At the Crossroads:
When Intellectual Property Law Meets Antitrust
(The pharmaceutical industry case)

Vincent Chiappetta
Willamette University College of Law

I. Defining the "Intersection"

A. The "happy family" – improving consumer welfare; maximizing aggregate social wealth

B. The "family quarrel" – different issues, conflicting methodologies; competitive appropriation versus public goods

C. Where does intellectual property leave off and antitrust take over?

II. Reconciliation Through Policy

A. Clear objectives, "simple" solutions

B. Antitrust: Preference for competition whenever we can get it. Other "values" treated elsewhere

C. Intellectual Property: A grudging "public goods" exception

1. Competitive appropriation and zero returns; investment decision distortion

2. Limited intervention to restore the appropriate balance

a. Locke versus Smith, Bentham and Mills. IP right not a right, but a carefully limited exception. Hohfeld, not Blackstone

b. The patent law example:

Useful arts, novelty, nonobviousness
Right to prevent making, using, selling
For the claims (invention)
For a limited time (20 yrs. from filing)
Public disclosure and enablement

3. Disconnects

a. Not an honor or a prize, a reluctant acknowledgement

b. A specific "loan" for specific purposes for a specific time

4. Too much IP is as bad as too little. More protection not better; not equivalent to more innovation

III. Some Doctrinal "Rules"

A. Strong preference for competition and antitrust

B. Keep intellectual property properly confined:

1. The substance - what is protected? In patents, involves the claims

2. The rights – protected from what? In patents, involves unauthorized making, using, selling, offering to sell, importing into the United States of the covered invention

3. The time – for how long? In patents, 20 years from date of application (with some possible extensions)

C. A few "crossroads" examples (versus parallel roads)

1. No obligation to license (or use) the substance for the rights protected during the term

2. Time: Post-expiration royalties prohibited.

3. Scope: Grant-backs, standards and pools/cross-licenses; tying (only with market power)

4. The rights: Exhaustion and "first sale"

IV. The Pharmaceutical Industry Situation

1. Generally, subject to antitrust

2. Within the IP rights, like other "property" used to compete

3. Outside the IP rights, greater antitrust problems

a. Inequitable conduct and prior art

b. Assertions of invalid rights

c. Term extensions: Hatch-Waxman

i. Explicitly gives extra term protection

ii. Incentives for generics: ANDA, pre-expiration use for filings and permitted challenges to listed patent validity

iii. Issues: multiple filings and multiple stays; settlements

At The Crossroads – When Intellectual Property Meets Antitrust

Developments in Antitrust Enforcement

Oregon State Bar - Antitrust, Trade Regulation and Unfair Trade Practices Section
December 4, 2002

Michelle Teed, Assistant Attorney General[1]
Oregon Department of Justice

This presentation will address issues that arise at the intersection of intellectual property law and antitrust. We will explore how regulators and courts grapple with these issues, using the ongoing pharmacy litigation as a case study.

I. General Developments In NAAG and AG Enforcement

A. Changes In States' Enforcement Effort

- Changes in the type of work Oregon and other states are doing.
- Presence of complex intellectual property issues and concerns.

B. NAAG

The National Association of Attorneys General (NAAG) serves the 50 state Attorneys General and the states in many different ways, including coordinating responses or positions on legislation, administrating common funds, and coordinating the filing of amicus briefs. Below is a brief summary of some of the recent NAAG activities.

Amicus activity

- Hytrin
- PhRMA

Conferences/Education/Coordination

- AWP/WAC (Average Wholesale Price/Wholesale Acquisition Cost)
- PBM (Pharmacy Benefit Managers)

[1] The statements made in these materials do not necessarily reflect the opinion or position of the Oregon Attorney General or the Oregon Department of Justice.

Federal Legislation

- Pharmaceuticals are at the forefront, at issue in approximately 150 bills before Congress.

- "Greater Access to Affordable Pharmaceuticals Act," (S. 812) sponsored by Senators Charles Schumer (D-NY) and John McCain (R-AZ), would modify the 1984 Hatch-Waxman Act which has allowed brand-name drug companies to keep lower-priced generic drugs off the market.

C. Oregon DOJ

State Legislation

Interim: Attorney General Myers' office chaired an Interim Study Committee to explore whether the indirect purchaser remedy could and should be expanded during the 2003 Legislative Session. Representatives from the business, legal and consumer communities comprised the Committee. Although it could not reach an agreement to propose an expansion of the new law regarding indirect purchasers, the Committee unanimously endorsed a legislative proposal to require plaintiff class action lawyers to notify the Attorney General of all class action lawsuits (these lawsuits would be direct purchaser lawsuits) brought on behalf of Oregon consumers in which claims under the Oregon Antitrust Act are alleged, and settlements of such actions.

2003 Session: Pre-session filings of interest.

D. Federal

Federal Trade Commission

- Strong working relationship with the states.
- K-Dur opinion.
- Hearings addressing:

- Healthcare
- Merger Remedies

U.S. Department of Justice

- Bid rigging is receiving some attention again.
- Echostar merger litigation.
- Healthcare – co-sponsored hearings with the FTC.

Food and Drug Administration

- Proposed/new FDA rule relating to the use of automatic 30-month stays in the drug patent listing process.

II. Pharmaceutical Cases

Pharmaceuticals Case Coordination

Litigation in the pharmaceuticals industry has become a leading topic for discussion and in the media. The National Association of Attorneys General (NAAG), through the leadership of Ohio Attorney General Betty Montgomery, convened a NAAG Task Force to study pharmaceutical pricing cases and certain practices in that industry. The effort covers practices that raise concerns in several areas of the law including antitrust, consumer protection and Medicaid Fraud such as the Federal False Claims Act and the Prescription Drug Marketing Act. The task force will review and address practices that raise concerns and potential claims under the antitrust, consumer protection and/or Medicaid Fraud laws at the federal and state level.

The task force has taken steps to advance communication and coordination among the various enforcement arms within the attorneys general offices, and better educate attorneys and staff, state agencies, and consumers on the legal issues and concerns presented by certain conduct. The task force put on a meeting in August 2002, which addressed issues related to

average wholesale prices (AWP) and how cases concerning this can be identified and investigated.

In addition to the task force, Oregon Attorney General Hardy Myers, in his capacity as Convener of the NAAG Antitrust Executive Committee, formed a NAAG Working Group, called the Antitrust Pharmaceuticals Working Group. This working group is co-chaired by Assistant Attorneys General Beth Finnerty (Ohio) and Meredyth Andrus (Maryland) and is charged with reviewing a number of different procedures within the antitrust multistate enforcement effort. The goals of this working group include earlier identification of cases and conduct of interest, finding ways to increase efficiencies in the states' pre-complaint investigation process, sharing information with our state and federal colleagues where appropriate, including creating a conduit for the flow of relevant case information to our Medicaid fraud and consumer protection colleagues, enhancing our expertise in this industry, and developing and refining the criteria for states to use in their case selection process.

Investigating and Litigating The Cases

Investigation and enforcement efforts in these cases can focus on several fronts. From the antitrust standpoint, recent investigations and litigation conducted by the state attorneys general have focused on three types of conduct. Each type of conduct has had the purpose and effect of preserving and extending the patent holder's exclusive right (monopoly) to market the branded drug and delay entry of a generic bioequivalent of the branded drug. Delaying generic entry eliminates competition between a generic alternative and the branded drug which, in turn, leads to higher drug prices to consumers, government agencies, health plans and businesses. It is generally accepted in the industry that generic entry causes a 30 to 70% reduction in the price of the drug at issue. Finally, the *Walker Process* doctrine is at issue in the current pharmaceuticals cases and underlies some of the discussion below.

1. Fraudulent Claims

The first area of inquiry addresses whether a company made false and misleading representations to the Patent and Trademark Office (PTO) and/or the Food and Drug Administration (FDA) to wrongfully obtain a patent on a drug and/or the listing of that patent in the FDA Orange Book. As a general rule, when a company obtains a patent on a drug, the patent holder is given the exclusive right (and, thus, a monopoly) to produce and sell that drug in the United States for a number of years. When the patent is listed in the FDA Orange Book, this triggers certain obligations on the part of the potential generic entrant under the Hatch-Waxman Act before it can enter into the market and compete with the patent holder. There are instances where a company has been accused of providing false or misleading information to the PTO or the FDA to wrongfully obtain a patent in the first instance or wrongfully extend (through a new patent on the same drug) a patent that is soon to expire. As a result, generic entry is delayed, or the incentive to bring a generic bioequivalent to market in competition with the branded drug is delayed, thereby preserving the monopoly on that particular drug. This presents potential violations of Section 2 of the federal Sherman Act and of those state antitrust and unfair competition laws that have similar or identical prohibitions against monopolies.

2. Misuse Or Abuse Of Administrative Provisions

The second area of inquiry addresses whether a patent holder has misused the provisions under the Hatch-Waxman Act to delay generic entry. Under Hatch-Waxman, a company that intends to enter into the market with a generic bioequivalent drug in competition with the branded drug must file an application and expression of intent to enter into the market. Once that application is filed, the patent holder has 45 days to file a patent infringement suit against the potential generic entrant if the patent holder believes the generic's entry into the market would infringe on the patent. Once the patent infringement action is filed, an automatic 30-month stay

goes into effect which prevents the generic from entering into the market until the patent infringement action is resolved. A potential abuse of this regulatory process could occur if a patent holder files a frivolous patent infringement lawsuit against the generic, thus invoking the 30 month stay provision and wrongfully extending the patent holder's monopoly on the drug during and possibly beyond that time period. This can give rise to a monopoly claim under the same laws as stated above.

3. Illegal Agreements That Restrain Trade

The third type of conduct that may present concerns occurs when the patent holder and a potential competitor settle a patent infringement suit with an agreement in which the generic agrees to delay marketing its generic drug until after the patent expires. A generic competitor may be paid significant amounts of money to enter into this agreement. This payment, which is sometimes referred to as a "reverse-payment," raises concerns about whether under certain circumstances, the settlement is nothing more than an unlawful agreement between two competitors to not compete. When examining these agreements, the states consider a number of factors, including whether the parties to the settlement have agreed not to compete in markets that are not part of the original patent infringement action (*i.e.*, the agreement goes beyond the subject matter of the patent litigation). Whether these agreements should be evaluated under the per se rule or under a Rule of Reason analysis is currently being considered in the Sixth Circuit[2] and the Eleventh Circuit.[3] Oregon DOJ has taken the position, as part of an *amicus curaie* brief to the Eleventh Circuit in the *Hytrin* litigation, that the per se rule can and should apply to certain types of these agreements.

[2] *In Re Cardizem CD Antitrust Litigation,* 105 F. Supp. 2d 682 (E.D. Mich 2000).
[3] *Abbott Laboratories, et al v. Louisiana Wholesale Drug Company, Inc. et al* (S.D. Fla) [the *Hytrin* Antitrust Litigation].

Specific Pharmaceuticals Cases

BuSpar: This case against Bristol-Myers Squibb is a monopoly and unlawful agreement case. The complaint alleges the unlawful maintenance of a monopoly in the BuSpar market through fraud on a government agency and through the use of an agreement with a generic competitor. BuSpar is a popular and unique anti-anxiety drug. The alleged unlawful conduct includes misrepresentations about the nature and scope of a new patent on BuSpar that led to Bristol committing fraud on the Food and Drug Administration to list the new patent in the FDA Orange Book. The states also allege in their complaint that Bristol entered into an unlawful agreement with a generic competitor to prevent it from competing with Bristol with cheaper generic version of BuSpar. The complaint contends that Bristol's conduct delayed generic competition which caused prescription drug prices to remain artificially high. Generic entry into the market generally has the effect of lowering the price of prescription drugs to consumers, by as much as 70% over a relatively short time period. Oregon is one of the lead states among a total of thirty-seven Attorneys General in the litigation. We are bringing our claims under federal and state antitrust laws. We are seeking injunctive relief, civil penalties and monetary remedies for the Office of Medical Assistance Programs (OMAP) and the Department of Corrections.

Taxol: This is a monopolization and unlawful agreement case brought against Bristol-Myers Squibb relating to its cancer fighting drug Taxol. The states allege that Bristol retained an unlawful monopoly in the Taxol market through by committing fraud on a government agency, the PTO, and by entering into an unlawful agreement with a generic competitor to keep the generic off the market. The complaint alleges that Bristol committed fraud on the PTO by making misrepresentations and material omissions about Taxol when Bristol sought a patent on Taxol. We allege that but for the misrepresentations and omissions, Bristol would not have

acquired the patent on Taxol. Subsequent to the issuance of the patent, Bristol entered into an alleged unlawful agreement with a generic competitor to defer entry of a generic bioequivalent to Taxol. Oregon is one of the lead states among the thirty-two Attorneys General in the litigation, and we are bringing our claims under federal and state antitrust laws. We are seeking injunctive relief, civil penalties and disgorgement.

Mylan: This monopolization case involving alleged unlawful conduct of cornering the market on ingredients used to manufacture two generic anti-anxiety drugs: lorazepam and clorazepate, is near a close. Unlawful conduct put Mylan Laboratories in a position to raise the price on lorazepam and clorazepate by 2000% to 3000%. Oregon joined the lawsuit with 33 other states. Oregon brought its claims under federal and state antitrust laws. The multistate lawsuit settled for $100 million in total damages, including full reimbursement of damages suffered by OMAP and the Oregon Department of Corrections. The damages are in the process of being distributed nationwide to consumers and states agencies. The value of the settlement to Oregon is over $1 million. We will disburse approximately $250,000 cy pres.

Non-Pharmaceutical Cases Of Interest

- Microsoft
- Compact Discs
- Echostar
- Phillips/Conoco Merger
- Salton (George Foreman ™ Grill)

CEDB9033.DOC

Make a copy of this form for your records and mail the original to:
Oregon State Bar MCLE, 5200 SW Meadows Rd., PO Box 1689, Lake Oswego, OR 97035-0889
(503) 620-0222 X368 or 1-800-452-8260 X368

Oregon State Bar Minimum Continuing Legal Education

MCLE Form 2. Group CLE Activity Accreditation Application

Pursuant to MCLE Rule 4.3, sponsors of Group CLE Activities must apply for accreditation no later than 30 days after the completion of the CLE activity.

Individual bar members may also apply on their own behalf for accreditation of a Group CLE Activity by using this form. No fee is required.

The sponsor fee is $40 for a program of 4 or fewer hours and $75 for a program of more than 4 hours. The sponsor fee for a series of programs not exceeding 3 hours in 3 consecutive months is $40. A sponsor fee is required for each repeat (live or electronic) of the programs. (See MCLE Rule 4.3(c).)

Name and address of person or organization applying (Please print. This will be mailing label):
Oregon State Bar
Antitrust, Trade Regulation and
Unfair Trade Practices Section

Applying As (check one):
☒ Sponsor
☐ Individual Member
Bar # _____

Phone: 503-778-5204
Contact Person (Sponsors only): John F. McGrory, Jr.

Title of CLE Activity: At The Crossroads: When Intellectual Property Law Meets Antitrust

Name of CLE Sponsor (if not the applicant):
Phone:

Date(s) and Location(s) of CLE Activity
Date(s): 12/4/02
Location(s) (city/state): Portland, Oregon

Number of credits requested:
General 1.5
Practical Skills _____
Prof. Resp.: Ethics _____ Child Abuse Rep_____ Diversity_____
TOTAL 1.5

Delivery method(s):
☒ faculty in room with participants; ☐ telephone to broadcast site; ☐ interactive video; ☐ satellite ☐ audiotape presentation; ☐ videotape presentation; ☐ interactive computer/internet; ☐ discussion leader present

Is this a replay?
☐ Yes ☒ No If yes, please identify program producer:_____

Will this program include the use of written materials?
☒ Yes ☐ No (If no, please explain)
Total pages: 19

Describe sponsor's experience in providing CLE activities (for non-OSB accredited sponsors): The Antitrust, Trade Regulation and Unfair Trade Practices Section regularly sponsors continuing legal education seminars for its members and other OSB sections. Each instructor has a high level of expertise in his/her area of practice.

This application will not be processed unless the following are enclosed:
✓ Copy of the program agenda showing timelines
✓ Biographical information on the program faculty
✓ Copy or sample (15-20 pages) of program's written materials - include ethics portion if applicable
✓ **Sponsor Fee**

Sponsor/Member Signature: J. F. McG. Jr.
Date: 1/3/03

John F. McGrory, Jr.

OSB MCLE Office Use Only:

☒ *Approved* ☐ *Denied*	*Fee Paid:* 12-30-02	*MCLE Credits:* *General:* 1.5
MCLE Dept.: Denise Cline	*Reciprocity?* ☐ *Yes* ☐ *No*	*Ethics:*
Date: 1-6-03	*Program No.:* 149 * 34	*General or Practical Skills:*
		Total: 1.5

Register Now for the December 4, 2002 CLE*

At The Crossroads: When Intellectual Property Law Meets Antitrust

This program, sponsored by The Antitrust, Trade Regulation and Unfair Trade Practices Section will address issues that arise at the intersection of intellectual property law and antitrust. The program will explore how regulators and the courts grapple with these issues, and will use the ongoing pharmaceutical litigation as a case study. There also will be an update on recent activities of the National Association of Attorneys General. Featured speakers are:

Michael Teed
Assistant Attorney General
Civil Enforcement, Antitrust

and

Professor Vince Chiappetta
Willamette University School of Law

When: Wednesday, December 4, 2002
4:00 – 6:00 p.m.

Where: Wells Fargo Tower
1300 SW 5th Avenue
Portland, Oregon
21st Floor
Conference Rooms A & B

Cost: **Free**
hors d'oeuvres provided
No host bar

Space is limited. Please sign up right away by responding to judy@tonkon.com

*1-1/2 MCLE credits – approval pending