WHAT’S NEW IN ANTITRUST

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WHAT’S NEW IN HEALTH CARE ANTITRUST:

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I. 2002/2003 – Back to the old and on with the new!

• “Been there, done that” -- provider “cartel” activity, messed up “messenger models” and reinvigorated enforcement
• “We’re clinically integrated and we need to fix prices!?” – FTC MedSouth advisory opinion and future challenges
• What about those hospital mergers?
• “I’m a hospital network -- Please take all of me, and no ‘tiering’”
• “Cut ‘em off at the pass” -- Unfair exclusion by the big guys or reasonable self-defense?
• “It’s OK, don’t worry about it” – Advisory opinions OK provider fee surveys and joint contracting by non-competing hospitals
• “They’re big and they might be bad,” let’s look at the payors”
• Drugs, drugs, drugs -- Brand-and-Generic Pharmaceutical Cases
• “Match Game 2002” – Residents react

II. Agency enforcement against provider cartel activity and “messenger model” abuses.

Either providers have gotten more aggressive, resulting in more enforcement actions against boycotts and price fixing, or the enforcement agencies are looking harder. They are also pushing for stronger remedies than just ordering physician organizations “not to do it again.”

A. FTC orders break-up of Napa Valley Ob/gyn group

FTC ordered a doctors’ group with virtually every obstetrician and gynecologist with active privileges at the two general acute care hospitals in Napa County, CA, disband and its member doctors to refrain from engaging in boycott and price fixing behavior in the future. The doctors were dissatisfied with their reimbursement under a capitated IPA in which they participated, pulled out, and refused to participate with health plans that did not meet terms they agreed upon collectively. Obstetrics and Gynecology Medical Corporation of Napa Valley, FTC File No. 011 0153 (2002). Information on the case can be found at http://www.ftc.gov/os/caselist/0110153.htm.

B. Texas physician group and its management company subsidiary cross “messenger model” border, ordered to stop fee contract negotiations for member physicians.

In November, the FTC issued a final consent order against Genesis Physicians Group, a Texas physician sponsored managed care network organization, and its management subsidiary, System Health Providers, inc., requiring them to cease joint managed care contracting activities on behalf of their 1250 participating physicians. System Health Providers,
Inc., Dkt. C- 4064 (FTC Nov. 2002). Genesis had previously worked under risk-model contracts, but had lost money. It shifted its focus to non-risk contracts. It allegedly sought to negotiate physician rates with payors, and discouraged its member physicians from contracting with managed care organizations other than on terms negotiated by Genesis or that met what it considered to be “market” standards. The Commission alleged the two organizations had abused the so-called “messenger model” of managed care contracting. That the network permitted its physicians to “opt out” of contracts it negotiated did not satisfy “messenger model” principles for avoiding allegations of improper price fixing. The FTC documents on the case can be found at http://www.ftc.gov/os/caselist/c4064.htm.

B. DOJ antitrust settlement requires North Carolina physician group to disband

In December, the Antitrust Division of the Department of Justice announced that it will require Mountain Health Care, an independent physicians organization headquartered in Asheville, North Carolina, to cease its operations and dissolve. The Department said that under a proposed settlement, Mountain Health Care will cease negotiating and contracting with health care plans on behalf of its participating physicians, a practice DOJ said resulted in consumers paying increased prices to Mountain Health Care's physician members for health care services. The DOJ complaint, stipulation to final judgment, and competitive impact statement are available at http://www.usdoj.gov/atr/cases/mountain.htm.

C. Colorado physician groups, officers and consultant ordered to stop improper price contracting

In July 2002, the FTC issued final consent orders barring two Denver-area physician associations, some of their leaders and their consultant to cease collective negotiations and contracting activity on behalf of their members. The orders are a further evolution of Commission enforcement direction in their targeting not only the associations themselves, but also certain responsible officers and the consultant who allegedly the physicians into the improper activity. Aurora Associated Primary Care Physicians, L.L.C. (FTC Dkt. C-4055 July 2002) and Physician Integrated Services of Denver, Inc. (FTC Dkt. C-4054 July 2002). Information on both cases is available at http://www.ftc.gov/bc/CommissionActions/2002.htm.

In August, the Commission followed with a proposed complaint and consent order against 8 separate associations of ob/gyn's and their consultant for similar joint contracting activities. In each of the Colorado matters, the Commission alleged that the purported “messenger” refused to communicate neutrally to participating providers price schedules that were not approved by the physician organization. Professionals in Women's Care, FTC File No. 0110175 (Aug. 20, 2002). http://www.ftc.gov/os/2002/08/profwomendo.pdf

D. Final order against boycott and price fixing by “union” of orthopedic surgeons in Delaware

The federal district court finally accepted the stipulation judgment and issued the final judgment against a physician “union” that had purported to act as a managed care contracting messenger for orthopedic surgeons, but was accused of being the hub of a conspiracy to fix prices and refused to deal in Delaware. United States v. Federation of Physicians and Surgeons, CA 98-475 JJF (D.Del. Nov.12, 2002). http://www.usdoj.gov/atr/cases/indx26.htm

III. FTC Advisory Opinion Says Per Se Rule of Illegality Won’t Apply to Collective Fee Negotiation by Clinically Integrated Physician Network
FTC Bureau of Competition staff advised MedSouth, Inc., a multi-specialty physician practice association in the Denver, Colorado area, that the staff does not intend to challenge MedSouth's proposed collective negotiation of payor contracts on behalf of members who participate in its clinical resource management program. (Feb. 19, 2002).

The MedSouth advisory opinion is the first written guidance issued by the FTC addressing in depth the amount and nature of clinical integration necessary to permit otherwise independent physician practices to collectively negotiate fees without violating federal price fixing prohibitions since the 1996 update to the Statements of Antitrust Enforcement Policy in Health Care issued jointly by the FTC and the Antitrust Division of the U.S. Department of Justice.

Under MedSouth's proposal, all physicians who are members of MedSouth physician practices will be required to participate in MedSouth's proposed clinical integration program. The program will have two major components. First, the physicians will use an electronic data record system that will permit them to access and share clinical data related to their patients, such as patient records, lab reports, treatment plans and prescription information. Second, MedSouth will monitor and analyze physician performance according to clinical practice guidelines and performance goals related to the quality and appropriate use of services. MedSouth maintains that the program will permit MedSouth physicians to improve patient care and outcomes, reduce medical errors, increase efficiency in the provision of services and reduce medical costs, and will discipline and terminate physicians who do not fully participate in the program and adhere to the program's standards.

Once its clinical program is operational, MedSouth proposes to market the services of its practice members to commercial third party payors, and to negotiate and execute contracts under which MedSouth members would provide services to health plan enrollees. All MedSouth members would be required to provide services under those contracts, and could not opt out. The physicians would not be precluded from participating in other networks or from contracting with payors independently if the payors did not contract with MedSouth.

The FTC staff opinion letter concluded that, based on the information provided by MedSouth, the group's proposed collective negotiation and contracting with payors on behalf of its members should not be deemed per se illegal price fixing. The letter stated that the proposed program appears to be capable of creating substantial partial integration of the MedSouth physicians' practices, and to have the potential to produce efficiencies in the form of higher quality or reduced costs for health care services provided by MedSouth physicians.

The letter also concluded that the collective negotiation of payor contracts appeared to be reasonably related to the integration, and to be reasonably necessary to the accomplishment of the program's objectives. On the facts presented, absent the assurance that the full panel of doctors would be involved in the network's contracts, physicians were not likely to be willing to support integration activities on which efficiencies depended. Also, the opinion letter said, “joint contracting may permit the network to allocate the returns among members of the network in a way that creates incentives for the physicians to make appropriate investments of time and effort in setting up and implementing the proposed program.”

The opinion warned, though, that “mere adoption of a common clinical information system by itself, without the other programs that MedSouth intends to implement, would not suffice to establish that otherwise competing members of a physician network have integrated...
their practices in a manner or to an extent that joint negotiation of prices could be deemed ancillary to an efficiency-enhancing joint venture."

The staff letter warned that the MedSouth network would be closely monitored, and that absent a demonstration that the network had achieved significant efficiencies outweighing anti-competitive effects, enforcement action would likely be recommended if MedSouth's physicians were able to use their collective power to force payors to contract with the network or to pay higher fees.

The letter relied on MedSouth's representation that its physicians have been and will continue to contract individually with payors that wish to contract separately. If that were not to remain the case, the staff said, enforcement action could result, given the relatively high proportion of MedSouth physicians on the medical staffs of important hospitals in the Denver area.

The staff's evaluation of geographic market issues is also notable. It focused on the need of payors to have representation from among MedSouth physicians in a defined subset of the Denver metropolitan area, rather than on questions of individual patients' willingness to travel further for health care services, which might have supported a larger geographic market finding.

Medsouth anticipated that its resource management programs would reduce utilization of services. Given the costs of program, the value of program to Medsouth would depend on either attracting additional revenue through efficiencies and product differentiation or on earning higher fees.

Other groups may seek to piggyback on Medsouth result. A risk is that some arrangements may be shams, or otherwise insufficient. Some providers will cast question as, “We went to negotiate managed care contracts and get higher fees. How much clinical integration is enough” This turns antitrust’s “ancillary restraint doctrine” upside down. Difficult questions are: How determine whether integration is “enough,” how does price fixing make the integration viable, and how apply rule of reason if per se not applicable.

Similar issues are already arising with hospital networks.

A copy of the advisory opinion is available at http://www.ftc.gov/bc/adops/medsouth.htm

IV. Major market players charged with cutting off market access to smaller competitors -- unfair exclusion or permissible self-defense

Examples – hospitals in battles with ambulatory surgery centers or specialized hospitals; PPOs fending off specialty service networks

A. Court denies preliminary injunction sought by supplemental network seeking to be offered as “enhancement” to PPO network

   1. Supplemental provider network offerings can raise new challenges and new settings for familiar antitrust arguments. An Indianapolis federal district court refused to grant a preliminary injunction for a supplemental network that challenged a PPO’s refusal to be offered by employer groups that offered the supplemental network as an enhancement to the

Gateway had alleged that Sagamore and its participating provider and part owner St. Francis Hospital conspired to exclude Gateway from the Indianapolis area market for health network services in violation of the federal and state antitrust laws.

2. Gateway provides access to a range of cardiac and orthopedic services on a global case rate basis—a single price for the entire package of required health care services. It offers this product to employer health plans on a zero dollar copay basis—100% payment by the plan. According the court, it offers to “piggyback” its product on the PPO offerings of customer accounts.

3. Sagamore operates a “traditional” PPO program. It is sponsored by a number of hospital systems, including two operating in the Indianapolis area. Its program is typically offered by employers on a 90-10, or 80-20 basis for participating providers, the former being the percentage of the allowable charge paid by the employer when in-network services are used. A 70-30 or 60-40 benefit design applies when out-of-network providers are used, until the participant reaches his or her annual out-of-pocket maximum.

4. Sagamore objected to employers offering Gateway as an “enhancement” that resulted in Sagamore providers who were not in the Gateway network not being full “preferred” providers under the benefit design implemented by the employer. Co-defendant St. Francis Hospital had informed Sagamore that it would reduce or eliminate its discount through Sagamore for groups that also offered the Gateway network, since the benefit design used for the Gateway product tended to steer patients away from St. Francis.

5. The court denied Gateway’s motion, finding “that Gateway has less than a negligible chance of success on the merits.” Specifically, the court found that plaintiff failed to prove the existence of any of several conspiracies alleged. It also failed to show that the challenged restraint had adversely impacted competition in a relevant market, the court stated. The plaintiff did not appeal denial of the preliminary injunction, and voluntarily dismissed its claims with prejudice.

B. Trial Court Refuses to Dismiss Claim against Hospital by Competing Surgical Center

A failed ambulatory surgery center can proceed with its antitrust claims against a hospital that allegedly bullied it out of business, a New York federal court ruled in August. Rome Ambulatory Surgical Center LLC v. Rome Memorial Hospital Inc., No. 5:01-CV-23, (N.D.N.Y. Aug. 22, 2002). The hospital allegedly reacted after 23 physicians on its staff opened a freestanding ambulatory surgical care center in competition with the hospital where they practiced. They initially had the support of three health plan operating in the area. The plaintiff claims that, in response, the hospital—the only one in the area—used price incentives to force health plans into exclusive contracts, intimidated surgeons to prevent them from using the new facility, and induced a network of local physician to refer outpatient surgery patients only to the hospital. Apart from the merits of the specific factual allegations, the case raises

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1 The speaker represented defendant Sagamore Health Network in this litigation.
thorny issues about the ability of a hospital to respond when its own staff doctors seek to compete with it.

A. Fifth Circuit upholds judgment for hospital defendant against monopolization charges by ambulatory surgery center

A judgment for a Louisiana public hospital charged with exploiting its market power over inpatient care to gain a competitive advantage in the outpatient surgery market was upheld Oct. 9 by the U.S. Court of Appeals for the Fifth Circuit because the plaintiff failed to define a proper relevant geographic market (Surgical Care Center of Hammond v. Hospital Service District No. 1 of Tangipahoa Parish, No. 01-30171, (5th Cir. Oct. 9, 2002).

The defendant operates North Oaks Medical Center, the largest hospital in Hammond, La., offering a full range of inpatient and outpatient services, including outpatient surgery. The plaintiff, Surgical Care Center of Hammond, alleged that the defendant pressured managed care companies to use North Oaks exclusively for both inpatient and outpatient care. Conditional discounts, a refusal to sign a patient transfer or blood type and cross match agreement, and a refusal to lend medical equipment to the plaintiff were all challenged as part of a monopolistic scheme. The court of appeals avoided having to deal with the controversial monopoly leveraging allegations, when it found that the plaintiffs had not put on sufficient evidence of a valid relevant geographic market, so no finding of market power by the defendant could be made. The court said that the plaintiff’s expert had tackled the geographic market issue solely by considering the defendant’s service area, without offering evidence, which the court said was essential in antitrust cases, of where people can practically go for services. It upheld dismissal of the case. The opinion can be found at http://www.ca5.uscourts.gov/opinions/OpinH

D. Excluded anesthesiologist survives motion to dismiss

The U.S. Court of Appeals for the First Circuit last month reinstated dismissed claims by Dr. Alga Morales-Villalobos against anesthesiologists, their group, and two hospitals in Arecibo, P.R., who allegedly maintained an exclusive dealing arrangement that prevented her from competing to offer her services in the town. (Morales-Villalobos v. Garcia-Llorens, No. 02-1499 (1st Cir. Jan. 14, 2003). The court rejected arguments that she had failed to adequately plead the relevant geographic market and that she failed to allege a cognizable antitrust injury that would give her standing. Text of the court’s decision is available at http://www.ca1.uscourts.gov/cgi-bin/getopn.pl?OPINION=02-1499.01A.

V. What about the payors?

New allegations are being pursued about alleged anticompetitive activities by payors. Perhaps more importantly, the Department of Justice has expressed particular interest in pursuing possible initiatives in the health insurance field. Its representative at the joint FTC – DOJ workshop on health care competition in September indicated that possible anticompetitive activity by health insurers was an enforcement priority for DOJ. It is considering issues of “monopsony” power by purchasers over provers and how to define product and geographic markets in managed care matters.

Examples of pending private litigation are:

A. Pennsylvania hospital charges Blue plan with monopolization
A suburban Philadelphia hospital sued Independence Blue Cross in May, claiming, among other things, that through most favored nation's clauses, all product participation policies, pressure on employers to enroll employees principally through IBC and hospital reimbursement rates depressed unreasonably and below hospital costs, IBC raises barriers to competition by other health plans in violation of the antitrust laws, and caused injury to the plaintiff hospital. Chester County Hospital v. Independence Blue Cross, No. 02-CV-2746 (E.D. Pa., complaint May 8, 2002). The case is in pre-trial proceedings. The defendant vigorously denies the allegations as to market power and anticompetitive conduct, and claims the plaintiff’s economic problems are the result of its own business judgments.

A. Cincinnati doctors sue health plans for allegedly conspiring to limit physician reimbursement

In January 2003, a state court judge denied the defendant HMOs’ motion to dismiss charges that they had conspired to reduce reimbursement rates to health care providers in violation of state antitrust law. Defendants had sought to compel arbitration pursuant to their contracts, and to dismiss the claim for injunctive relief. The judge ruled that the arbitration clause did not apply to the alleged conduct and also that the Ohio Valentine Act, which defendants characterized as allowing only the state Attorney General to sue for injunctive relief, also authorized suits by private plaintiffs.

The Butler County Medical Society and the Academy of Medicine of Cincinnati filed suit in June 2002 against Aetna Health, Humana Health Plan of Ohio, Anthem Blue Cross and Blue Shield and United Healthcare of Ohio, alleging that the defendants conspired to enter into illegal agreements with hospitals in the Greater Cincinnati area to reduce the reimbursement rate paid from insurance companies to doctors. The complaint cited the reduction in the number of hospital organizations (14 to 5) despite an increase in population since 1991, as well as the comparative reimbursement rates for doctors in Cleveland, Columbus and Dayton.

V. The agencies look to the future, while the FTC takes a fresh look back at old hospital mergers

The FTC and DOJ have launched six months of public hearings on competition and antitrust in health care, focusing on a broad range of policy and enforcement issues. This follows a two day workshop last September. These unique public forums will give providers, payors, employers, consumers and scholars an opportunity to raise and pursue a wide range of concerns. The Antitrust Division and the FTC plan to hold three to five days of hearings per month between March 2003 and October 2003, exclusive of August 2003. Ways in which the antitrust laws can accommodate and foster improved quality of care and health outcomes is likely to be an important topic beyond familiar positions from the provider and payor community. The impact of group purchasing organizations on health care innovation and smaller medical device manufacturers is also likely to be topic.

The agencies anticipate that the hearings will culminate with the preparation of a comprehensive joint report. Further information about these hearings will be posted on the

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2 The speaker was co-counsel for the plaintiff in filing of the complaint, but is no longer involved in the case.

Meanwhile, the enforcement agencies have been on a long losing streak in hospital merger cases. The FTC is now taking a hard look backwards to see if some of the mergers that have been permitted actually have resulted in harm to competition and higher prices to consumers. It is reviewing (and that includes subpoenas) the impact of mergers in at least three states, Missouri, Illinois, and California. Empirical evidence of harm may be valuable proof to use either in taking on one of these consummated mergers, or in analyzing new proposed mergers. There is no statute of limitations on government antitrust injunctive actions.

VI. FTC and DOJ Give OK to other provider collaborative initiatives

A. Provider surveys of fee schedules

The Department of Justice had Federal Trade Commission Bureau of Competition have each issued recent business advice letters giving a green light to provider groups seeking to conduct fee surveys. One planned to survey its members’ fee schedules and the other prices paid by payors, and both planned to publish the results. They each got favorable guidance, along with warnings to adhere to proper antitrust precautions to avoid boycotts and price fixing risks. Letter to Jerry B. Edmonds (re Washington State Medical Association), Sept. 23, 2002 http://www.usdoj.gov/atr/public/busreview/200260.htm and FTC Bureau of Competition Letter to Greg Binford (re PriMed Physicians), Feb. 6, 2003 http://www.ftc.gov/bc/adops/030206dayton.htm

B. Network of non-competing hospitals.

DOJ also issued a favorable business review letter for a network of independent community hospitals in Michigan that sought to negotiate collective with employers, but where the hospitals had distinct service areas and were not competitors. The hospitals told DOJ that proprietary data collected from participating hospitals would be treated confidentially, that no individual members would have access to any other member’s costs or prices, and that participating hospitals will remain free to contract individually with health care plans and other payers or to join other provider networks.

VIII. Lawsuit Challenges “Resident Match” Program

The resident match program has operated for years to match medical residency applicants with residency programs. Applicants rank their top preferences, and the programs rank applicants. Applicants are then assigned to their match. The program has been challenged under the antitrust laws. Paul Jung v. Association of American Medical Colleges, D.C.D.C. No. 1:02CV00873 (complaint May 7, 2002).

Plaintiffs have attacked the system broadside. The claim has been filed against a Who’s Who of health education and training organizations and teaching institutions. It is denominated a class action, both for plaintiffs, and for defendant institutions.

The fundamental claim is that applicants are effectively forced to apply through the match program and then are assigned to a single program. This prevents applicants from
benefiting from competition among programs, such as by programs bidding higher resident
salaries and stipends for the most desirable candidates.

The defendants will claim that the match program affords major efficiency benefits to
both applicants and institutions, outweighing any reduction in competition. May 7 in federal court
alleges

VII. Brand-Generic Pharmaceutical Cases -- Hatch-Waxman Act and Orange Book
Manipulation Litigation

There has been an explosion litigation involving alleged restraint of trade and
monopolization in the prescription drug field, largely focused on exclusion of generic competition
by brand name manufacturers. The topic is too broad for thorough discussion here, but a brief
outline is provided. We will not be able to touch on all the cases pending. So far, hospitals
have been fairly quiet as potential plaintiffs, though they can be included in some of the plaintiff
class actions.

A. FTC and Private Enforcement

FTC began investigating the antitrust implications of certain pharmaceutical patent
settlements as early as 1999, and filed complaints and consent orders initially in two matters
(Cardizem CD and Hytrin) in March of 2000. See FTC Press Release, FTC Charges Drug
Manufacturers with Stifling Competition in Two Prescription Drug Markets, March 16, 2000,

Since then, the FTC has broadened its interest in this behavior from the patent
settlements to Orange Book listings and Citizen Petitions by brand manufacturers.

1. Recent activities:

3 This outline focuses on Hatch-Waxman Act related antitrust litigation in the pharmaceutical industry. Other cases include the monopolization litigation against Mylan Laboratories regarding Lorazepam and Chlorazepate. The FTC, fifty State Attorneys General, and two classes of third party payors negotiated settlements with defendants Mylan, Cambrex Corp., and Gyma Laboratories in a series of lawsuits alleging that the defendants entered into anticompetitive agreements to control the market for the pharmaceutical ingredients used ingeneric lorazepam and clorazepate. FTC v. Mylan Laboratories, Inc., Civil 1:98CV03114 (TFH) (D.D.C. 2000) (http://www.ftc.gov/os/2000/11/mylanordandstip.htm). The District Court for the District of Columbia approved the settlements in early February 2002. The case involved an important FTC initiative to seek restitution of overcharges for indirect purchaser consumers. A direct purchaser class action against some of the defendants is still pending.

The FTC also settled allegations against Hearst Corporation concerning its acquisition of a competing publisher of prescription drug data. FTC v. The Hearst Trust, Civ. A. No. 01 119 (D.D.C. Oct. 2001) (see http://www.ftc.gov/opa/2001/12/hearst.htm). The FTC sought disgorgement of alleged monopoly profits and it also has opposed part of a request for attorneys fees by class plaintiffs’ counsel in the parallel private antitrust litigation, on the ground that much of the work had been done by the FTC, so a larger share of the dollars paid out by the defendant should go to injured parties and not to plaintiff class counsel.
a) Extensive FTC activity and private class action litigation initiated by consumer groups and health plans.

b) In 2002, the FTC and DOJ have held hearings on competition and intellectual property law “to develop a better understanding of how to manage the issues at the intersection of competition and intellectual property law and policy.”

B. Background Basics

1. Brand Name vs. Generic Drugs
   a) Consumers save an estimated $8 to 10 billion per year by purchasing generic rather than brand name drugs.

   b) Generic drug companies generally introduce their drugs into the market at roughly 70% of the brand name drug price; additional generic entry may cause the drug price to drop to 50% or less of the brand name price.

   c) By May 2006, the patents on brand name drugs that have combined national sales of roughly $20 billion are expected to expire.

2. The Way We Were: Drug Patents Before 1984
   a) Brand name drug manufacturers filed new drug applications (“NDAs”) with the FDA in order to begin marketing their drug.

   b) Generic drug companies generally could not begin marketing their version of the drug until:

      (1) The brand name drug manufacturer’s patent expired, which usually took 14 years.

      (2) The generic manufacturer meets the FDA’s bioequivalency standard for the brand name drug.

   a) Amended the Federal Food Drug and Cosmetic Act to accomplish competing objectives:

      (1) Encourage generic drug entry;

      (2) Protect existing incentives for brand name drug manufacturers to invest in developing new drugs

   b) Procedure Under Hatch-Waxman

      (1) Brand name manufacturer process
(a) Brand name manufacturers still file NDAs and submit detailed studies to achieve FDA approval for their drug.

(b) Manufacturers list their patents claiming the drug in the FDA’s “Orange Book.”

(2) Generic manufacturer process

(a) Generics can file an Abbreviated New Drug Application (“ANDA”). An ANDA allows a generic manufacturer to “tag along” on the brand name drug manufacturer’s safety studies so long as it proves its drug’s “bioequivalence” with the brand name drug.

(b) For every patent relevant to the brand name drug, the generic ANDA filer must certify either that the patent has expired, will expire, was never filed, or “that such patent is invalid or will not be infringed by the drug for which approval is being sought.” The latter is called a Paragraph IV certification.

(c) A Paragraph IV certification may permit the generic manufacturer to enter the market before the relevant brand name patent expires. But it triggers another section of Hatch-Waxman that permits the brand name manufacturer to sue for patent infringement and automatically stay the FDA’s approval of the generic drug for thirty months or a final order in the infringement suit.

(d) This provision delays entry of the generic and subjects the generic company to the costs of an infringement suit, but protects the brand name drug manufacturer’s research and development investment by preventing generic entry that infringes the brand name drug’s patent.

(e) Hatch-Waxman gives generic manufacturers incentive to bear the cost of the infringement litigation by granting to the first ANDA filer an exclusive marketing period of 180 days during which no other generic can market a version of the brand name drug.

C. Hatch-Waxman Catch-22

1. Hatch-Waxman was supposed to facilitate generic entry. But it also created loopholes for brand name manufacturers to delay generic entry. Currently there are two popular types of cases:

   a) The Patent Infringement Litigation “Settlement”

      (1) Hypothetical: Generic manufacturer makes a Paragraph IV certification claiming its product does not infringe or the brand
name patent is invalid. Brand name manufacturer automatically sues the generic drug manufacturer for patent infringement to delay the generic drug’s entry for thirty months, regardless of the suit’s merit. Brand name manufacturer will spend money on the suit, but will continue to earn monopoly profits on its drug.

(2) Then the brand name manufacturer “settles” the infringement litigation by agreeing to pay the generic manufacturer a portion of its monopoly profits in exchange for the generic’s agreement to stay off the market.

(3) Recent examples of cases involving allegations of such anticompetitive patent settlements include:


(c) FTC complaint and settlement involving Schering-Plough Corp., Upsher-Smith Labs, and American Home Products relating to K-Dur, a potassium chloride supplement worth $220 million per year. Schering paid first-ANDA filer Upsher $60 million and licensed several products of minimal value in exchange for Upsher’s agreement to delay selling its (or any other) generic version of K-Dur. Somewhat similar terms with AHP. The FTC recently settled its complaint with AHP. See

(d) In private litigation, the Hytrin and Cardizem CD courts have declared challenged agreements per se illegal. The agreements went beyond the scope of the patents at issue in the infringement litigation. See In re Terazosin Hydrochloride Antitrust Litigation, 164 F. Supp.2d 1340 (S.D. Fla. 2000); In re Cardizem CD Antitrust Litigation, 105 F. Supp.2d 682 (E.D. Mich. 2000), appeal pending (6th Cir.).

b) Examples of other private litigation raising similar issues: A few of the other patent antitrust lawsuits in private litigation (where there has been no parallel FTC case) include:

(1) In January of 1997, Bayer, Barr, and The Rugby Group signed an agreement involving Cipro, Bayer’s brand name product, whereby Barr agreed not to sell its generic version of Cipro in the United States in exchange for payments of $24 million each to Barr and Rugby. The FTC has been investigating the arrangement, but has filed suit. Private litigants have filed several class action and individual lawsuits, many of which have been combined for multi-district litigation in the Eastern District of New York. On October 1, 2001, that court remanded eight indirect purchaser claims filed under California, Florida, Kansas, and Texas state antitrust and consumer protection laws to their respective state courts, rejecting defendants’ arguments that federal question and diversity jurisdiction existed.

(2) Over thirty private antitrust lawsuits have been filed against Zeneca Co., its successor AstraZeneca, PLC, and Barr Laboratories, Inc., (“Barr”) in connection with an allegedly anticompetitive patent settlement relating to the cancer drug tamoxifen. The complaints allege that after Barr successfully challenged Zeneca’s patent for the drug in 1992, instead of marketing its generic drug, it signed a “confidential settlement agreement” with Zeneca that conceded the patent suit in exchange for $21 million and a license to sell a generic manufactured by Zeneca.

(3) A federal court June 21 threw out two federal class action antitrust lawsuits brought by consumers and third-party payers alleging AstraZeneca illegally tried to keep generic versions of the heartburn drug Prilosec off the market (Twin City Bakery Workers and Welfare Fund v. Astra Aktiebolag, S.D.N.Y., Nos. 01-CIV-9730 (JSR) and 9105 (JSR), dismissed with prejudice 6/21/02).
The class actions alleged AstraZeneca’s patent litigation against generic drug companies In re Omeprazole Patent Litigation, was a sham to keep generic versions of Prilosec off the market. However, in his decision to dismiss the federal antitrust claims with prejudice, Judge Jed Rakoff of the U.S. District Court for the Southern District of New York said the plaintiffs failed to show that AstraZeneca’s Prilosec patent infringement suits against 10 generic drugmakers constituted sham litigation or unlawfully blocked the generics from the market. The judge said plaintiffs could not show that the underlying patent litigation was “objectively baseless” to avoid application of the Noerr-Pennington doctrine.

c) Eleventh Hour Orange Book Listings

(1) Hypothetical: Generic manufacturer files an ANDA, makes a Paragraph IV certification, wins the resulting patent infringement lawsuit, and is about to start marketing its generic drug when the brand name drug manufacturer lists another patent in the FDA’s Orange Book claiming the pioneer drug. This listing automatically delays approval of the generic drug for another 30 months until it can be determined whether the generic drug infringes on the “new” patent. What if this second Orange Book listing is without merit and made in bad faith?

(2) Recent examples of cases involving such allegations include:

(a) In re Buspirone Patent Litigation and Antitrust Litigation, 185 F. Supp. 2d 363; 2002 U.S. Dist. LEXIS 2626; 2002-1 Trade Cas. (CCH) P73,596 (S.D.N.Y. 2002) (holding defendants were not immune under Noerr-Pennington doctrine from antitrust liability); In re Buspirone Patent Litigation and Antitrust Litigation, 185 F. Supp. 2d 340 (S.D.N.Y. 2002) (finding that the generic competitors’ version of buspirone did not infringe defendant’s patent, and that the patent would be invalid if it did cover such uses). Preliminary agreement on a settlement for hundreds of millions of dollars has been announced.


D. Selected Private Litigation Issues
1. Who has standing? What law governs? Federal antitrust law generally gives remedy only to “direct purchasers”. This excludes individual consumers and typical HMO and third party payors that pay pharmacies for prescription drugs. Consumers and third party payors may seek treble damages in states that have created a remedy for indirect purchasers under their own state antitrust laws (so-called Illinois Brick repealer states). In other states (the majority), various types of common law claims, such as unjust enrichment claims, may be pursued.

2. Overlapping remedies: FTC sues for disgorgement; State attorneys general sue under state antitrust and federal laws; generic drug manufacturer sues for lost profits; direct purchasers sue under the Clayton Act for overcharges and for unjust enrichment; indirect purchaser sue under state laws in repealer states and for unjust enrichment. Will manufacturer have to pay duplicative damages?

3. Questions of Proof

   a) How should damages be measured? Damages could be measured as the greater expense incurred for the brand name product in comparison to the expense that would have been incurred had the generic drug been available. A plaintiff will need to show the date generic entry would have occurred, rate of market penetration, etc.

   b) Does plaintiff have to litigate the patent dispute issues to win the antitrust suit? If, in absence of allegedly collusive settlement, brand name manufacturer would have prevailed on patent claim, and enjoined entry by generic maker, where is the harm to competition and consumers?

      (1) In In re Ciprofloxacin Hydrochloride Antitrust Litigation, 166 F.Supp.2d 740 (E.D.N.Y. 2001), the district court rejected defendants’ arguments that the court had federal question jurisdiction and found that plaintiff’s claims did not require resolution of an issue of federal patent law. The district court ruled that it would be a valid legal theory to argue that absent the collusive deal, the parties would have reached an alternative settlement under which the generic drug could have reached market, perhaps under a licensing agreement.

      (2) This legal theory, if supported on the facts in a given case, would make it unnecessary for a plaintiff to relitigate the patent law issues. The court therefore found that it lacked jurisdiction and found remand to state court proper. In contrast, the administrative law judge in the FTC’s Schering-Plough case indicated that if generic would not have won the patent infringement case, there likely could not be an antitrust violation from the settlement activity.