About Recent Developments

Recent Developments is published six times a year by the ABA Antitrust Section Health Care and Pharmaceuticals Committee and contains summaries of recent federal and state court cases, government enforcement actions, and other “recent developments” involving antitrust and privacy issues in the health care and pharmaceutical industries.

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FEDERAL COURT CASES

FTC Prevails in Suit against St. Luke’s Health System
St. Alphonsus Medical Center-Nampa et al. v. St. Luke’s Health System Ltd., No. 1:12-cv-00560 (D. Idaho)

On January 24, 2014, U.S. District Judge B. Lynn Winmill of the Idaho District Court held that St. Luke’s Health System Ltd.’s acquisition of Saltzer Medical Group’s independent physician practice violated the Clayton Act and the Idaho Competition Act. Judge Winmill found that a divestiture of the Saltzer assets was appropriate given the high likelihood that the combined entity could negotiate higher reimbursement rates from health insurance plans that ultimately would be passed on to the consumer. This decision came four months after the completion of an October bench trial involving the merging parties, the Federal Trade Commission (FTC), the Idaho attorney general, and two rival hospitals.

The case against St. Luke’s started in November 2012 when two rival hospitals (St. Alphonsus and Treasure Valley Hospital LP) sued to block the transaction. The plaintiff hospitals alleged that they would be harmed by an immediate decline in referrals from Saltzer, which would force them to lay off staff. However, Judge Winmill denied the plaintiff hospitals’ preliminary injunction bid, holding that the hospitals could not demonstrate the alleged anticompetitive effects of the deal.

In March 2013, the FTC and the Idaho attorney general joined the case and, together with the health care provider plaintiffs. At the October trial, the expanded group of plaintiffs convinced the court that the merger would lead to higher health care costs for employers and consumers. More specifically, Judge Winmill appears to have concluded that the goal of the acquisition may have been to improve patient outcomes, recognizing that there was a trend in compensation to bill for expensive medical procedures rather than secure positive medical outcomes for a patient’s health and quality of life and that the acquisition attempted to return to a patient-centric system. However, he also concluded that, given that the combined entity represented 80 percent of primary care physicians in the Nampa, Idaho area, the merged firm’s dominance would give it too much negotiating leverage over health insurance plans and posed too high a risk for increased rates. In granting a permanent injunction, he found that the goal of rewarding providers through patient outcomes could be reached through other methods that were not anticompetitive or disadvantageous to consumers.

The Memorandum Decision and Order can be found at:

Multiple Class Actions Filed in Pay-For-Delay Suits against Teva and Boehringer

In January, Boehringer Ingelheim Pharmaceuticals Inc. and Teva Pharmaceuticals USA Inc. were the subject of three new federal antitrust class actions filed by: (1) drug distributor American Sales Co. in the District of Connecticut;
(2) a health and welfare fund of the International Union of Painters and Allied Trades, Council 21 in the District of Minnesota; and (3) a health and welfare fund for NECA-IBEW in the Eastern District of Pennsylvania, (collectively “Complaints”). A similar suit was filed in November 2013 by wholesaler Miami-Luken Inc.

The proposed class actions allege that Boehringer conspired with certain generic pharmaceutical manufacturers to pay them to not produce and sell a generic equivalent of Aggrenox, a stroke medicine. According to the Complaints, Boehringer began marketing and selling Aggrenox in 1999 after receiving a patent and U.S. Food and Drug Administration (FDA) approval. According to the Complaints, Aggrenox quickly became a commercial success with profits of $366 million by 2008.

Boehringer filed a patent infringement suit after Barr Pharmaceuticals Inc., a Teva subsidiary, which had sought FDA approval to market its own version of Aggrenox. In a settlement of this lawsuit, Boehringer (i) paid Barr $120 million over seven years, (ii) granted Barr a license to sell an authorized generic version of Aggrenox under Boehringer’s New Drug beginning in July 2015, and (iii) agreed to a co-promotion agreement.

The Complaints all allege that the $120 million patent settlement and co-promotion agreement were a pay-for-delay deal that delayed Barr’s independent introduction of a generic Aggrenox product in violation of antitrust and unfair trade practice laws. The Complaints allege that as a direct result of the defendants’ pay-for-delay agreement, the members of the various proposed classes paid more for Aggrenox than they would have paid otherwise. On behalf of the proposed class, plaintiffs are seeking a judgment declaring unlawful the payment agreement with Barr; an injunction pursuant to Section 16 of the Clayton Act; and attorney fees, compensatory and treble damages.

The defendants have not yet filed a response to the Complaints.

**Judge Rules Actavis Decision Only Requires Scrutiny of Cash Deals**

*Louisiana Wholesale Drug Co. Inc. v. SmithKline Beecham Corp., No. 2:12-cv-00995 (D.N.J.)*

On January 24, 2014, New Jersey federal Judge William H. Walls affirmed dismissal of an antitrust class action by direct purchasers of Lamictal, a medication prescribed to treat epilepsy and bipolar disorder, against GlaxoSmithKline LLC (GSK) and Teva Pharmaceutical Industries Ltd (Teva). Direct purchaser plaintiffs alleged that a “no authorized generics” (No-AG) provision in a settlement agreement between GSK and Teva violated federal antitrust laws. Under the settlement agreement, GSK permitted Teva to sell generic versions of lamotrigine, the active ingredient in Lamictal, before the relevant patent expired. In return, GSK agreed not to launch its own authorized generic versions of Lamictal products during Teva’s first-filer exclusivity period.

In December 2012, Judge Walls granted GSK and Teva’s motion to dismiss the direct purchaser suit, finding that *In re K-Dur Antitrust Litigation*, 686 F. 3d 197 (3d Cir. 2012), applied only to deals that included cash settlements. Plaintiffs appealed, but in July 2013 the Third Circuit remanded to the District Court for review in light of the Supreme Court’s decision in *Federal Trade Commission v. Actavis*, 133 S. Ct. 2223, 570 U.S. ___ (2013). At the District Court, Plaintiffs filed a motion to reconsider dismissal, arguing that under *Actavis* a No-AG provision is subject to antitrust scrutiny under a rule-of-reason standard.
The District Court disagreed and found that *Actavis* requires rule-of-reason scrutiny to be applied only to agreements in which the parties exchange cash. Specifically, Judge Walls interpreted *Actavis* to lay out a three-part test for determining when to apply antitrust scrutiny to a settlement agreement where the District Court must ask whether (i) the agreement includes a reverse payment; (ii) the reverse payment was large and unjustified; and (iii) the parties to the agreement had market power and exercised it, resulting in unjustified, anti-competitive consequences. In other words, the District Court will apply rule-of-reason antitrust scrutiny only after the first two steps are met.

The District Court held that whether an agreement includes a reverse payment under step one hinges on what the parties exchanged in the settlement, and must include an exchange of money. That the agreement conferred substantial financial benefits on the parties is not sufficient to advance to step two of the test. Applying this standard, the District Court found that the agreement between GSK and Teva did not include a reverse payment, as the agreement only prohibited GSK from introducing its own authorized generic of Lamictal during Teva’s first filer exclusivity period. The District Court denied the direct purchasers’ motion to reconsider, concluding that since *Actavis* applies only to settlements that contain a cash exchange, the decision did not change the District Court’s dismissal of the direct purchasers’ case.

**Directs Purchasers’ Fee Request Reduced While Indirect Purchasers Reach $2.2 Million Settlement in Vitamin C Antitrust Case**

_In re Vitamin C Antitrust Litig., No. 1:06-md-01738 (E.D.N.Y.)_

A federal judge reduced direct purchasers’ request for $13.7 million in fees and expenses to $4 million following a March 2013 jury verdict that found that North China Pharmaceutical Group Corporation (NCPG) and its vitamin C manufacturing unit HeBei Welcome Pharmaceutical Company Limited participated in a conspiracy to fix prices in China’s vitamin C industry. The jury awarded the direct purchaser plaintiffs $54 million that was later trebled to $153 million. In May 2013, the direct purchasers’ attorneys filed a motion seeking an additional $13.7 million in fees and expenses arguing that the District Court should not apply an offset for attorneys’ fees and expenses received from previous settlements with the other defendants because an enhancement to the direct purchaser attorneys’ lodestar amount was justified based on the difficulty of the litigation.

On December 30, 2013, Judge Brian Cogan of the Eastern District of New York rejected this argument, applied a nearly $10 million offset, and reduced the $13.7 million request to $4 million. Judge Cogan concluded that the overall fee request was reasonable and commended the direct purchaser attorneys for overcoming, “factual and legal issues … that have never been considered in this district and very possibly would be unique anywhere.” However, Judge Cogan reasoned that “[f]ailing to apply an offset amounts to a windfall,” which “would be manifestly unreasonable” and that he did “not see the linkage between an enhancement and an offset for fee recoveries that have actually been received.” He
added the additional $4 million in fees and expenses with interest to the final judgment.

The total amount awarded is approximately $157 million. NCPG and HeBei have appealed to the United States Court of Appeals for the Second Circuit.

In addition, in December 2013, indirect purchasers of vitamin C reached a $2.2 million settlement with defendant Weisheng Pharmaceutical Company Limited and its parent CSPC Pharmaceutical Group Limited. The indirect case was stayed during the direct purchaser damages case. Following the conclusion of that trial, settlement talks between the indirect purchasers, Weisheng, and CSPC resumed in summer of 2013 and eventually resulted in the $2.2 million settlement which if approved by the court, will leave only NCPG and HeBei defending against the indirect purchasers’ antitrust claims.

Federal Judge Agrees to Enforce 2012 Settlement Agreement between UPMC and Highmark

UPMC v. Highmark Inc., et al., No. 2:12-cv-00692 (W.D. Pa.)

In December 2013, a Pennsylvania U.S. District Judge ordered the University of Pittsburgh Medical Center (UPMC) and insurer Highmark Inc. to dismiss their longstanding mutual antitrust lawsuits and agreed to enforce a 2012 settlement agreement. On December 31, 2013, Chief Judge Joy Flowers Conti signed the Order, which dismissed the action with prejudice. As a result, Highmark must compel its affiliate West Penn Allegheny Health System Inc. to abandon West Penn’s 2009 antitrust lawsuit against UPMC and UPMC must drop its 2012 antitrust claims against Highmark and West Penn.

The antitrust suits have been proceeding since 2009 when West Penn accused UPMC and Highmark of attempting to stifle competition by conspiring to create a monopoly. West Penn subsequently became a Highmark affiliate, with UPMC filing antitrust lawsuits against Highmark and UPMC during the acquisition process. UPMC and Highmark had agreed to a tentative settlement in May 2012, which was mediated by Pennsylvania Governor Tom Corbett’s office. A draft settlement was presented by UPMC and a settlement was reached on October 23, 2013. However, a dispute arose when Highmark subsequently expanded the release language to include all current and future litigation to which they are both parties.

$4.75M Antitrust Settlement Approved in DDAVP Suit

In re: DDAVP Indirect Purchaser Antitrust Litig., No. 05-cv-2237 (S.D.N.Y)

On December 18, 2013, U.S. District Judge Cathy Seibel approved a $4.75 million settlement in a class action suit against pharmaceutical companies Ferring, BV and Aventis Pharmaceuticals, Inc. (a subsidiary of Sanofi). The plaintiffs, indirect purchasers of DDAVP, initially brought suit in the Southern District of New York alleging that the defendants delayed the approval and sale of generic versions of DDAVP, an antidiuretic drug marketed by Sanofi. The plaintiffs’ class includes all DDAVP tablet purchasers from February 18, 2001 to December 31, 2010. The judge also approved plaintiffs’ attorney’s fees of $1,567,500. Ferring will contribute $3.95 million and Aventis $800,000 to the settlement fund.

This is the second antitrust suit settled by the defendants in this matter. In 2011, the defendants
settled with a proposed class of direct purchasers of DDAVP for $20.25 million. Both suits stemmed from allegations that the defendants misled the United States Patent and Trademark Office (USPTO) to extend the DDAVP patent after the initial patents were set to expire. The USPTO initially granted the defendants’ patent, allowing them to file patent infringement suits against generic producers of DDAVP, resulting in an automatically 30-month stay on approval by the FDA of generic versions of DDAVP. When the courts held that the defendants fraudulently obtained the patent, DDAVP purchasers filed suit claiming that the defendants artificially delayed approval of generic DDAVP through frivolous litigation.

**Defendants Argue that Noerr Immunizes Settlements in Pay-for-Delay Cases**

*Fed. Trade Comm’n v. Watson Pharm., Inc. et al., No. 1:09-cv-00955 (N.D. Ga.)*

The FTC’s suit against AbbVie Products LLC, Par Pharmaceuticals Cos. Inc., Paddock Laboratories Inc., and Actavis Inc. for alleged payments to delay generic entry through Hatch-Waxman Act patent settlements resumed last month. For several months, the defendants delayed their response to the FTC complaint, in part due to a procedural dispute related to private actions over the same drug at issue in the Actavis case, Androgel. U.S. District Court Judge Thomas W. Thrash Jr. of the Northern District of Georgia set a January 15, 2014 deadline for Actavis and other drug makers to respond to the FTC’s pay-for-delay complaint. Along with their answer, Par, Paddock, and AbbVie, filed a motion to dismiss the FTC’s case, arguing that the Noerr-Pennington doctrine shielded them against the agency’s antitrust claims because a federal court had previously approved the patent settlement underlying the case.

The companies argued that the court’s consent judgment in the patent case mandated an entry date that the parties had agreed on, and that the order triggered Noerr immunity. The district court, however, never considered the application of the doctrine because it granted the parties’ motion to dismiss on grounds that the settlements were legal.

The motion is the most recent development in a series of events since the FTC accused the companies of delaying the entry of generic Androgel to the detriment of consumers. Last year, the Supreme Court revived the FTC’s case against the drug makers by ruling that pay-for-delay agreements are subject to federal antitrust law under a rule-of-reason standard. Prior to the Actavis ruling, several courts held these agreements to be legal provided they did not exceed the scope of the patent—a legal standard that the Supreme Court rejected.

**District Court Grants Direct Purchasers’ Motion for Class Certification in Antitrust MDL against AstraZeneca**

*In re: Nexium (Esomeprazole) Antitrust Litig., No. 1:12-md-02409 (D. Mass.)*

A Massachusetts district court granted direct purchaser plaintiffs’ motion for class certification in the multidistrict litigation related to AstraZeneca’s alleged monopolization scheme to prevent generic versions of Nexium from entering the market. Nexium is a proton pump inhibitor used for the treatment of acid reflux disease and generates more than $3 billion in sales each year.

In their complaints, the plaintiffs allege that AstraZeneca entered into non-competition agreements with co-defendants Ranbaxy Pharmaceuticals, Inc., Teva Pharmaceutical
Industries, Ltd., and Dr. Reddy’s Laboratories Ltd., offering to exchange money in return for the companies’ agreement to delay marketing their generic drugs until May 27, 2014. These payments were allegedly disguised as funds to settle patent infringement suits if the generic companies agreed to drop their challenges to Nexium patents. The plaintiffs contend that low-priced generic versions of Nexium would have been available to consumers as soon as April 14, 2008, but, because of AstraZeneca’s agreement with the generic companies, consumers were forced to pay higher prices for branded Nexium.

The direct purchaser plaintiffs, including wholesalers and retailers such as Walgreens, Safeway, and Kroger, brought the suit under federal antitrust laws. Plaintiffs moved for class certification July 2013. Defendants opposed, arguing that courts have suggested there should be a minimum of 40 members to grant class certification and that the magnitude of damages suggests the most appropriate course would be to proceed on a joinder basis. Judge Young of the District of Massachusetts disagreed and granted plaintiffs’ motion for class certification on December 11, 2013, noting that the class size in conjunction with subjective factors like the location of class members and judicial economy demonstrate that plaintiffs meet the numerosity requirement for class certification.

Payors Win Class Certification in Evanston Northwestern Follow-On Litigation
In re: Evanston Nw. Healthcare Corp. Antitrust Litig., No. 1:07-cv-04446 (N.D. Ill.)

Almost four years after first moving for class certification, purchasers of inpatient and hospital-based outpatient services from North Shore University Health System (formerly Evanston Northwestern Healthcare) were granted class certification. The class alleges that Evanston Northwestern Healthcare’s acquisition of Highland Park Hospital in 2000 resulted in higher prices. The FTC challenged the same transaction, finding that it had led to “substantially higher” cost increases, and required North Shore and Highland Park separately to negotiate rates with payors.

The plaintiffs’ initial class certification motion was denied in March 2010. The district court held that the plaintiffs had not satisfied Rule 23(b)(3)’s predominance prerequisite given that the plaintiffs could not establish that North Shore had uniformly raised prices.

Upon an interlocutory appeal, the Seventh Circuit vacated and remanded the district court order, finding that the plaintiffs had met the predominance requirement and that price uniformity is not necessary to claim a classwide injury. In granting class certification, the district court relied on the Seventh Circuit’s support of the “difference-in-differences” methodology proposed by the plaintiff’s expert to overcome manageability concerns. The court endorsed the use of common evidence to show that all of the class members suffered some antitrust impact.

On remand, the district court found that the plaintiffs had satisfied the Rule 23(a) prerequisite and that superiority was the only class-certification requirement remaining. North Shore’s main argument against superiority was that it had a contract right to arbitrate (rather than litigate) disputes against the managed care organizations (MCOs).

According to U.S. District Court Judge Chang, it was not clear that the MCOs in the suit were required to arbitrate the antitrust claims. Judge Chang decided to certify the class without considering the possibility of arbitration and
relied instead on the court’s ability to decertify or alter the class later.

**Federal Judge Awards Prime Healthcare Temporary Injunction in Christ Hospital Bankruptcy Case**


In March 2013, Prime Healthcare Services Inc. filed suit in a New Jersey court against rival hospital owner Hudson Hospital Holdco (now CarePoint Health). Prime alleged that CarePoint stifled competition in violation of New Jersey law by campaigning to prevent it from acquiring hospitals in New Jersey and Rhode Island. The complaint alleged that through the orchestration of political, union, and community opposition, CarePoint forced Prime’s hospital purchase agreements to fall through, allowing CarePoint to then purchase them at a lower price. In particular, Prime alleged that CarePoint sought to make it untenable for Prime to purchase Christ Hospital after Prime had infused the hospital with $6 million to keep it afloat while finalizing the deal to purchase the hospital. CarePoint then purchased the struggling facility for $10,000 less than the price agreed upon between Prime and Christ Hospital.

In a December 2013 ruling, a New Jersey bankruptcy judge disagreed, ruling that Prime failed to take necessary steps to secure its own interests in the deal. The judge noted that “Prime had complete notice and knowledge of the terms of the sale of hospital assets but did not object to the sale or apply for any adequate protection of its interests.” The judge ruled that his dismissal of Prime’s economic tort claims would have no bearing on ongoing litigation over Prime’s allegations of broader anticompetitive behavior by Hudson, which apply to other hospital acquisition deals.

Prime appealed the dismissal, and on January 7, 2014, a New Jersey federal judge granted Prime a temporary injunction against the bankruptcy court’s order. Oral arguments on the stay were held on January 16, and the parties await a decision.

### Correction on “Effexor Suit Stalled Until Supreme Court Decides K-Dur Cert Petition.”

The December 2013 issue of Recent Developments incorrectly stated that a stay was in effect in *In re Effexor XR Antitrust Litigation*. While a stay was originally put in place in 2012, it was lifted after the Supreme Court released its decision in *Actavis*. The judge granted the FTC permission to file an amicus brief relating to the *Actavis* decision and no-authorized-generic commitments. The judge is expected to release a decision on the motion to dismiss early this year. We regret the error.
Pennsylvania Revives Conspiracy Claims in Challenge to Skelaxin “Pay-For-Delay” Agreement

Hygrosol Pharm. Corp. v. Roberts et al., No. 00213 (Ct. Com. Pl. Cnty. of Phila.)

On December 13, 2013, a Philadelphia County judge reinstated two previously dismissed counts brought against generic drug marketer Mutual Pharmaceutical Co., Mutual’s Chairman Richard Roberts (collectively “Mutual”), several Mutual affiliate companies, and Pfizer subsidiaries King Pharmaceuticals, Inc. and King Pharmaceuticals Research and Development, Inc. (collectively “King”).

Researcher Spiridon Spireas and Mutual have been engaged in litigation for several years, stemming from disputes over the ownership, use, and commercialization of patented technology used in the development of a generic muscle relaxant. Spireas alleged that Mutual and King entered into agreements to delay entry of a generic version of King’s Skelaxin product. Mutual’s generic version would have used technology licensed from Spireas and Mutual would have been required to pay Spireas a royalty pursuant to the terms of license agreement.

Spireas and co-plaintiff Hygrosol Pharmaceutical Corp. filed a complaint in November 2012 accusing Mutual, in concert with King, of racketeering activity under New Jersey’s RICO statute, civil conspiracy, and interference with contractual rights. On May 1, 2013, the court dismissed the plaintiffs’ racketeering claims and dismissed the contract interference and conspiracy claims against all defendants except King. The court’s December 13, 2013 decision revives the contract interference and civil conspiracy claims, but reaffirms dismissal of the RICO charges.

The dispute dates back to 1998, when Spireas and his co-inventor entered into a license agreement with Mutual that granted Mutual rights to make, sell, or sub-license drug products developed using Spireas’ patented technology in the United States. Pursuant to the license agreement, that technology was to be used by Mutual to develop a generic version of metaxalone, a muscle relaxant marketed in the U.S. by King under the brand name Skelaxin. In 2003, Mutual filed an abbreviated new drug application (ANDA) under the Hatch-Waxman Act seeking FDA approval to sell generic Skelaxin using Spireas’ technology. According to Spireas’ allegations, Mutual was positioning itself between 2003 and 2005 as a potential rival to King, as the two companies battled before the FDA and in federal court patent litigation. Spireas therefore anticipated that, upon FDA approval, Mutual would enter the market with a generic metaxalone pharmaceutical and would pay Spireas a royalty fee under the 1998 license agreement.

Spireas claims Mutual altered its business strategy in 2005 to one of collusion instead of competition. Specifically, Mutual and King allegedly “sabotage[d] Mutual’s pending ANDA for a generic form of Skelaxin” and teamed up to prevent other generic entry in exchange for a $35 million payment from King to Mutual, plus additional future royalties. Spireas alleges that Mutual and King determined that it would be more profitable to “stand down” from their competitive posture and divide Skelaxin’s monopoly profits than for Mutual to market a generic version of Skelaxin and share its revenues with plaintiffs under the 1998 agreement.

Spireas previously challenged this arrangement in 2010 in the Eastern District of Pennsylvania under Section One of the Sherman Act. However, that
complaint was dismissed for lack of standing. The present state court civil allegations were initially dismissed earlier this year because the court had ruled that Mutual, as signatory to the 1998 license agreement, could not interfere with its own contract. Upon reconsideration, the court held that additional named defendants could plausibly have conspired to cause Mutual to violate its agreement with Spireas.
AGENCY DECISIONS AND OTHER ACTIVITES

FTC Holds Workshop Examining Impact of Recent Legislative and Regulatory Naming Proposals on Competition in the Market for Biologics


On February 4, 2014, the FTC held a public workshop in Washington, D.C. to examine competition issues surrounding biologics and follow-on biologics.

The workshop stemmed from the FTC’s longstanding interest in promoting competition in the pharmaceutical industry, and focused specifically on how state regulations and naming conventions affect the development of follow-on biologics and competition in the market for biologics. Biologics represent the fastest-growing sector of pharmaceuticals and include vaccines, antitoxins, blood products, proteins, and monoclonal antibodies. These medicines consist of molecules that typically are larger and more structurally complex than “small molecule” pharmaceutical products. Biologic medicines also tend to be extremely expensive, which may limit access to these life-extending treatments.

The pathway for FDA approval of generic drugs (“small molecule” pharmaceuticals) was been streamlined by enactment of the Hatch-Waxman Act in 1984. Not until 2010, however, did Congress pass the Biologics Price Competition and Innovation Act to establish an analogous streamlined pathway for FDA approval of follow-on biologics. The FTC held the workshop to explore the reasons why the FDA has yet to approve any follow-on biologic based on a “reference” biologic and to examine recently considered and passed state laws that could affect the incentives for manufacturers to develop follow-on biologics using the new abbreviated approval system. Some commentators expressed concerns that these new state laws could hamper the development of lower-cost follow-on biologics.

Participants examined competition between branded and generic drugs under Hatch-Waxman, considered how new state regulations concerning biologics could affect compliance costs and other regulatory costs for follow-on biologics, discussed what the FTC, FDA, and other branches of the federal government could do to enhance competition and accommodate the development and approval of follow-on biologics, and discussed the circumstances under which potential entrants would be willing to invest in the development of follow-on biologics in order to use the abbreviated pathway.

The FTC is accepting public comments concerning these topics until March 1, 2014. Comments may be submitted at: https://ftcpublic.commentworks.com/ftc/biologics-workshop/

FTC Interested Dental Care Services and CODA’s Proposed Standards


On December 2, 2013, the staffs of the FTC Office of Policy Planning, Bureau of Economics, and Bureau of Competition (collectively, “FTC staff”) made a submission to the American Dental Association’s Commission on Dental Accreditation (CODA). CODA published
Accreditation Standards for Dental Therapy Education Programs to encourage the development of a nationwide dental therapy profession in the United States. Dental therapist professionals are more common in other countries where they provide preventive and basic reparative dental services, much like dentists, but typically at a lower cost. Dental therapists differ from dental hygienists, in that they are trained and licensed to provide some, but not all, services traditionally carried out only by licensed dentists.

FTC staff recognized that in dental care, as in other areas of health care, workforce modifications expanding the use of mid-level providers can increase the supply of basic services and improve the overall quality of care. Because the oral health workforce is not well distributed, access to dental care is inadequate in many areas. Dental therapists are likely to be the most effective at expanding access to care, especially to the underserved.

FTC staff commented that CODA’s proposed dental therapists’ standards might help encourage the development of a nationwide dental therapy profession that could enhance competition in the supply of dental services. Nevertheless, the FTC staff cautioned that the standards’ effectiveness may be limited if they include statements about a supervising dentists’ responsibility for diagnosis and treatment planning. Although the standards do not specify the type of supervision, they could be interpreted to require supervision by an on-site dentist. This requirement would eliminate any ability of the dental therapists to provide cost-effective care in underserved markets. The FTC staff recommends that states are the more appropriate authority to address licensing and scope of practice.

The FTC staff also commented that CODA should consider developing additional standards for master’s and graduate level programs to train dental therapists to conduct oral evaluations and develop treatment plans without an on-site supervising dentist.

**FTC Proposes Consent Agreements with Marketers of Genetically Customized Nutritional Supplements**


Two marketers of genetically customized nutritional (GCN) supplements agreed to settle several FTC complaints against them, including charges of deceptive advertising and misleading health claims, and charges that their data security practices were unfair and deceptive. The proposed consent agreements are subject to a thirty-day public comment period and will terminate after twenty years, with certain exceptions.

GeneLink, Inc., also doing business as GeneLink Bioscience, Inc., and its former subsidiary foru™ International Corporation, formerly known as GeneWize Life Sciences, Inc., marketed GCN supplements and a skincare product through a multi-level marketing network. According to the FTC complaints, the companies made false and unsubstantiated claims that violated the FTC Act. GeneLink and foru™ represented that (i) their GCN supplements were proven to be able to mitigate generic disadvantages that they identified through their own generic assessments, (ii) the GCN supplements reduced an individual’s risk of impaired health or illness, and (iii) the GCN supplements treated or mitigated diabetes, heart disease, arthritis, and insomnia. GeneLink and foru™ also represented that their skincare products were scientifically proven to reduce wrinkles and improve skin firmness, and enhance or diminish other ailments. Other FTC complaints alleged that the companies unlawfully engaged in
inadequate information security practices related to the collection, use, disclosure of personal information including social security numbers, bank account numbers and, genetic information.

The proposed settlements are designed to prevent GeneLink and foru™ from engaging in similar conduct in the future and to prohibit the companies and their affiliates from: (i) making any representation that a covered product is effective in the diagnosis, cure, mitigation, treatment or prevention of any disease, unless such representation is not misleading and is based upon competent and reliable scientific evidence including clinical trials to substantiate that the claim is true; (ii) making any representation about the health benefits, performance or efficacy of any covered product or covered genetic test or assessment unless such representation is not misleading and is based upon competent and reliable scientific evidence to substantiate that the claim is true; (iii) misrepresenting the existence, contents, validity, results, or conclusions of any test, study or research; and (iv) misrepresenting the extent to which they maintain and protect any personal information collected from or about their customers.

FTC Settles Deceptive Advertising Charges Against Four Fad Weight Loss Products for Over $37 Million

The FTC settled charges with four entities for over $37 million as part of its ongoing initiative to stop misleading claims for weight loss and body-slimming products. Operation Failed Resolution targets national marketers who used deceptive and misleading advertising claims to sell weight loss products. On January 7, 2014, the FTC announced settlements with four entities: Sensa Products, LLC, L’Occitane, Inc., HCG Diet Direct, and LeanSpa, LLC.

Sensa Products marketed a powdered food additive that claimed to make users feel full faster by enhancing a meal’s taste and smell. The FTC charged Sensa with using deceptive advertising, unsubstantiated clinical claims, and misleading expert endorsements. Sensa settled the charges for $26.5 million.

L’Occitane marketed a body cream that they claimed had body-slimming capabilities. The FTC charged that these claims were unsupported by reliable medical or scientific evidence. L’Occitane has agreed to pay $450,000.

HCG Diet Direct marketed a diluted liquid form of human chorionic gonadotropin (hCG)—a hormone produced by the human placenta. HCG Diet Direct claimed that users would experience substantial weight loss by combining a reduced caloric diet with one drop of hCG per meal. The FTC charged the entity with mislabeling drugs under the FDA Act, false claims of FDA approval, misleading endorsements, and other false and unsupported claims. HCG Diet Direct settled for $3.2 million, but the judgment is suspended based on HCG’s inability to pay.

LeanSpa marketed acai berry and colon cleansing weight loss products. The FTC charged LeanSpa with deceptive weight loss claims and misleading free trial advertisements, and alleged that many users paid for recurring monthly shipments without notice. LeanSpa settled the charges for over $7 million, and litigation continues against others who were part of LeanSpa’s affiliate network.

FTC Requires Divesture of Two Hospitals in Approving Community
Health Systems, Inc.’s Acquisition of Health Management Associates, Inc.


In late January, the FTC approved the $7.6 billion acquisition of Health Management Associates, Inc. (HMA) by Community Health Systems, Inc. (CHS), with the condition that two HMA hospitals be divested within six months after the final order is issued. The FTC alleged that the combination would lessen competition for general acute-care services in Etowah County, Alabama (including the City of Gadsden) and Darlington County, South Carolina. Specifically, the FTC required the divestiture of 216-bed Riverview Medical Center in Gadsden and 116-bed Carolina Pines Regional Medical Center in Hartsville, South Carolina to a Commission-approved buyer within six months. In addition, the proposed order requires that the companies hold the hospitals to be divested as separate assets and continue to maintain their competitive viability until the sales are completed. Finally, for the next ten years, CHS is required to provide prior notice to the FTC of any proposed acute care inpatient hospital acquisitions in the Darlington County and Etowah County areas.

Gadsden currently has only two significant general acute-care inpatient hospitals, HMA’s Riverview Medical Center and CHS’s 346-bed Gadsden Regional Medical Center, and combining the two would give CHS a near-monopoly in the area. In the Darlington County area, the major hospitals are CHS’s Carolinas Hospital-Florence, with 310 beds, HMA’s 116-bed Carolina Pines Regional Medical Center, and 453-bed McLeod Regional Medical Center. The acquisition would therefore reduce the number of competing in patient acute care hospitals in the area from three to two.

The largest hospital system in the country, HCA, has 162 hospitals and reported $33 billion in revenue last year. After the acquisition, CHS will have 204 hospitals, with a combined bed count of over 31,000, in 29 states and expected revenue of approximately $20 billion.

FTC Staff Signals Support for Proposed Massachusetts Law Removing Physician Supervision Requirements for Nurse Practitioners and Nurse Anesthetists


At the request of Massachusetts State Representative Kay Khan, the FTC Staff provided comments last month on Massachusetts House Bill 2009. The bill is currently under consideration by the Massachusetts Legislature and, if approved, would promote independent practice by nurse practitioners (NPs) and nurse anesthetists (NA) in the Commonwealth. Specifically, the bill: (i) removes a requirement that NPs (and NAs delivering preoperative care) enter into formal supervisory agreements with physicians to order tests or prescribe medication; (ii) allows NAs greater independence in administering and supervising intravenous anesthesia; and (iii) allows NAs and NPs to dispense, administer, and prescribe certain controlled substances.

The FTC Staff noted that providing NPs and NAs with greater independence and authority would allow advanced practice registered nurses (APRNs) to provide care in underserved communities throughout the state, which would significantly enhance access to health care for Massachusetts citizens, particularly in light of the provider shortages facing the state. In addition,
the staff said, expansion of the supply of health care providers would tend to reduce health care costs, especially because APRNs tend to be lower-cost providers than physicians dispensing the same care. The Staff also suggested that lessening restrictions on NAs and NPs would be consistent with encouraging new models of health care delivery, like expansion of limited service clinics and team-based care that may be successful in different practice settings, or treating different patient populations. Finally, the Staff recognized that patient safety concerns justified certain supervisory, licensing, and oversight requirements, but noted that loosening restrictions on APRN practitioners had resulted in enhanced health care outcomes in other states without creating or exacerbating patient risk.
INTERNATIONAL

France’s Competition Authority Fines Merck’s Schering-Plough Unit €15.3M

See http://www.autoritedelaconcurrence.fr/user/standard.php?id_rub=482&id_article=2283

On December 19, 2013, France’s Competition Authority (Autorité de la concurrence) fined Merck & Co.’s Schering-Plough unit €15.3 million (approximately $20.9 million) for an alleged abuse of a dominant position by attempting to suppress generic competition for its drug Subutux. In addition, the competition authority fined Merck and Schering-Plough’s supplier Reckitt Benckiser with fines of €414,000 and €318,000, respectively, for their roles in the anticompetitive agreements. The investigation was a result of a complaint by Actavis-owned Arrow Generiques, after it faced difficulty in finding entry into the French market with a generic version of Subutux.

From as early as 2005, Schering-Plough, Merck, and Reckitt Benckiser allegedly made efforts to prevent a generic version of Subutux manufactured by Arrow from gaining market share. Through rebates and customer loyalty programs aimed at both physicians and pharmacists, the companies allegedly sought to curb the rate of generic substitution at both the prescription and delivery levels. Further, Schering-Plough held training seminars to induce their clients to fear switching to the generic version. The company stated that there existed a “risk of misuse and trafficking” of generic Subutux, a claim with no real factual basis. As a result, a generic buprenorphine had a penetration rate that was half the rate of similar generic drugs during their first year on the French market.

Schering-Plough did not contest the allegations and agreed to take appropriate actions to ensure compliance with competition law when marketing its drugs against generic competition.

EC Fines J&J and Novartis for Alleged Pay-for-Delay Agreement in Netherlands


On December 10, 2013, the European Commission (EC) announced the imposition of significant fines against U.S.-based Johnson & Johnson and Swiss pharmaceutical giant Novartis AG. The EC found that the companies’ Dutch subsidiaries had entered into an agreement that had the effect of delaying generic entry of a pain-relieving product commonly used by cancer patients in the Netherlands. After taking into account the seventeen-month duration of the agreement and its seriousness, the EC fined J&J €10.8 million ($14.8 million) and Novartis €5.5 million ($7.5 million).

The EC launched an investigation into J&J and Novartis’ practices in October 2011. In January 2013, the EC sent a formal statement of objections to the parent companies, J&J subsidiary Janssen-Cilag B.V. and Novartis subsidiary Sandoz B.V. According to the EC, J&J’s branded fentanyl-based patch Duragesic had lost its patent protection in the Netherlands in 2005. At that time, Sandoz was prepared to launch its generic fentanyl patch. Sandoz’s entry appeared imminent, as the company had already produced the necessary packaging material for its generic product.
The EC alleges that, rather than compete, Sandoz and Janssen-Cilag agreed to delay Sandoz’s entry into the market under the pretext of a “co-promotion agreement.” Rather than engage in legitimate co-promotional activities, Sandoz instead agreed not to enter the market in 2005 and 2006 in exchange for monthly payments that exceeded what Sandoz expected to earn if it had sold its generic product. In support of its allegations, the EC relies on internal company documents that describe Sandoz agreeing to forego market entry in exchange for “a part of [the] cake” and to “keep the high current price.” The agreement ended in December 2006 when a third party was poised to launch a generic fentanyl patch.

The EC’s investigation of J&J and Novartis is part of its broader inquiries into the European pharmaceutical sector. Following its examination of the industry in 2008 and 2009, the EC has also filed competition complaints against manufacturers of antidepressants and cardiovascular medications. The EC has also monitored patent settlements in the sector closely and has issued policy recommendations designed to facilitate speedier market entry.

**EC Report Cites a Decrease in Patent Settlement Agreements that Attract a High Level of Antitrust Scrutiny**


On December 9, 2013, the EC issued a report on patent settlement agreements between originator and generic companies, finding that while the number of overall settlements had risen, the number of settlements that are problematic from an antitrust perspective had decreased. The report includes settlements that relate to patent infringement, patent validity, and other commercial disputes.

The report covers the period from January 1, 2012 to December 31, 2012, and is based on patent settlement agreements of 53 originator and 66 generic companies. The report characterizes “problematic” patent settlements as those that delay generic entry into the market, reach beyond a patent’s period of protection, or restrict a generic company’s ability to challenge the validity of the originator’s patent. According to the report, the most problematic agreements, which attract the highest degree of antitrust scrutiny are those in which an originator limits a competitor’s access to the market while simultaneously providing monetary compensation or a “value transfer” that aids the generic company in increasing marketability.

The results of the study showed that only 7 percent of all settlements (12 of 183) fell into the “problematic” category. The report further revealed that these problematic types of settlements have decreased over the years. Given that the total number of overall patent settlements has increased, the EC concluded that its antitrust actions have “not hindered companies in settling patent disputes nor driven them to litigate such disputes until the end...[and] in most cases companies are able to find solutions that are unproblematic under EU antitrust rules.”

**EC Approves State Aid for Innovative Medical Services**


The EC has approved state aid for telemedicine services in Saxony, concluding that the aid, subject to certain restrictions, is in line with Article 107(3)(c) of the Treaty on the functioning of the European Union (TFEU) since it does not
adversely affect trading conditions and makes medical care more accessible for citizens. Article 107 generally limits the ability of member states of the European Union to distort competition by providing state aid or support to a specific industry or private entity.

The aid in question would support the setup of a platform for telemedicine services in eastern Saxony to improve access to medical services for citizens in remote areas. Telemedicine allows patients to consult with their doctors remotely, thus providing the ability to deliver medical care to patients that cannot easily visit a healthcare provider in person. Carus Consilium Sachsen GmbH (Carus), a specialist medical sponsor, and T-Systems International GmbH (T-Systems), a subsidiary of Deutsche Telekom, will receive the aid to build the telemedicine platform.

The aid carries certain restriction to limit potential distortions of competition. Carus and T-Systems cannot freely develop new telemedicine applications for the telemedicine platform. This measure helps prevent potential foreclosure concerns arising from the aid beneficiaries’ control of the telemedicine platform. Third parties will also be allowed to offer health services on the platform for a reasonable fee that will be capped for a period of 10 years.

This is the first EC state aid decision in the sector.

UK’s OFT Settles Home Medicine Cartel Investigation


Hamsarde 3149 Limited, which owns Quantum Pharmaceutical Limited and Tomms Pharmacy, agreed to pay over £380,000 in a settlement arising out of an Office of Fair Trading (OFT) investigation. The investigation related to a market-sharing agreement between Quantum and Lloyds Pharmacy Limited, a subsidiary of Celesio AG, over the supply of prescription medicines to nursing homes. Specifically, the companies had agreed not to supply their own prescription drugs to each other’s existing nursing home customers.

Lloyds took advantage of the OFT’s leniency policy in bringing this agreement to the OFT’s attention. Under the leniency policy, the first company to report its participation in a cartel may qualify for immunity from fines. So long as it continues to cooperate with the OFT, Lloyds is not expected to pay a fine. In addition, Hamsard’s penalty has been reduced from £646,426 to £387,856 due to Hamsard’s admission and agreement to cooperate under the OFT’s leniency policy.

In calculating the financial penalties, the OFT took into account the seriousness of the infringement, the relevant turnover, and any mitigating and/or aggravating factors. An OFT Senior Director said, “[t]hese two companies have admitted to entering into a cartel to reduce competition for supplies to care homes, which look after some of the most vulnerable members of society. We consider this type of market sharing to be a serious breach of competition law.”