights to that technology and thus to protect your investment.

Conversely, as a small company looking to outlicense or obtain a corporate partner for your technology, you want to maximize the consideration you receive in the shortest amount of time and preserve as many rights to the technology as possible. Because these can be polar opposite positions, it is important that each party understand the objectives of the other when creating protective provisions in the strategic alliance.

One of the easiest ways for a small company to increase the purchase price of its technology is to use an auction to initiate a

bidding war. Auctions create competition, which may make the large company willing to pay more for the technology. However, when choosing a potential partner, it is important that the small company look not only at the total upfront dollars, but also at what resources and efforts the larger company will devote to the technology after it has acquired the rights. Accordingly, in addition to the dollar values, the small company should have clear criteria and processes for selecting the larger company with which it wishes to partner its technology.

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## BIO 2004

### MORGAN LEWIS LIFE SCIENCES PARTNER LEADS SPEAKING PANEL

JUNE 8 • 2:15 – 3:45 PM

INTELLECTUAL PROPERTY/LEGAL TRACK

#### *Achieving Economies in Patent Protection Without Reducing Deal Value* Manya S. Deehr

Seasoned patent attorneys, a deal attorney and a valuation expert will address why patent prosecution is so costly and will explore mechanisms for reducing costs, including developing alternative forms of protection and mechanisms for disposing of intellectual property, all without significantly reducing the value of the patent portfolio.

Join us for the discussion or stop by exhibit booth #1220. We hope you can also attend our cocktail reception for clients and friends of the firm on June 7, 5:30–8:30pm, Palace Hotel, San Francisco, CA.

## Morgan Lewis

C O U N S E L O R S   A T   L A W

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In an auction, the large company must distinguish itself from the other bidders, while at the same time ensuring that it is not paying too much for the technology. The large company should perform appropriate and adequate due diligence to minimize any surprises down the road, especially on the intellectual property and development activities that have progressed the technology to its current state. If the large company comes across any potential issues with or uncertainties about the technology, the strategic alliance agreement should be drafted with representations and conditions tailored to the specific facts. By addressing these potential eventualities through specific provisions in the agreement rather than waiting to see if they arise, the parties can proceed with the strategic alliance with a greater sense of certainty.

Next, the parties must agree on how to structure the financial provisions. The small company may want to receive most if not all of its payments upfront; but, for obvious reasons, the large company may want to pay for the technology as it is developed. One alternative could be smaller but more numerous payments coupled with funding of the small company's employees who are performing research and development work. Such smaller payments could continue to fund the small company and progress the technology. In exchange for the early, small payments, the large company could then make larger milestone payments upon the small company's achieving certain later

development or technical milestones, or pay a greater royalty or profit share percentage upon a product finally reaching the market. The small company could then receive a greater total cash return while the large company can ensure that it is only paying the greater dollar amounts after the technology has been proven. As a second alternative, if the small company requires larger upfront payments, there could be protective provisions for the large company allowing for reimbursement for certain of the upfront payments if milestones are not achieved or if there are delays in development. In addition, these transactions can include royalty reductions for generic competition or competitive products, and required payments to third parties.

#### *Protecting the Progress of the Collaboration*

As noted above, a strategic partnership between a large company and a small company may make excellent sense from both companies' perspectives. In addition to both sides desiring to achieve workable financial provisions, both parties have an interest in seeing the collaboration progress. A small company looking for growth may want its technology to have the opportunity to be fully developed and commercialized. On the other hand, a large company looking to license technology from, or collaborate with, a smaller company, may want the flexibility to match its obligations to future events and its assessment of the profit potential. Because each side has different priorities, each party

should strive to understand the other party's objectives when creating protective provisions in the strategic alliance.

Diligence provisions are customary in a strategic alliance agreement. These provisions serve as a guideline for the parties to expend efforts throughout the relationship. Parties' diligence obligations are often benchmarked against a commercially reasonable efforts standard, which may be one customary in the industry or one that reflects a party's particular characteristics. Strategic alliance agreements also sometimes set forth timetables for targeted achievement. However, the internal and external factors that can impact these timetables need to be understood so that the parties can avoid subjecting themselves to unclear or unacceptable obligations, giving up property rights or conferring unintended advantages on others.

In addition to diligence provisions, in order to keep an ongoing strategic alliance thriving, the parties should establish mechanisms for monitoring the progress of the collaboration. One such mechanism is to set up joint committees consisting of representatives from both parties. Second, or as an alternative, each party could have the obligation to supply periodic reports to the other detailing its activities, achievements and future objectives. Additionally, the agreement should provide for prompt notification to the other party upon the occurrence of certain events, e.g., the achievement of milestones or the occurrence of adverse events. This "checks and balances" system will allow the parties to monitor their progress toward a prosperous strategic partnership.

Next, the parties must know how to deal with potential problems to ensure continuous success throughout the collaboration. Protective provisions addressing these sensitive subjects are usually heavily negotiated between the parties. A noncompete provision can avoid potential problems by restricting a party from competing with its strategic partner

Morgan Lewis is pleased to announce that **Mark Mansour** has joined our FDA/Healthcare Regulation Practice. Prior to his arrival, Mark practiced at a leading regulatory firm in Washington, D.C., where he represented multinational food, pharmaceutical, agribusiness, biotechnology and consumer products corporations on issues ranging from packaged foods to functional foods and dietary supplements. In addition, Mark served as Assistant General Counsel and Director of Global Regulatory Affairs with the Kellogg Company, where he was responsible for conceiving and implementing the company's global regulatory policies.

To view Mark's full biography, or for additional information, please visit [www.morganlewis.com](http://www.morganlewis.com), or contact Mark at 202.739.6366 or [mmansour@morganlewis.com](mailto:mmansour@morganlewis.com).

during the collaboration and perhaps for a period of time after the partnership has terminated, thereby ensuring that the parties focus on the collaboration product and do not become distracted by other opportunities. Restrictive clauses can prevent a company from using or disclosing, without authorization, the trade secrets it learned from its strategic partner prior to the termination of their venture. In addition, it may also be appropriate for the agreement to provide mechanisms for resolving tie votes between the parties, including how the casting vote is determined. Because litigation can be time-consuming and expensive, the parties should also consider including dispute resolution clauses in their agreement. By having such protective provisions, if disagreements requiring settlements arise, early awareness of legal ramifications can allow those disputes to be addressed before they are unnecessarily escalated.

Needless to say, no one plans for failure, but what if the relationship goes sour? As remedial provisions are fundamental to any legal agreement, the applicable remedies should be addressed broadly in the strategic alliance agreement. The agreement should set forth penalties for delays and termination rights available to the parties (whether with or without cause). However, upon termination of the agreement, certain rights should remain and certain covenants should survive. For example, if termination is due to a party's breach, the nonbreaching party may, rather than terminating, want to retain its licenses to the product and continue with the breaching party, but on different economic terms. Similarly, it may be appropriate for certain covenants, such as noncompete and nonsolicitation clauses, to survive the agreement notwithstanding termination of the alliance.

### **Protecting Against Distractions and Disalignment**

Once the companies have entered into an alliance, how does each party ensure that the other does not become distracted and lose interest in the collaboration? A small company may see the collaboration as a means to grow its capabilities and reputation

and, after entering into the alliance, may be content to assume a passive role and dedicate its efforts to its next great idea. Conversely, a big company may see the collaboration as just another strategic building block, or it may believe that an in-house project or another outside company has a more promising product that will produce the same results, and thus switch its focus and resources to such other projects. It is therefore essential that the strategic alliance agreement be structured to ensure that each party remains focused on the collaboration's goals and does not become distracted by items that are not core to such goals.

First, by specifying the downstream rights of the parties, the agreement can establish expectations and responsibilities for the parties and for the future of the product. Depending on the nature of the collaboration, it may be appropriate for the agreement to set forth the respective manufacturing and supply responsibilities of each party. The parties may find that maintaining focus on the collaboration is best achieved by having the parties co-develop and co-promote the product. In such cases, these rights may be fixed and linked to a profit-split financial arrangement, or may be further enhanced with options to convert to a royalty structure.

Second, the agreement should describe the lead party's roles and responsibilities. The parties should clearly identify the niche technology of the strategic alliance. For example, the parties may want to prioritize certain indications, products or territories over others, or they may want to define each party's responsibilities in communicating and meeting with regulatory authorities. It should also be decided which party is in charge of booking sales for the product.

Third, commitment is key to a successful collaboration. An avenue to ensuring commitment is for the strategic alliance agreement to define a scope of exclusivity for the technology or product involved in

the venture. The exclusivity can continue for as long as the research and development is ongoing or last for a definite period measured by the commercialization of the technology or product. While negotiating the exclusivity clause, the parties may allow exceptions for internal or third-party programs, keeping in mind that such other programs should not distract either party from achieving the goals of the collaboration.

Fourth, if the parties authorize the use of collaboration technology outside of the venture, they should define clearly any limitations to be placed on such use, for example, field or territory limitations. Similarly, if such outside use is authorized, the parties could establish mechanisms for splitting any returns, as well as any applicable buy-in rights. Terms for royalties or other reward-sharing mechanisms in connection with such usage should be unambiguously stated in the agreement to avoid any future disagreement. Also, the parties should establish mechanisms for the sharing of information generated using the collaboration technology outside of the partnership.

Another feature present in some collaborations is for the large company to offer a quid product to the small company. Because a quid product may be unrelated to the collaboration product, it may be a distraction; however, a quid product can also serve as a means to prepare the small company for its responsibilities in the alliance. Alternatively, the quid product may be one that is complementary to the collaboration product and thus fits with the small company's capabilities and needs. This arrangement provides the small company with a second product to promote and simultaneously puts additional resources behind the product that the large company may not have been able to dedicate. If a quid product is part of the collaboration, the parties will need to delineate the scope of rights that accompany the quid product, the mechanism for choosing the quid product, and the point

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While substantial publicity and analysis of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 highlight the law's generally favorable pharmaceutical and biotechnology provisions, the new Medicare legislation also includes dramatic new coverage and reimbursement provisions likely to cause significant changes in the medical device and supply industries. However, unlike the pharmaceutical industry, which is likely to see expansion opportunities from the new law, the medical device and supply industries will have to navigate the new environment carefully to continue to be competitive. For the home medical equipment industry, in particular, the new Medicare Act will have a significant impact on product reimbursement methodologies, which in turn

will affect product development strategies and financing for development.

The medical equipment sectors chiefly affected by the Act include:

## HOME MEDICAL EQUIPMENT MANUFACTURERS

Following years of analysis and debate, the law shifts payment for Medicare-covered durable medical equipment ("DME") and certain other equipment and supplies from a fee-schedule-based reimbursement system to a competitive acquisition model. This represents the most significant of the legislation's changes for manufacturers and suppliers of DME and related products. Overall, this new program will have a significant impact on home medical equipment manufacturer, distributor and supplier relationships, as suppliers compete for Medicare contracts and experience declining reimbursement. Manufacturers will incur significant price pressure from suppliers and must consider manufacturing and distribution efficiencies.

Declining reimbursement (to varying degrees, depending on product type) also will have significant effects on development strategies for pipeline DME products — some new medical technologies may be rendered commercially nonviable in a competitive bidding environment. Vertical integration is likely to accelerate. Venture capital and financing for technologies and companies will reflect these reimbursement considerations.

### Scope

The competitive bidding program will begin in 2007 — initially phasing in the ten largest metropolitan areas in 2007, followed by the eighty largest areas in 2009. Individual product categories may be phased in over time as well, most likely beginning with high-volume products and products representing the greatest opportunity for savings. The law vests broad authority with CMS, and the final scope of competitive bidding will turn on a number of discretionary determinations reached by the agency during the next three years. For this reason, the industry now seeks to address many of the challenges presented

by the program through participation in regulatory processes.

New (and current) FDA Class III devices will be excluded from competitive bidding, as will inhalation drugs, parenteral and nutritional supplies, and custom orthotics and prosthetics.

### Pre-Competitive Bidding Reimbursement Freeze and Reductions

In the three-year period prior to the implementation of competitive bidding, existing DME fee schedule payment amounts will be frozen. In addition, certain product categories specifically identified by the HHS Inspector General are scheduled for cuts in 2005, based on the reported data. Products such as nebulizers, hospital beds, mattress systems, diabetic supplies and wheelchairs, among other product types, therefore, could incur significant reimbursement reductions, ranging from 3% to 22%, for 2005.

### Extension of Reductions Beyond Bid Areas

Once the competitive bid program is in effect, CMS will be able to use bid information from one competitive bidding region to adjust payment amounts in other geographic regions not under a competitive bidding structure. As a result, some reimbursement levels may, in effect, be nationalized, and reductions in early implementing regions could cause accelerated reductions in other areas, preempting the contemplated multiyear phase-in period.

## DME SUPPLIERS

Suppliers, as direct recipients of reimbursement, will experience first-line economic pressures from the new competitive bidding program. Where Medicare rates are reduced, suppliers could see erosions in VA, state and third-party payer rates, especially in regions where rates are governed by "most favored nation" terms or where other payers automatically adjust to Medicare rates. Suppliers will seek to renegotiate terms with manufacturers and distributors to preserve margins by spreading reimbursement reductions. Suppliers will critically assess the profitability of each product category, and brand and restructure inventory accordingly. Supplier consolidation,

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# REGULATORY LANDSCAPE

as well as the emergence of disease-specific niche suppliers, should be expected as suppliers seek strategies to maintain profitability. Supplier-specific provisions include:

- Establishment of quality standards for DME suppliers applied by independent accreditation organizations. The standards are intended to prevent and limit supplier reduction in quality and services due to efforts to streamline costs.
- Imposition of in-person practitioner-patient examination for high-utilization items.
- In anticipation of increased direct-to-physician marketing, CMS will review efforts to steer physician and patient product selection based on profitability. Also, while physicians may prescribe a particular brand product for a beneficiary, Medicare will pay only the reimbursement amount tied to the HCPCS code category to which the product is assigned.

## INPATIENT HOSPITAL EQUIPMENT MANUFACTURERS

Under current law, a new technology for inpatient hospital care is eligible for add-on Medicare payment if CMS determines that the technology substantially improves diagnosis or treatment and is inadequately reimbursed under the current inpatient hospital prospective payment system (“PPS”) DRG rate. The new law requires an opportunity for public comment on whether a technology substantially improves diagnosis or treatment, and improves the formula used to calculate whether a DRG provides inadequate

reimbursement. Also, the law eliminates the budget neutrality impediment, which had limited add-on expenditures. As a result, more inpatient technologies should qualify for additional reimbursement under PPS.

## CLINICAL LABORATORIES

The Act also calls for a competitive bidding demonstration for clinical laboratory services (pap smears and colorectal screening tests are excluded from this program). In addition, the law extends the existing fee schedule freeze for a five-year period, beginning this year. While the freeze presents economic limitations on fee scheduled tests, this outcome was considered by the industry as more favorable than the mandatory co-payment for laboratory services initially proposed in the legislation. While the freeze will present continued economic challenges and force laboratories to consider new efficiencies, many newer tests absent from the fee schedule are not directly subject to the freeze.

## MEDICARE COVERAGE PROCESS CHANGES

The Act includes several procedural coverage reforms relevant to the entire device industry.

### National Coverage Determinations (“NCDs”)

For those manufacturers seeking Medicare coverage determinations of national scope, the Act codifies more predictable procedures and enhanced transparency. These changes will be welcome news to manufacturers seeking to navigate the “black box” NCD

process, which carries virtual “all or nothing” consequences. While the changes are promising, it remains to be seen whether the reforms will render the process less cumbersome and more expeditious.

### Local Coverage Determinations (“LCDs”)

LCDs represent an important pathway for coverage, particularly for small to midsize device companies seeking to introduce new technology in local markets and test coverage theories before seeking an NCD. Effective July 1, 2004, the Act requires CMS to develop a plan to evaluate LCDs and decide which should be adopted nationally and to what extent greater consistency among LCDs may be achieved. In addition, carriers in the same geographic area will be required to consult with one another on all new LCDs. It is still unclear what immediate impact, if any, these provisions will have on the LCD process. To the extent the LCD process becomes more coordinated among individual contractors, it will be even more important for device manufacturers to have coordinated and well-articulated coverage theories early in the LCD process.

Unlike the legislation’s more coherent pharmaceutical provisions, the provisions relevant to medical equipment manufacturers and suppliers consist of multiple individual technical requirements. Although the most dramatic changes are outlined above, the legislation will change the industry’s regulatory environment in other ways.

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*Morgan Lewis’ Life Sciences Practice is one of the largest in the nation, with approximately 200 lawyers whose practice and experience are significantly devoted to the life sciences industry. Additionally, we have more than 200 professionals with life sciences degrees, nearly a third of whom have advanced degrees in life sciences disciplines. We have expressly developed our practice to “**protect the complete life sciences product life-cycle,**” with depth and quality in all important areas, whether regulatory, transactional or litigation. For more information regarding Morgan Lewis’ Life Sciences Practice, please contact the group’s Chair, Stephen Paul Mahinka, at 202.739.5205 or [smahinka@morganlewis.com](mailto:smahinka@morganlewis.com).*

in time when the small company will obtain rights to the quid product, as well as what happens with the quid product if the collaboration is terminated.

In sum, before committing to a long-term partnership, each company should evaluate the relative benefits and strategic consequences that such an arrangement entails. The collaboration agreement should be negotiated in detail to reflect the parties' interests and true intent and to protect each party's goals and interests. The agreement should set forth the particular stages of product development and capabilities required, the scope of rights from co-promotion to booking of sales, and the level of independence each party has in the collaboration, as well as how the collaboration may be terminated if the relationship ends.

Throughout the course of heavy negotiations for a definitive agreement, both parties should remember that they need to work together over an extended period of time for their mutual benefit. Including detailed terms and provisions in the collaboration agreement is a good way to protect both parties' interests. However, a successful strategic alliance will require each party to commit to the collaboration and understand the other party's goals and objectives, as well as its own.

Although there are a number of common catch-all protective provisions used to ensure a successful strategic alliance, the exact terms of such an arrangement are extremely variable. It is critical that the parties consult with their attorneys, accountants and financial advisors to carefully craft their intents into the strategic alliance agreement, thus ensuring that each party is able to protect against the downside while maximizing the upside.

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## FTC'S BOLD PRESCRIPTIONS FOR PATENT SYSTEM MAY HAVE ADVERSE EFFECTS FOR PHARMACEUTICALS

In the first installment of its report exploring the role of the patent laws and the antitrust laws in promoting innovation, the FTC recommends several far-reaching changes to the patent laws. Like an earlier report in which it made legislative recommendations, its July 2002 report entitled *Generic Drug Entry Prior to Patent Expiration*, the report is issued by the Commission itself, not its staff. This underscores its seriousness, and distinguishes it from numerous other reports studying competition issues, such as the *September 2003 Report of the State Action Task Force*, the July 2003 report entitled *Possible Anticompetitive Barriers to E-Commerce*, and the May 1996 report entitled *Anticipating the 21st Century: Competition Policy in the New High-Tech, Global Marketplace*.

The FTC plans to issue a second report with the Antitrust Division of the Department of Justice in the next few months, with recommendations for changes in antitrust law and policy at the patent-antitrust frontier. Both reports arose out of a series of hearings conducted jointly by the FTC and the Department of Justice in the spring and summer of 2003 to explore the relationship between the antitrust laws and intellectual property laws.

The FTC report makes ten primary recommendations for reforming the patent laws. The reforms would require legislation, alterations in Patent Office procedure, and different approaches by the Federal Circuit Court of Appeals (and district courts) to the resolution of certain patent issues. The recommended reforms are as follows:

- Permit interested parties to review and, if they choose, challenge issued patents at the PTO without resorting to court litigation.
- Ease the burden of proving patent invalidity by abandoning the "clear and convincing evidence" standard and replacing it with a "preponderance of the evidence" test.
- Make it easier to show that an invention is "obvious" by changing the application of the test for finding "commercial success" and the requirements for combining prior art to show obviousness.
- Increase funding for the Patent and Trademark Office so that the agency has additional resources to review patent applications more carefully and critically.
- Modify the PTO rules or procedures (a) to permit the patent examiner to obtain more information from potential patentees and (b) to allow additional review of patents in areas such as the semiconductor, software and biotechnology industries.
- Consider the potential competitive harm before extending the scope of patentable subject matter.
- Require all domestic patent applications to be published 18 months after they are filed.
- Enact legislation barring infringement actions based on claims asserted in continuation patents if the alleged infringement occurs before the amended claims are published.
- Before allowing a patentee to recover treble damages for "willful infringement," require the patentee to prove either (a) that it provided actual written notice of infringement to the defendant, yet the defendant continued to infringe, or (b) that the defendant deliberately copied the patentee's invention, knowing it to be patented.
- Incorporate economic insights and competition policy concerns into court and PTO patent decisions.

**Parties should remember that they need to work together for their mutual benefit.**

In addition to its recommendations for legislative changes in PTO practices and procedures and in judicial analysis, the FTC report indicates that the Commission intends to be more active in filing amicus briefs in important patent and patent/antitrust cases, will ask the PTO to reexamine questionable patents, and will seek to increase its liaison with the PTO.

Many of the FTC's recommended changes appear to have been spurred by concerns about "patent thickets" — situations in which patents are so numerous and overlapping that it becomes difficult to develop and commercialize a product without obtaining licenses from an inordinate number of patent holders. Such situations — common in the consumer electronics industry, and, according to some, an increasing problem in biotechnology as well — can be exacerbated when some of the patents are of poor quality. Similar concerns may exist in less extreme situations in which an improvidently issued patent may discourage competitors from subsequent innovation.

In contrast to other industries, the FTC notes that, with respect to pharmaceutical products, the current patent system generally works well. Unlike the computer hardware and software industry, innovation in the pharmaceutical and biotech industry is dependent on patent information disclosure and is also far more costly. Relatively few patents are required to protect products in the pharmaceutical industry, and patent thickets are "generally not a concern." The FTC also noted "the relative ease of imitation" and the

more drastic effect of competition. Because of laws and practices favoring the prescription of generics, once there is a generic counterpart, there is a "more rapid decline in the pioneer share of the market." In addition, effective patent life is also shorter because of the time required to obtain FDA approval. However, the FTC's dramatic recommendations would apply to all industries, and could make it more difficult in some cases for companies to obtain and enforce patents, and to be fully compensated for patent infringements.

To address the FTC's concerns about questionable patents going unchallenged because of the high costs of litigation and the existence of patent thickets barring competition, the FTC proposes easing the burdens of litigation on the defendant. Thus, for example, the FTC would lower the burden of proof for invalidating a patent from "clear and convincing evidence" to "preponderance of the evidence." It also proposes making it easier to demonstrate that a patent is obvious by making it easier to combine references for obviousness as well as putting a burden on the patentee to demonstrate a nexus between the invention and commercial success.

Because of the somewhat different litigation scenario that exists for pharmaceutical products under the Hatch-Waxman Act, the FTC's proposed solutions seek to remedy issues that do not exist with respect to pharmaceutical patent litigation. As noted above, there is no patent thicket issue with pharmaceuticals, and Hatch-Waxman has already provided generics the incentive to

challenge pharmaceutical patents. Because of the relative cost of litigation versus the rewards of successfully prevailing, it is rare for any commercially successful product not to be the subject of a Paragraph IV notice that either challenges the validity of the patent or claims noninfringement, or both. It would seem that all patents covering commercially successful products that can at least reasonably be challenged are already being challenged.

Further, as courts have noted, chemistry is unpredictable in a way that the mechanical arts are not. Accordingly, courts should be more hesitant to find patents in the pharmaceutical area obvious and Congress should be more hesitant to lessen the obviousness standard.

Similarly, the FTC's proposed change to the basis for a finding of willful infringement is premised on a concern that companies avoid reading competitors' patents for fear of willful infringement, a concern that does not exist in the pharmaceutical area. In Hatch-Waxman cases (and in the pharmaceutical area generally), there is no question that the generic companies are well aware of the patents covering the branded products. In contrast, until receiving a Paragraph IV letter, a proprietary company generally has no certain knowledge of who is preparing to file an ANDA. Any change to the burden on the patentee to demonstrate willful infringement based on the supposed reluctance of companies to review patents is thus especially inappropriate in the pharmaceutical context.

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## QUICKHITS

### COMBINATION DRUG PRODUCTS INELIGIBLE FOR HATCH-WAXMAN PATENT EXTENSIONS

On March 24, the Federal Circuit in *Arnold Partnership v. Dudas* upheld the denial of a patentee's application for patent term extension for a combination drug product, each active ingredient of which had previously received Food and Drug Administration approval as a stand-alone drug product. The Hatch-Waxman Act provides, among other things, for a period of marketing exclusivity

for pioneer drug products to compensate for the patent term lost during the lengthy FDA approval process. The patent term extension is only available, however, for "the first permitted commercial marketing or use" of the product. The court held that, to receive exclusivity, "at least one of the claimed active ingredients must be new to the marketplace as a drug product."

*For more information, please contact Willard K. Tom, a partner in the firm's Antitrust Practice, at 202.739.5389 or wtom@morganlewis.com.*

The recommendations are certain to be controversial, but their unanimous adoption as a report of the Commission itself, and the length of the hearings and analysis that followed, suggests that the

FTC will be tenacious in pursuing them. It will be interesting to see if the FTC recommends equally dramatic changes to the antitrust laws in the second installment of its report.

For more information, please contact Willard K. Tom, a partner in the firm's Antitrust Practice, at 202.739.5389 or wtom@morganlewis.com, or Janet B. Linn, a partner in the firm's Intellectual Property Litigation Practice, at 212.309.2110 or jlinn@morganlewis.com.

## EVENTS, SPEECHES & ARTICLES

### Morgan Lewis–Sponsored Life Sciences Events

#### Life Sciences Greenhouse Gala

February 17, 2004, Pittsburgh, PA

#### PABIOTECH/Pittsburgh Life Sciences Greenhouse Executives Dinner

March 3, 2004, Pittsburgh, PA

#### Morgan Lewis/Bay City Capital Joint Life Sciences Event

April 21, 2004, San Francisco, CA

#### BIO 2004 Annual Convention

June 6–9, 2004, San Francisco, CA

### Life Sciences Speeches & Articles

#### Business and Finance/Securities

##### New York Biotechnology Association's 13th Annual Meeting

*Life Sciences Joint Ventures in the Sarbanes-Oxley Environment*

Edward A. Reilly, Jr.

March 1, 2004, New York, NY

#### Pharmaceuticals/Biotechnology/Medical Devices

##### The International Lawyer

*From Farm to Fork: The Impact on Global Commerce of the New European Union Biotechnology Regulatory Scheme*

Mark Mansour

Spring 2004, Washington, D.C.

##### FDLI Update

*Strategic Implications of FDA's Proposed Safety Reporting Requirements*

Lawrence S. Ganslaw

Michele L. Vockrodt

March/April 2004

##### National Corn Growers Association European Union Traceability and Labeling Regulations Conference

*The International Regulation of Agricultural Biotechnology*

Mark Mansour

March 16, 2004, Washington, D.C.

##### Washington Legal Foundation: International Regulation of Biotechnology

*Do New Legal and Regulatory Challenges Threaten Advances in Agricultural Biotech?*

Mark Mansour

March 17, 2004, Washington, D.C.

### Bioethics, The Law & Litigation Forum 2004

*How to Prepare the Marketplace and the Regulatory Environment for Innovations: Biotechnology as a Test Case in Ethics, Public Acceptance and Regulation*

Mark Mansour

April 16, 2004, Houston, TX

### BIO 2004 Annual Convention

*Achieving Economies in Obtaining Patent Protection without Reducing Deal Value*

Manya S. Deehr

June 8, 2004, San Francisco, CA

### Intellectual Property

#### American Bar Association Section on Intellectual Property Law Georgetown University Law Student Outreach Program

*What Is IP Law?*

Erich E. Veitenheimer, III

February 26, 2004, Washington, D.C.

#### University of Georgia Biotechnology Seminars for Biochemistry and Molecular Biology Students

*Intellectual Property in Biotechnology*

Erich E. Veitenheimer, III

March 2, 2004, Athens, GA

#### American Conference Institute Program: A Tactical and Practical Guide to Freedom to Operate Analysis, Opinion Writing, and Strategies for Minimizing Risks in the Pharmaceutical, Biotech and Chemical Industries

*Planning and Conducting an Effective Freedom to Operate Search*

Michael S. Tuscan

Manya S. Deehr

April 26, 2004, San Francisco, CA

### Fraud and Abuse

#### 2004 Pennsylvania Bar Institute 10th Annual Health Law Institute

*Corporate Investigations: Role of the Attorney —*

*Ethical Issues/Legal Constraints in Internal Investigations*

John C. Dodds

March 17, 2004, Philadelphia, PA

#### 2004 ABA White Collar Crime Conference

*Health Care Fraud and Abuse*

John C. Dodds

May 3–5, 2004, Miami, FL