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Summary
Mr. McGough has twenty years of legal experience relating primarily to the procurement, licensing, and litigation of pharmaceutical, biotech, and chemical patents. Mr. McGough has conducted numerous patent due diligence analyses for pharmaceutical and biotech clients in connection with corporate acquisitions and divestitures and licensing deals. He advises clients on the entire range of related issues, including freedom-to-operate, ownership, patentability, and patent and regulatory exclusivity under the Hatch-Waxman Act. Hi s patent due diligence analyses for major pharmaceutical and biotech companies were profiled in the June 2004 edition of *Intellectual Property Law & Business (American Lawyer Media)* .

Mr. McGough 's clients include world-leading innovative pharmaceutical and biotech companies, preeminent chemical and manufacturing firms, and prominent biotech and pharmaceutical start-ups. Mr. McGough worked for thirteen years as in-house patent counsel for Merck & Co., Inc., and was responsible for patent and trade secret matters that were of material importance to Merck and its affiliates. Prior to Merck, Mr. McGough was an associate attorney with the law firms of Kenyon & Kenyon and Morgan & Finnegan. Mr. McGough is a member of the New York Bar, New Jersey Bar, and the bars of the United States Supreme Court, the United States Court of Appeals for the Federal Circuit, and the federal district courts of New York and New Jersey. He is admitted to practice as an attorney before the United States Patent and Trademark Office. Mr. McGough holds law degrees from St. John 's University School of Law (J.D. 1985) and New York University School of Law (LL.M. 1991). He received undergraduate and graduate degrees in chemical engineering from Manhattan College (B.Ch.E. 1980, M.Ch.E. 1981), where he was admitted to Tau Beta Pi and received a Mobil Oil Corporation graduate fellowship.

Mr. McGough has published on patent-related issues in leading journals including the *Harvard Journal of Law and Technology* and the *Food Drug Cosmetic Law* Journal. He has lectured on patent law at forums including the American Bar Association Antitrust Section. Mr. McGough has also served as an expert witness on patent law and the Hatch-Waxman Act in the case *In Re Cardizem® CD Antitrust Litigation* (E. D. Mich. 2003).

Franklin Pierce Law Center
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Due Diligence Presentation

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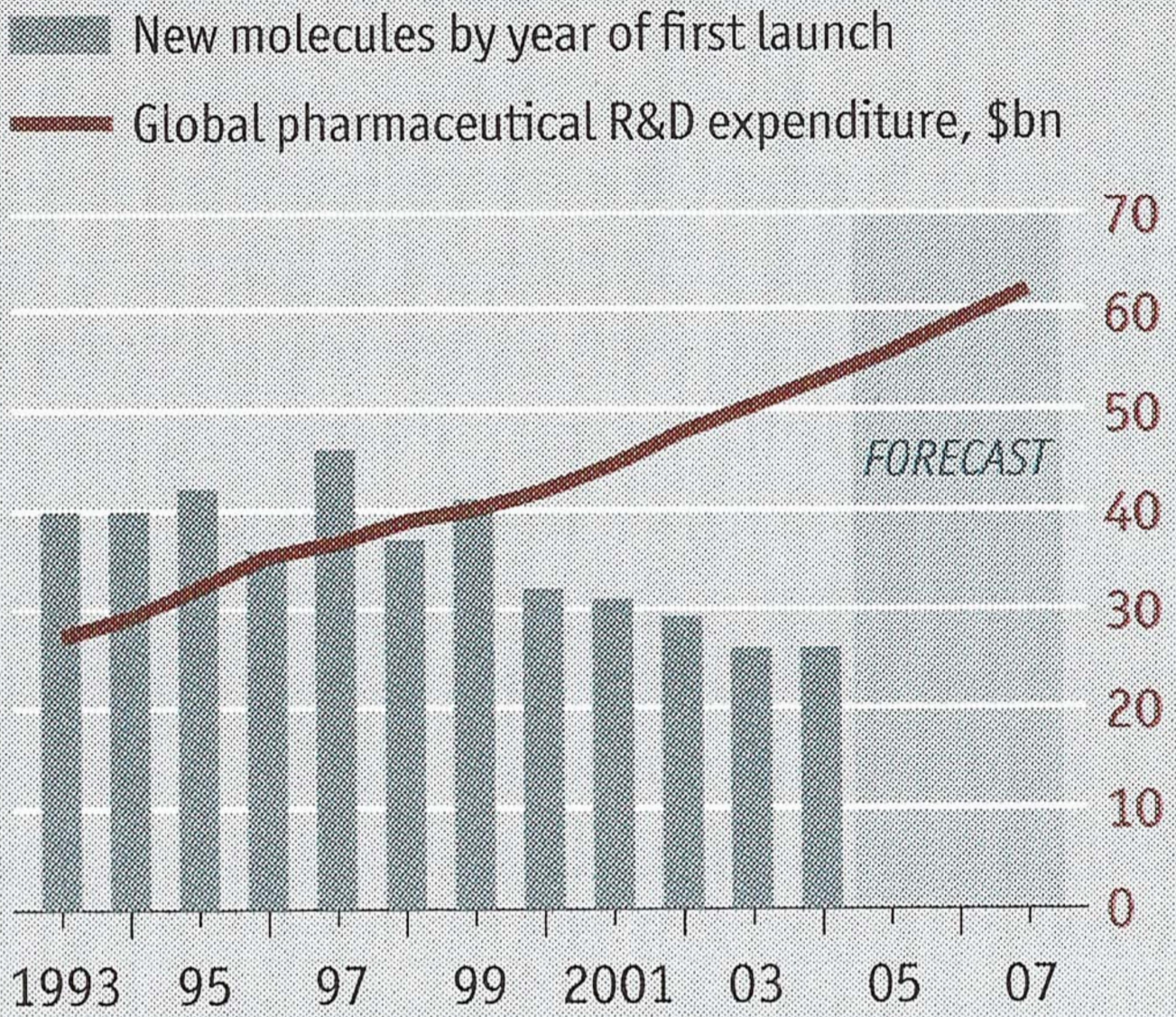
Growth in Pharmaceutical Licenses and Acquisitions

"One third of the molecules now in development originated in biotech companies. In-licensed molecules have had a higher chance of success…because big drug companies tend to [scrutinize] these offerings more closely…."

Testing Times-Getting More Out of Pharmaceutical R&D, The Economist, June 18-24 (2005).

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Spending more, getting less



Source: CMR International

Growth in Pharmaceutical Licenses and Acquisitions

- "Partnerships are vital to the future of the pharmaceutical industry. Big drug companies can't invent new drugs fast enough to replace those losing patent protection." *Trial and Error-How Eli Lilly's Monster Deal Faced Extinction-But Survived*, Wall Street Journal, April 27, 2005.
- "Pfizer will pay $1.9 billion cash to buy antibiotic firm Vicuron." Barrons, June 20, 2005.

Growth in Pharmaceutical Licenses and Acquisitions

- "In 1999, Merck entered into only ten outside alliances. [In the past three years] the company has signed 141 such deals, an average of 47 a year. Last year, it reviewed 5,000 potential partnership opportunities." *Research Chief Stirs Up Merck By Seeking Help of Outsiders*, Wall Street Journal, June 7, 2006.

Growth in Pharmaceutical Licenses and Acquisitions

- "Successful deals are premised on sound patent protection. Patents 'make information and technology transferable, facilitating the sharing of knowledge that permits firms to specialize their research and production activities'." Remarks of FTC Chairman Deborah Majoras, Patent Reform Conference (June 9, 2005 Washington, D.C.).

Growth in Pharmaceutical Licenses and Acquisitions

- An accurate assessment of IP rights is critical: intellectual property now accounts for over two-thirds of corporate assets. Baruch Lev, NYU Stern School of Business.

Patent Due Diligence

Analyze:

- Ownership/ Third-Party Obligations/Status
- Freedom-to-Operate
- Claim Scope/Term/Territory
- Non-patent I.P.
- Patentability/Validity/Enforceablity
- Antitrust and Regulatory Issues
- SEC Concerns

Ownership/ Third-Party Obligations/Status

- Have adequate ownership rights been conveyed to the prospective licensor or assignor? (Review all assignments - do not rely on electronic records or summaries.)
- Does a third-party have ownership or license rights, or a security interest, in the patent portfolio at issue?

Ownership/ Third-Party Obligations/Status

For example:

- Does the U.S. or another party have rights due to federal funding of the invention?
- Are there pre-existing licenses that affect the deal?
- Has the portfolio been pledged as collateral to secure financing?

Ownership/ Third-Party Obligations/Status

- Be aware of confidentiality and ownership issues. *See Mass. Eye & Ear Infirmary v. QLT Phototherapeutics*, 2005 U.S. App. LEXIS 11754 (1st Cir. June 16, 2005) (alleged wrongful disclosure of data acquired during license due diligence).



alert®

(Caffeinate)

Important Information: Alert ® is indicated for patients 18 years of age or older. Alert ® should be taken with food.

Hypothetical

- Did the ‘123 Patent and ‘456 Patent inventors assign all of their rights in the patents to Vision?
- Did the Kansas Medical College faculty member have the right to assign his interest in the ‘456 Patent to Vision? Was his work related to the ‘456 Patent federally funded?
- Does Vision have the right to license or assign the ‘123 and ‘456 Patents? Does Adams Bank hold a security interest in the patents which restricts licensing or assignment?

Ownership/ Third-Party Obligations/Status

- Have all applicable fees (e.g., PTO maintenance fees) been paid? (Confirm status with the patent offices of each relevant jurisdiction.)
- Has the patent been the subject of a litigation, reexamination, reissue, or opposition proceeding?

Freedom-to-Operate

- Have all of licensor's/assignor's patents and patent applications been identified? For example, are there relevant manufacturing or screening assay patents?
- Are there trade secrets or other I.P. (e.g., copyrighted software) that need to be considered.
- Conduct independent FTO search for third-party patents and patent applications.

Hypothetical

- Serene Pharma '789 Patent:

  "A method of modulating fatigue in a sleep-deprived mammal comprising administering a somnambulant receptor antagonist to the mammal."
- 2004 discovery: ALERT® is a somnambulant receptor antagonist.
- FTO concern?

Hypothetical

- Serene ‘789 Patent is inherently anticipated by sale and use of ALERT® more than one year prior to the ‘789 Patent effective filing date. *See SmithKline Beecham Corp., et al. v. Apotex Corp., et. al.* (Fed. Cir. 2005) (inherent anticipation does not require recognition of the inherent disclosure in the prior art at the time the prior art is created).

Claim Scope, Term, and Territory

- Is there patent coverage in all commercially-significant jurisdictions? Does patent coverage vary by jurisdiction?
- Is the claim scope adequate to cover commercial embodiments of interest?
- Is the patent term adequate?
- Are there design-around options?

Hypothetical

- ‘123 Patent satisfies term and territory criteria, but does it cover ALERT®?
- ‘456 Patent may not cover approved use of ALERT®; no issued foreign counterparts of ‘456 Patent.
- Does the Blue Ridge generic infringe either patent? Could other competitors develop bioequivalent, non-infringing generics?

Hypothetical

- Literal scope of the ‘123 Patent claims depends on the meaning of “erodible polymer”.

Hypothetical

Vision:

- Specification definition controls- “erodible polymer” captures any (long-chain) polymer that functions throughout the digestive system. *Cf.* *AstraZeneca AB v. Mutual Pharmaceutical Co.* (Fed. Cir. 2004)(specification descriptions of “surfactant” trumped broader ordinary meaning).

Hypothetical

Blue Ridge:

- "Erodible polymers" were not defined to include pH-dependent polymers like EON. *Cf. Merck & Co. Inc. v. Teva Pharmaceuticals USA, Inc.* (Fed. Cir. 2005)(specification definition did not trump ordinary meaning of "about").

Hypothetical

- *Phillips v. AWH Corporation*, 415 F.3d 1303 (Fed. Cir. 2005): "[t]he best source for understanding a technical term is the specification from which it arose, informed, as needed, by the prosecution history."

Hypothetical

- Did amending "long-chain erodible polymer" to read "erodible polymer" surrender coverage for EON polymer formulations? *See Insituform Technologies, Inc., et al. v. Cat Contracting, Inc., et al.* (Fed. Cir. 2004).

Hypothetical

Vision:

- Amending "long-chain erodible polymer" to read "erodible polymer" was not narrowing – it merely clarified a term which the PTO found confusing.
- Can rebut the *Festo* presumption that "erodible polymer" is not entitled to any range of equivalents even if the amendment was narrowing.
- Deletion of "long-chain" was not directly relevant to EON; EON is still an "erodible polymer". *See Insituform.*

Hypothetical

Blue Ridge:

- "Erodible polymer" is not entitled to any range of equivalents:

  (1) EON was foreseeable – designing a pH-dependent polymer was predictable given what was known about erodible polymers.

  (2) Amendment was narrowing and bore a direct relation to EON – while EON is a "long chain polymer", it is not an "erodible polymer".

Hypothetical

- Should Vision ask Blue Ridge to provide a sample of its generic? What if the sample can't be adequately tested during the 45-day Hatch-Waxman window? Does Vision risk antitrust liability if it obtains a sample and then sues Blue Ridge in the face of inconclusive test results?

Hypothetical

- Does the ‘123 Patent cover ALERT®? Did Vision inadvertently surrender coverage of GPA polymer formulations when it deleted the term “long chain”?

Hypothetical

- Do the ‘456 Patent claims require treatment of sedation caused by administration of a therapy?
- If so, the claims cover an off-label use.
- An inducement of infringement claim cannot be asserted against Blue Ridge under 35 U.S.C. § 271(e)(2) based on an off-label use. *Warner-Lambert Co. v. Apotex Corp.* (Fed. Cir. 2003).

Patentability/Validity/Enforceablity

- Has all material prior art been cited during prosecution of the patents and patent applications at issue? (Compare U.S./PCT/EPO prior art and prior art cited in related patents and patent applications.)
- Conduct independent prior art search.
- Best mode: carefully scrutinize any U.S. patent or patent application that claims priority from a foreign application.

Patentability/Validity/Enforceablity

- Prosecution affidavits are a cause for concern. *See Purdue Pharma, et. al. v. Endo Pharmaceuticals, et. al.*, 438 F.3d 1123 (Fed. Cir. 2006): case remanded to determine if repeated representations regarding "surprisingly discovered" dosage range benefits constituted inequitable conduct where patentees failed to disclose that the "discovery" was based only on "insight", and had no empirical basis.

Hypothetical

The United States hospital clinical trial:

- Was the trial confidential? What formulation was tested? What were the results?
- Does the role of third-party clinicians raise an inventorship concern?

Hypothetical

- Was the trial an "experimental use". *Cf.* *Lisle Corp. v. A.J. Mftr. Co.*, 398 F.3d 1306 (Fed. Cir. 2005); and *SmithKline Beecham Corp., et al. v. Apotex Corp. 365 F.3d 1306* (Fed. Cir. 2004)(*vacated*)(non-confidential clinical trial was not an experimental use).
- Consider objective evidence regarding whether Vision retained control over testing, purpose of testing, and submission of test reports to Vision.

Hypothetical

The ALERT® NDA food effect data:

- '123 Patent: "We have discovered that compositions of the claimed invention achieve maximum plasma levels of active ingredient more than 12 hours (e.g., 16-18 hours) after ingestion."
- NDA: 16-18 hour Tmax only after eating.

Hypothetical

Vision:

- Food effects were never at issue during prosecution.
- Failure to cite problems with commercial embodiment, or over-emphasizing invention's benefits, is not inequitable conduct. *CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333 (Fed. Cir. 2003).
- Even if the food effect data was material, an intent to deceive cannot be inferred on these facts.

Hypothetical

Blue Ridge:

- PTO examiner should have been allowed to decide whether the food effect data was inconsistent with the asserted Tmax benefit. *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1256 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1071 (1998).
- Intent can be inferred - incomplete description of Tmax misled the examiner into believing that the invention had non-existent benefits (a greater, food-independent Tmax). *Cf. Purdue Pharma, supra*.

Hypothetical

- If Vision's "discovery" was only based on "insights" gained from the authoritative prior art article, the '123 Patent could have a serious inequitable conduct problem under *Purdue*.
- Vision might try to distinguish *Purdue* on grounds that it did not make "consistent and repetitive" representations regarding Tmax.

Antitrust and Regulatory Issues

- Can the patent in issue be listed in the Orange Book? *68 Fed. Reg. 36676-712 (June 2003).* Can the patent benefit from patent term restoration or non-patent market exclusivity?
- Could a competitor pursue a "carve-out" of an approved label and avoid the Hatch-Waxman Paragraph (IV) 30 month statutory bar? *Purepac Pharmaceutical Co. v. Thompson* (D.C. Cir. 2002).

Hypothetical

- Continued listing of the '456 Patent in the Orange Book risks liability under Section 2 of the Sherman Act. *In re Buspirone Patent Litigation* (S.D.N.Y. 2002). Enforcing the '451 Patent against Blue Ridge could also lead to sham litigation antitrust claims.
- In light of *Purdue*, enforcing the '123 Patent could lead to *Walker Process* fraud and sham litigation antitrust claims. *Nobelpharma AB v. Implant Innovations, Inc.* (Fed. Cir. 1998).

Hypothetical

- Can Elite or Vision settle Blue Ridge's ALERT® patent challenge without risking antitrust liability?

Hypothetical

Schering-Plough Corp v. F.T.C.:

- Settlements provided for: (1) generic entry after ANDA approval but before patent expiration; (2) Schering's acquisition of exclusive licenses to a generic manufacturer's products; and (3) substantial cash payments to generic manufacturers.

Hypothetical

Schering-Plough – FTC Positions:

- While not *per se* illegal, settlements constituted an unreasonable restraint of trade.
- Rule of reason analysis applies; focus on whether the settlements were anticompetitive – was there a detrimental market effect? What entry dates might have been agreed to in the absence of payments?
- A simple compromise as to generic entry date, and a litigation expense payment of $2 million or less to a generic manufacturer, is not objectionable.

Hypothetical

Schering-Plough - Eleventh Circuit Opinion:

- Do not apply *per se* or rule of reason analysis – consider instead (1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects.
- Do not consider patent invalidity except in *Walker Process* or sham litigation cases.

Hypothetical

Schering-Plough - Eleventh Circuit Opinion:

- "Substantial and overwhelming evidence" that royalty payments were considered to be fair consideration for the licenses at issue.
- No evidence that patents were invalid.
- Payments were not suspect because of the generic manufacturers' agreement to delay market entry.

Hypothetical

Schering-Plough - Eleventh Circuit Opinion:

- "A prohibition on reverse-payment settlements would reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought anticompetitive."
- FTC petition for rehearing *en banc* denied. Petition for *certiorari* under consideration by the Supreme Court.

Hypothetical

In re Cardizem CD Antitrust Litigation (6th Cir. 2003):

- Paying generic $40 million/year to delay market entry after ANDA approval was a horizontal agreement to eliminate competition and was a *per se* violation of Section 1 of the Sherman Act, irrespective of the strength of the underlying patent.
- Generic manufacturer did not relinquish its claim to 180 days of market exclusivity and created a "bottleneck" to approval of subsequently-filed ANDA's.

Hypothetical

In Re Ciprofloxacin Hydrochloride Antitrust Litigation (E.D. N.Y. 2005):

- Rule of reason analysis applies.
- Plaintiff must prove an adverse effect on commerce in the relevant market by a restraint of trade beyond the scope of the claims of the patent in issue.
- Absent *Walker Process* fraud or sham litigation, the potential invalidity of the patent is immaterial.

Hypothetical

- The FTC, other generic manufacturers, ALERT® purchasers, and STOPP may contend that the settlement violates antitrust laws, even under *Schering-Plough*, as the '123 Patent is not only invalid, but was also obtained by *Walker Process* fraud.

Hypothetical

- Settlement must be recorded with FTC and Justice Department within 10 days of execution. *See* Medicare Modernization Act of 2003 ("MMA") revisions to Hatch-Waxman.
- No *Cardizem CD* "bottleneck" problem- Blue Ridge will lose 180-day exclusivity under MMA.
- The two $3 million payments should be characterized as up-front license fees.
- Deal with the '456 Patent in a separate agreement or consent judgment.

SEC Issues

- Sarbanes Oxley: Are the facts relating to Vision's potential inequitable conduct or other aspects of Blue Ridge's patent challenge "material facts" that must be included in Vision's quarterly and annual reports? *See* Sarbanes-Oxley Act, Pub. L. 107-204, 116 Stat. 745 (2002)("SOX").
- Sections 302 and 906 of SOX require CEO's and CFO's to certify that the reports "do not contain any untrue statement of a material fact or omit to state a material fact."

SEC Issues

- *Cf. Asher, et al. v. Baxter Int'l*, 377 F.3d 727 (7th Cir. 2004): "fraud on the market" securities law claim reinstated – defendant's "safe harbor" disclaimer accompanying earnings projections may not have been sufficiently specific in light of problems (e.g., quality control failures) that had been identified internally.

SEC Issues

- Minimize securities law and SOX exposure by regular analyses of I.P. portfolios covering significant products or processes.
- Implement practices which analyze the same factors that would be considered during an acquisition or license of such portfolios.

Hypothetical

Summary:

- Cannot rely on ‘456 Patent.
- Need more information about the polymers to assess potential for design-around and patent coverage under the ‘123 Patent.
- No FTO problem with respect to Serene patent.
- Need more information to determine if the ‘123 Patent is invalid in light of the clinical trial.
- Inequitable conduct issue under *Purdue*.
- While settlement may be opposed by FTC and purchasers, it could be upheld under *Schering-Plough*.
- Corporate representations about ALERT® market exclusivity and sales projections create SOX and SEC concerns.

Patent Due Diligence

- "Diligence is the mother of good luck."
  Benjamin Franklin
  Poor Richard's Almanac

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