

The AIPLA Antitrust News

A Publication of the AIPLA Committee on Antitrust Law

October 2012

Chairs' Corner

Thank you Richard Taffet for your excellent leadership as Chair of our Antitrust Committee for the past two years. We have had interesting and informative programs and newsletters, and the AIPLA Board and Amicus Committee have continued to rely upon us for input on IP/antitrust issues.

Geoff Oliver and I look forward to leading the Antitrust Committee this coming year. We have begun subcommittees to focus on three substantive IP/antitrust areas that are very active at this time: standards, pharmaceuticals, and acquisitions. Our subcommittee chair for standards is Rick Stark (RStark@cravath.com), for pharmaceuticals is Paul Ragusa (Paul.Ragusa@bakerbotts.com), and for acquisitions is Geoff Oliver (gdoliver@jonesday.com). If you have an interest in any of those areas, please contact the subcommittee chair directly. In addition, we will continue our newsletter published for each meeting. If you are interested in writing an article for the newsletter, please contact our newsletter editor, David Swenson (David_Swenson@baylor.edu). If you have ideas for future activities for our committee, please contact Geoff Oliver or me (kenneth.frankel@finnegan.com).

In October, we held a telephone conference in which our subcommittee chairs updated our members on recent events in their focus areas. At the Annual Meeting in October, we are presenting speakers on the hotly debated issue of whether injunctive relief and ITC exclusion orders should be available in connection with standards-essential patents. And for the Spring Meeting, we are working with other committees to plan a plenary program on enforcing patent rights globally in view of antitrust and competition law, and will be planning a committee meeting as well. Members of our committee also participated in an inter-committee group to provide input to the AIPLA Board and Amicus Committee on potential amicus participation in Supreme Court review of the antitrust standards for settlements of Hatch-Waxman Act patent infringement suits.

This issue of our newsletter has informative and interesting articles on the FTC's proposed premerger notification rules for pharmaceutical patent licenses, the recent decision by the Federal Circuit regarding the scope of the "safe harbor" provisions for pharmaceuticals and certain post-FDA approval activities, and bad faith litigation involving assertion of trade secrets.

We look forward to this upcoming year for our committee.

AIPLA Antitrust Committee

Ken Frankel, Chair
Finnegan, Henderson, Farabow, Garrett &
Dunner, LLP
kenneth.frankel@finnegan.com

Geoffrey D. Oliver, Vice-Chair
Jones Day
gdoliver@jonesday.com

David G. Swenson, Editor
Baylor Law School
david_swenson@baylor.edu

ANTITRUST SIDE EFFECTS

FTC PROPOSES EXPANDED PREMERGER NOTIFICATION FOR PHARMACEUTICAL PATENT LICENSES

Stephen A. Stack
Irene Ayzenberg-Lyman
Dechert LLP
stephen.stack@dechert.com
irene.ayzenberg-lyman@dechert.com

On August 13, 2012, the Federal Trade Commission (“FTC” or “Commission”) announced proposed amendments to its premerger notification rules governing the types of exclusive patent right transfers that require antitrust approval. The proposed rules are limited to the pharmaceutical industry and are part of the FTC’s ongoing efforts to increase its scrutiny of deals between drug manufacturers.¹ If implemented, the rules will broaden the types of exclusive pharmaceutical patent right licenses that would potentially be reportable under the Hart Scott Rodino Act (“HSR Act”).² The proposed rule will not become effective until after the notice-and-comment process, but little change is expected in the final version.

¹ Historically, for example, the FTC has targeted pharmaceutical companies who have settled patent infringement suits by entering into so-called pay-for-delay settlements. In fact, since 2003, drug manufacturers have had to notify the antitrust enforcement agencies about any patent settlements in which they enter. The proposed new rule offers yet another way for the FTC to scrutinize agreements between drug manufacturers.

² 15 U.S.C. § 18a.

The HSR Act and Rules

Under the HSR Act and rules, parties to acquisitions of assets or voting securities that meet certain size thresholds must file reports with the FTC and the Antitrust Division of the Department of Justice and wait a specified period of time before consummating their proposed transactions.³ The waiting period provides the federal antitrust enforcement agencies an opportunity to determine whether the transaction at issue may substantially reduce competition in violation of the antitrust laws. Either agency can challenge the transaction by seeking a preliminary injunction in federal district court or seek some other remedy, such as divestiture, to cure the alleged harm to competition. Failure to file can result in civil penalties of up to \$16,000 for each day of default, in some cases amounting to several million dollars.⁴

Intellectual Property Licenses as “Acquisitions of Assets”

For the HSR Act to apply, a transaction must constitute an “acquisition of voting securities or assets.”⁵ Outright assignments of all rights to intellectual property are well-recognized as asset acquisitions, reportable under the HSR Act where the transaction triggers the filing thresholds. This principle applies to all forms of intellectual property, including copyrights, trademarks, patents, and know-how.⁶ In

³ See 15 U.S.C. § 18a(a).

⁴ ABA SECTION OF ANTITRUST LAW, ANTITRUST LAW DEVELOPMENTS, 400 & nn. 455-59 (7th ed. 2012).

⁵ *Id.*

⁶ See ABA SECTION OF ANTITRUST LAW, PREMERGER NOTIFICATION PRACTICE MANUAL, Interpretation # 27 (4th ed. 2007) (hereinafter “ABA HSR Manual”) (FTC position is that grant of exclusive “intellectual

addition, however, the FTC’s long-held position—conveyed through informal guidance—has been that even the *partial* transfer of exclusive intellectual property rights, such as in a license, can also constitute reportable asset acquisitions under the HSR Act under certain conditions. This is true even if exclusivity is limited to a particular field of use, territory or time period.⁷

The FTC did not deem all partial transfers of exclusive rights to be reportable, however. One notable exception was a license in which the licensor parted with the right to sell and distribute the product, but retained the right to manufacture. This was on the theory that such a license should properly be viewed as a distribution agreement rather than an asset acquisition.⁸ In the FTC’s words, an exclusive patent license was potentially reportable if it transferred “the bundle of rights to use a patent to exclusively manufacture a product, develop the product for all potential uses, and sell that product without restriction,”⁹ whereas a patent license that granted the licensee the exclusive rights to use and sell the product, but not to manufacture the product,

was not potentially reportable,¹⁰ “[e]ven if the grantor ha[d] no intent to manufacture the licensed products”¹¹

Another feature of the FTC’s position on exclusive licenses concerned so-called “co-rights.” As understood by the FTC, co-rights are rights retained by the licensor to co-market or co-promote the product, or to share responsibility for seeing the licensed product through the regulatory approval process, but not to independently develop or market the product. The FTC has always taken the position that the licensor’s retention of co-rights does not make a license nonexclusive—and therefore non-reportable—for HSR purposes.¹²

property” license is the transfer of an asset); FTC Premerger Notification Office Informal Opinion Informal 9307006 (hereinafter “FTC Informal Op.”), *available at* <http://ftc.gov/bc/hsr/informal/opinions/9307006.htm> (explaining that the grant of an exclusive trademark constitutes an asset acquisition).

⁷ See, e.g., FTC Informal Op. 0510016, *available at* <http://ftc.gov/bc/hsr/informal/opinions/0510016.htm> (“[T]he grant of an exclusive license to certain intellectual property, even [if] limited in duration, and even [if] limited in field of use . . . is considered the transfer of an asset.”).

⁸ Premerger Notification; Reporting and Waiting Period Requirements, 77 Fed. Reg. 50,057, 50,059 (Aug. 20, 2012) (to be codified in 16 C.F.R. pt. 801) (hereinafter “FTC Amendment Notice”).

⁹ *Id.* at 50,058.

¹⁰ See, e.g., FTC Informal Op. 9508008, *available at* <http://ftc.gov/bc/hsr/informal/opinions/9508008.htm> (transaction not reportable where it “only involves the granting of marketing and distribution rights . . . and [licensor] retain[s] its exclusive rights to manufacture the [p]roduct”); FTC Informal Op. 0205013, *available at* <http://ftc.gov/bc/hsr/informal/opinions/0205013.htm> (no asset acquisition where licensor retains right to manufacture compound, even where licensee will have a right to use the compound to make the finished product, and even where the licensee will have “back-up” manufacturing rights in the event of a supply disruption).

¹¹ FTC Informal Op. 0510016, *available at* <http://ftc.gov/bc/hsr/informal/opinions/0510016.htm>.

¹² FTC Amendment Notice, *supra* note 8, 77 Fed. Reg. at 50,059.

The FTC's Proposed New Rule

The FTC's proposed amendments will, if implemented, broaden the types of exclusive *pharmaceutical patent* licenses that would potentially be reportable under the HSR Act.¹³ Specifically, pharmaceutical deals in which a patent holder retains the right to *manufacture* the patented product but transfers the exclusive rights to use and sell the product would now become potentially reportable under the new rules.

The FTC bases this industry-specific change in its interpretation on its experience, purportedly derived from previously reviewed pharmaceutical deals, that “in the pharmaceutical industry, the right to manufacture is far less important than the right to commercialize.”¹⁴ The new rule therefore de-emphasizes “the weight given to manufacturing rights in determining whether or not exclusive rights to a patent are being transferred.”¹⁵ Instead, the focus is on whether an exclusive patent license transfers “all commercially significant rights.”¹⁶ The FTC defines “all commercially significant rights” as those rights that allow only the recipient of the exclusive patent to “use” the patent in a particular therapeutic area, or specific indication within a therapeutic area.¹⁷ A therapeutic area covers the intended use of the patent, while indications are subsets of therapeutic areas. For example, under the new

rules if a patent holder grants an exclusive license to all commercially significant rights for all veterinary indications for its drug, but retains the rights for all human indications, an asset acquisition has occurred.¹⁸

The new rule would not affect the FTC's treatment of co-rights, the retention of which would not render an otherwise exclusive license nonexclusive. The proposal also does not affect transfers of licenses limited to the right to market, distribute or sell a product, which will continue to be treated as non-reportable distribution agreements.¹⁹

Rule v. Guidance?

Until now, the FTC's interpretation of the HSR Act relative to intellectual property licenses has taken the form of informal guidance rather than formal rules. It is not clear why in this instance the FTC chose to change its interpretation by rulemaking rather than simply announcing a change in its guidance. A rulemaking proceeding obviously gives the Commission a better opportunity to refine its interpretation based on outside comments, but there may be another advantage as well.

The principal authority supporting the FTC's position that partial intellectual property licenses can be asset acquisitions is a single 1960 district court decision. In *United States v. Columbia Pictures Corp.*,²⁰ the court held that a 14-year exclusive copyright license for television distribution of a studio's movie

¹³ Press Release, FTC Seeks Public Comments on Proposed Amendments to the Premerger Notification Rules Related to the Transfer of Exclusive Patent Rights in the Pharmaceutical Industry (Aug. 13, 2012), *available at* <http://www.ftc.gov/opa/2012/08/hsr.shtm>.

¹⁴ FTC Amendment Notice, *supra* note 8, 77 Fed. Reg. at 50,059.

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ *Id.* at 50,059-50,060.

¹⁸ *Id.* at 50,060.

¹⁹ *Id.* at 50,062 (highlighting that a distributorship agreement in which the licensee “is only handling the logistics of selling and distributing the product on [patent holder's] behalf” would not constitute an asset acquisition under the new rules).

²⁰ 189 F. Supp. 153, 181-82 (S.D.N.Y. 1960).

library was an “acquisition of assets” for purposes of Section 7 of the Clayton Act’s prohibition against anticompetitive mergers. To the extent that the Commission felt some uncertainty relying on this authority, rulemaking may offer some help.

The HSR Act gives the FTC power to define the terms used in the statute, but only in accordance with the notice-and-comment requirements of the Administrative Procedure Act.²¹ In the event of a challenge to its interpretation, a rule authorized by statute—which defines with specificity the statutory term “acquire assets”—could bolster the Commission’s legal position more effectively than a mutating, informal guidance.

Exclusive Licenses in Non-Patent and Non-Pharmaceutical Transactions

As stated earlier, the FTC’s rule proposal is limited specifically to *patent* licenses in the *pharmaceutical* industry, which the Rule defines explicitly in terms of the following codes from the North American Industry Classification System (“NAICS”):

- 325411 Medical and Botanical Manufacturing
- 325412 Pharmaceutical Preparation Manufacturing
- 325413 In-Vitro Diagnostic Substance Manufacturing
- 325414 Biological Product (except Diagnostic) Manufacturing

The FTC emphasizes, however, that the transfer of exclusive intellectual property rights to products that fall outside these product codes “remains a potentially reportable event under the Act.”²² FTC interpretations that elaborate on the concept of exclusive license will therefore continue to apply to determine whether transfer of specific rights in those industries constitutes an acquisition of assets. For example, under the existing guidance:

- The license of rights to sell and distribute is not reportable unless it includes manufacturing rights;²³
- The acquisition of a future right to manufacture is not reportable;²⁴
- The acquisition of a “back-up” manufacturing right by the licensee (which kicks in only if the licensor breaches its supply obligations) is not sufficient to make a sales and distribution license reportable;²⁵
- Sublicensing rights are irrelevant to whether the licensee has an exclusive license;²⁶

²¹ 15 U.S.C. § 18a(d)(2)(A).

²² FTC Amendment Notice, *supra* note 8, at 50,059.

²³ *See* note 10, *supra*.

²⁴ FTC Informal Op. 0403006, *available at* <http://ftc.gov/bc/hsr/informal/opinions/0403006.htm>.

²⁵ FTC Informal Op. 0205013, *available at* <http://ftc.gov/bc/hsr/informal/opinions/0205013.htm>.

²⁶ FTC Informal Op. 9910014, *available at* <http://ftc.gov/bc/hsr/informal/opinions/9910014.htm>.

- Where a development and collaboration agreement presently grants exclusive rights (not options) to products to be developed in the future, the relevant acquisition of assets takes place when the development agreement is signed, rather than when future products are identified as subject to the exclusive rights;²⁷ and
- Where an existing exclusive license is converted into an assignment with a modified royalty arrangement, but no increase in the rights or duration of the license, the conversion is not an asset acquisition.²⁸

It is also worth re-emphasizing that the new rule applies only to patent rights. Even in the pharmaceutical area, a license of rights to intellectual property other than a patent—such as a trademark—will be covered by the existing informal guidance.

Intellectual Property Valuation Issues

To say that an exclusive patent license is an acquisition of an asset does not necessarily make it reportable. For the HSR Act filing requirement to apply, certain filing thresholds based on the size of the transaction and in many cases the size of the parties must

also be triggered.²⁹ While the size-of-person test is straightforward,³⁰ the size-of-transaction test is not. In fact, it is somewhat anomalous.

The FTC’s rules provide that “[t]he value of assets to be acquired shall be the fair market value of the assets, or, if determined and greater than the fair market value, the acquisition price.”³¹ This concept is not easily applied to intellectual property licenses in which the consideration is a future royalty stream. The FTC’s position is that if the acquiring person is able to estimate the future royalties, then the purchase price is determinable, and it equals the gross amount of the royalty stream, *without any discount to present value*.³² If, however, the future royalties are too speculative to be reasonably estimated, then the test reverts to fair market

²⁹ Without regard to the size of the parties, transactions valued under \$50 million (as adjusted) do not require an HSR filing, and transactions valued at more than \$200 million (as adjusted) require an HSR filing unless an HSR exemption applies. The filing thresholds are required to be adjusted annually to keep pace with inflation. The above thresholds as currently adjusted for 2012 are \$68.2 million and \$272.8 million, respectively. The transaction must also not qualify for any exemption under the Act and Rules. *See* 15 U.S.C. § 18a(c) (listing exempt transactions) and 16 C.F.R. §§ 802.1 – 802.80 (same).

³⁰ The size-of-person test looks to the net sales of the entity as stated in its last regularly prepared annual income statement and the total assets of the entity as stated in its most recent regularly prepared balance sheet. 16 C.F.R. § 801.11(c).

³¹ 16 C.F.R. § 801.10(b). The fair market valuation must be made by the board of directors of the ultimate parent of the acquiring person or an entity delegated by the board. *Id.* at § 801.10(c)(3).

³² ABA HSR Manual, *supra* note 6, Interpretation # 86; FTC Informal Op. 0103002, *available at* <http://ftc.gov/bc/hsr/informal/opinions/0103002.htm>.

²⁷ FTC Informal Op. 0205006, *available at* <http://ftc.gov/bc/hsr/informal/opinions/0205006.htm>;

FTC Informal Op. 0806027, *available at* <http://ftc.gov/bc/hsr/informal/opinions/0806027.htm>.

²⁸ FTC Informal Op. 9909007, *available at* <http://ftc.gov/bc/hsr/informal/opinions/9909007.htm>.

value, which does permit discounts to present value and for other contingencies as well.³³

In practice, specific milestone payments that are not subject to any contingency will always be valued at face value with no present-value discount,³⁴ and a product that already has an established sales history in the market may also require a similar undiscounted valuation.³⁵ At the other extreme, royalties based on future sales of products in development will usually be too speculative to require an undiscounted valuation. The more difficult issues arise, of course, between these extremes.

Another frequent HSR valuation issue arising under intellectual property licenses involves the acquisition of worldwide rights. In that setting, foreign rights enter into the size-of-transaction calculation only if those rights have generated sales into the U.S. in the most recent fiscal year exceeding \$50 million, as adjusted (\$68.2 million for 2012).³⁶ This may be the case, for example, with a foreign manufacturing license where the products are exported to the United States. In other cases, however, it would be necessary to allocate the value of the worldwide license between the U.S. and foreign rights.³⁷

Conclusion

While the FTC's proposed amendment to its HSR rules will apply only to pharmaceutical patent licenses, the proposal serves as a reminder to all intellectual property lawyers that licenses of exclusive intellectual property rights in any industry can be subject to the premerger notification requirements of the HSR Act, even where only partial rights are being licensed. The FTC's interpretations of this requirement are not self-evident, and parties to licensing transactions should exercise care in determining whether they have a filing obligation in order to avoid the risk of significant civil penalties.

³³ ABA HSR Manual, *supra* note 6, Interpretation # 87; FTC Informal Op. 9607001, *available at* <http://ftc.gov/bc/hsr/informal/opinions/9607001.htm>; FTC Informal Op. 0805021, *available at* <http://ftc.gov/bc/hsr/informal/opinions/0805021.htm>.

³⁴ ABA HSR Manual, *supra* note 6, Interpretation # 87.

³⁵ See FTC Informal Op. 9401003, *available at* <http://ftc.gov/bc/hsr/informal/opinions/9401003.htm>.

³⁶ 16 C.F.R. § 802.50(a).

³⁷ FTC Informal Op. 9912003, *available at* <http://ftc.gov/bc/hsr/informal/opinions/9912003.htm>; FTC Informal Op. 0205001, *available at* <http://ftc.gov/bc/hsr/informal/opinions/0205001.htm>.

**MOMENTA V. AMPHASTAR - NEW
IMPLICATIONS ON PATENTS
CLAIMING TESTING METHODS AND
THE BIOSIMILARS INDUSTRY**

Sandra Lee and Sean McDonagh³⁸
Baker Botts
sandra.lee@bakerbotts.com
sean.mcdonagh@bakerbotts.com

In *Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.*,³⁹ the Federal Circuit held that the so-called “safe harbor” provisions which permit pharmaceutical manufacturers to develop and submit information without committing patent infringement include certain post-FDA approval activities required for drug products. This case involved method claims claiming testing steps required for regulatory approval. As a result of the holding, these types of method patents may no longer be asserted when the infringing activities are carried out in the context of pre- and post-FDA drug approval.

Case Summary

Amphastar Pharmaceuticals, Inc., International Medication Systems, Ltd., and Watson Pharmaceuticals, Inc. (collectively, “Amphastar”), filed the first Abbreviated New Drug Application (“ANDA”) for enoxaparin and were granted 180 days of generic

exclusivity as the first ANDA filer.⁴⁰ Momenta Pharmaceuticals, Inc. and Sandoz, Inc. (collectively, “Momenta”), subsequently filed an ANDA. Momenta, the first manufacturer to receive marketing approval, sold its generic enoxaparin product for over a year, before Amphastar received FDA approval.

The patent at issue, U.S. Patent No. 7,575,886, claims methods of analyzing samples of enoxaparin, a low molecular weight heparin drug.⁴¹ The patent, owned by

⁴⁰ Under the regulatory framework established by the Drug Price Competition and Patent Term Restoration Act (the Hatch-Waxman Act), an applicant for approval of a generic form of an existing drug is not required to submit clinical studies of safety and efficacy, but may instead rely on the determination of the Food and Drug Administration (“FDA”) that the branded drug (the “reference listed drug”) is safe and effective. In accordance with the abbreviated new drug application (“ANDA”) process, the generic applicant must demonstrate that the generic product is bioequivalent to the reference drug and has the same active ingredients as the reference drug. 21 U.S.C. § 505(j)(2)(A)(iv). To demonstrate that the generic drug and the reference drug are the “same,” the ANDA filer must demonstrate that the generic drug is “identical in active ingredient(s).” 21 C.F.R. § 314.92(a)(1).

⁴¹ U.S. Patent No. 7,575,886, relates to methods of analyzing heparin digested to yield enoxaparin, and the asserted claims cover comparisons of enoxaparin to a characteristic chromatography reference standard determined by Momenta. In effect, the claims describe how to analyze a sample of enoxaparin to ensure conformity to the USP Monograph standard, as required by the Federal Food, Drug and Cosmetics Act (“FDCA”). Enoxaparin is not a single drug molecule but a variable mixture of many related compounds. As a result of the variability, it may not be not feasible for generic manufacturers to demonstrate perfect molecular identity of enoxaparin to the reference listed drug, Lovenox®. The Food and Drug Administration (“FDA”) instead requires manufacturers to demonstrate that it is biochemically equivalent, i.e., that a defined proportion of the

³⁸ Ms. Lee is a partner and Mr. McDonagh an associate in the New York office of Baker Botts, LLP, where their respective practices encompasses all areas of life sciences related patent work, including patent procurement, licensing, litigation, and counseling.

³⁹ 686 F.3d 1348 (Fed. Cir. 2012).

Momenta Pharmaceuticals, Inc., discloses certain testing methods needed to obtain regulatory approval. When Amphastar received FDA approval, Momenta filed suit and obtained a preliminary injunction in the District Court against Amphastar's enoxaparin product.

Amphastar asserted that any infringing activity was protected by the safe harbor of 35 U.S.C. § 271(e)(1).⁴² However, the District Court ruled in favor of Momenta, noting that the safe harbor did not apply to Amphastar's post-approval testing activity. The District Court referenced the Federal Circuit's opinion in *Classen Immunotherapies, Inc. v. Biogen IDEC*⁴³ in support of its holding. In particular, the District Court noted the following:

“The only activity which will be permitted by [the safe harbor] is a limited amount of testing so that generic manufacturers can establish the biological equivalency of

generic product possesses a distinguishing chemical structure. The FDA established a “standards for identity” to guide the determination of whether enoxaparin was contained the same active ingredients as Lovenox, the most pertinent of which are “equivalence in disaccharide building blocks, fragment mapping, and sequence of oligosaccharide species” and “equivalence in biological and biochemical assays.” The FDA additionally identified a number of techniques which could, in theory, be used to determine equivalence, including electrophoresis, chromatography, and spectroscopy.

⁴² 35 U.S.C. § 271(e)(1) provides that: “It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention...solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.”

⁴³ 659 F.3d 1057 (Fed. Cir. 2011).

a generic substitute...[T]he generic manufacturer is not permitted to market the patented drug during the life of the patent; all that the generic can do is test the drug for purposes of submitting data to the FDA for approval.”⁴⁴

Amphastar appealed, and the Federal Circuit reversed the decision. The Federal Circuit held that the safe harbor provisions of 35 U.S.C. § 271(e)(1) apply not only to otherwise infringing activities undertaken prior to FDA approval, but also those activities post-approval provided that such activities were “reasonably related” to testing required by federal law.⁴⁵ Because, as Momenta conceded, Amphastar was required under the FDCA to maintain quality control inspection records for possible inspection by the FDA, this information was “submitted” for the purposes of the safe harbor.

The majority opinion noted that the holding was not inconsistent with the Federal Circuit's 2011 *Classen* ruling. Rather, the cases are distinguishable in that *Classen* concerned studies that were not mandated by the FDA, but where any resulting adverse events were reported as a matter of course. Here, the Court distinguished the facts in that the testing was in fact required for the FDA's continued approval. As such, the Federal Circuit clarified that the safe harbor provisions apply to all studies mandated by the FDA.

⁴⁴ *Momenta Pharmaceuticals v. Amphastar Pharmaceuticals*, 2011 WL 5114475 at *10 (D. Mass.) (quoting *Classen*, 659 F.3d at 1071).

⁴⁵ The majority opinion of the Federal Circuit was written by Judge Moore, who wrote the dissent in *Classen*. Chief Judge Rader wrote the majority opinion in *Classen*.

Chief Judge Rader dissented, emphasizing the portions of the *Classen* holding which indicated that the safe harbor provision is directed and limited to pre-marketing approval. The dissent also provides a summary of the legislative history of the safe harbor, noting that post-marketing activity and in particular commercial sales were not intended to be exempted from liability for infringement. The dissenting opinion concluded that the decision would render worthless manufacturing test method patents.

Discussion

Underlying the *Momenta* holding is the complex relationship between federal drug testing requirements under the FDCA, bioequivalence requirements under the Hatch-Waxman framework, and patent exclusivity. The quality control methods claimed in *Momenta*'s asserted patent were incorporated into the United States Pharmacopeia ("USP") monograph for enoxaparin. The FDCA requires that drug batch quality control testing is conducted in accordance with the testing methods provided by the USP (or like compendium).⁴⁶ Alternative testing methods must be demonstrated to the FDA's satisfaction to be equivalent or superior to the USP testing method.⁴⁷ As a result, while Amphastar was free to develop a competing quality control testing method, it would have been required to demonstrate that the test was at least equivalent to *Momenta*'s patented methods. This could have been a barrier to entry for subsequent generic manufacturers.

The *Momenta* case is instructive with regard to similar issues emerging in the era of follow-on biologics under the Biologics Price Competition and Innovation Act of 2009

("BPCI Act"). One similar issue with follow-on biologics is the extent of testing required to demonstrate biosimilarity with a biologic therapeutic reference product as required for marketing approval under the BPCI Act. A follow-on biologic application for marketing approval must include, at minimum, analytical studies demonstrating that the follow-on biologic is "highly similar" to the reference product, as well as animal studies and human immunogenicity studies.⁴⁸ *Momenta* demonstrates that proving biosimilarity of more complex drugs and biologics may be challenging. The holding may limit the ability of patent owners to enforce patented methods necessary to proving such biosimilarity, and accordingly, may influence the development of follow-on biologics.

Despite a first filer exclusivity incentive to develop the testing methods at issue, Amphastar was unable to do so. Over a year passed after the innovator patents were declared invalid before the first generic competitor, *Momenta*, entered the market. Although *Momenta* was able to sell its generic product for a period without generic competition, had the patent been enforceable, *Momenta* could have enjoyed a prolonged period of exclusivity.

Momenta may impact an innovator's decision regarding whether to patent testing methods or maintain such methods as trade secrets. Drug manufacturers are permitted to maintain as trade secrets with the FDA "any commercially valuable plan, formula, process or device that is used for making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort," provided that there is "a direct relationship between the trade secret and the

⁴⁶ 21 U.S.C. § 351(b).

⁴⁷ 21 C.F.R. § 211.194(a)(1)-(2).

⁴⁸ Section 351(k) of the Public Health Services Act.

productive process.”⁴⁹ As the dissenting opinion noted, however, several downsides may be associated with such a shift to trade secret protection including decreased financial incentive to innovate, diminished collaboration and dissemination of information, widespread duplication of effort, and less robust monographs.

The *Momenta* decision may not be the final word on safe harbors as a petition for *certiorari* in the *Classen* case is pending before the Supreme Court.⁵⁰ If granted, the Supreme Court may address the safe-harbor clause once again. Alternatively, the Federal Circuit may decide to review the *Momenta* decision *en banc*. The outcome of any further decisions will be closely watched and widely anticipated by both pharmaceuticals and biologics manufacturers.

⁴⁹ 21 C.F.R. 20.61.

⁵⁰ The question presented in the *Classen* petition for certiorari, and for which the Supreme Court invited the Solicitor General to submit a brief on behalf of the United States is, “Whether the Federal Circuit’s interpretation of 35 U.S.C. § 271(e)(1)’s safe harbor from patent infringement liability for drugs – *an interpretation which arbitrarily restricts the safe harbor to pre-marketing approval of generic counterparts* – is faithful to statutory text that contains no such limitation and decisions of this Court rejecting similar efforts to impose extra-textual limitations on the statute.” Petition for Writ of). Certiorari at (i), *GlaxoSmithKline v. Classen Immunotherapies, Inc.*, (No. 11-1078) (U.S. Feb. 28, 2012) (emphasis added).

ELEMENTS OF A TRADE SECRET SHAM

Kristen Voorhees
Skadden, Arps, Slate, Meagher & Flom, LLP
Kristen.voorhees@skadden.com

A trade secret sham is the bad faith assertion of a trade secret in violation of antitrust laws. Trade secret defendants sometimes file antitrust counterclaims in response to allegations of trade secret misappropriation. While there are different types of antitrust counterclaims, the most common of which alleges that the lawsuit is a meritless attempt to improperly interfere with the defendant’s ability to compete with the plaintiff. Used correctly, this little-known counterclaim could be a powerful tool for defendants who feel they are facing a truly baseless or improperly motivated suit. Most claims, however, usually fail under the *Noerr-Pennington* doctrine of immunity. This article highlights the elements of the antitrust counterclaims that survive.

I. The Sham Litigation Counterclaim

Bad faith attempts to petition courts (known as sham litigation suits) are not immune from antitrust liability under the *Noerr-Pennington* doctrine, and can constitute an improper attempt to monopolize in violation of antitrust laws.⁵¹ The primary antitrust basis for a sham litigation claim is section 2 of the Sherman Act, which prohibits monopolization or attempted monopolization of “any part of trade or commerce.”⁵² The

⁵¹ See *Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961); *United Mine Workers of America v. Pennington*, 381 U.S. 657 (1965); *California Motor Transport v. Trucking Unlimited*, 404 U.S. 508 (1972).

⁵² See 15 U.S.C. § 2 (2004). The “sham litigation” doctrine can also apply to state law claims of unfair

party asserting a section 2 claim must allege and prove that the plaintiff (1) possessed or attempted to possess monopoly power in the relevant market, and (2) caused anticompetitive harm in the relevant market.⁵³ Sham litigation, if shown, satisfies the first element of a section 2 claim. To be a sham, the lawsuit must (1) be objectively baseless “in the sense that no reasonable litigant could expect success on the merits . . . ,” and (2) conceal “an attempt to interfere directly with the business relationships of a competitor.”⁵⁴ In *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, the Supreme Court held that bad faith enforcement of a patent may violate the antitrust laws.⁵⁵

The trade secret analogue of a *Walker Process* claim first arose in *CVD, Inc. v. Raytheon Co.*, in which the First Circuit held that bad faith enforcement of a trade secret can constitute a violation of section 2 of the Sherman Act.⁵⁶ In *Raytheon*, the court

competition. *See, e.g., Monolithic Power Sys., Inc. v. O2 Micro Int'l Ltd.*, No. C04-2000CW, 2007 U.S. Dist. LEXIS 22556, *18 (N.D. Cal. 2007); *Zeller v. Consolini*, 59 Conn. App. 545, 553, 758 A.2d 376 (2000); *Computer Assocs. Int'l, Inc. v. American Fundware, Inc.*, 831 F. Supp. 1516, 1523 (D. Colo. 1993). *But see, e.g., Salomon S.A. v. Alpina Sports Corp.*, 737 F. Supp. 720, 724 (D.N.H. 1990) (declining to extend the doctrine to unfair competition).

⁵³ *Id.*; *see, e.g., Forro Precision, Inc. v. Int'l Business Machines Corp.*, 673 F.2d 1045, 1058 (9th Cir. 1982).

⁵⁴ *See Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc.*, 508 U.S. 49, 50 (1993).

⁵⁵ *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172, 177-78 (1965) (enforcement of a patent obtained by fraud may constitute monopolization in violation of the Sherman Act).

⁵⁶ *CVD, Inc. v. Raytheon Co.*, 769 F.2d 842, 851 (1st Cir. 1985), *cert. denied*, 475 U.S. 1016 (1986) (“[T]he threat of unfounded trade secrets litigation in

required clear and convincing evidence that the plaintiff knew the trade secret was invalid.⁵⁷ In the few cases that have since discussed *Raytheon*-type antitrust counterclaims, the courts rarely mention the clear and convincing standard and do not appear to recognize it as a required element. The other elements of the counterclaim in *Raytheon*, however, appear unchanged: the party asserting sham litigation must prove that: (a) the trade secret claim was objectively baseless, (b) the plaintiff subjectively intended to interfere with a competitor, and (c) the litigation had an anticompetitive effect.

A. Objectively Baseless

To prove a sham, the defendant must first show that the trade secret claim was objectively baseless. Establishing the baselessness of the claim requires an analysis of the merits of the claim. There are two key elements of a trade secret claim: (1) a valid trade secret⁵⁸ and (2) misappropriation.⁵⁹

bad faith is sufficient to constitute a cause of action . . .”).

⁵⁷ *See id.* (“[A]n antitrust plaintiff [must prove] in addition to the other elements of an antitrust violation, by clear and convincing evidence, that the defendant asserted trade secrets with knowledge that no trade secrets existed.”).

⁵⁸ Under the Uniform Trade Secrets Act, a trade secret is “information” that (i) derives “independent economic value” from not being “generally known” or “readily ascertainable” and (ii) “is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.” UNIF. TRADE SECRETS ACT § 1(4) (1985). *See also* Restatement (First) of Torts § 757 (1939), cmt. b (providing six factors for determining whether a trade secret exists).

⁵⁹ Misappropriation includes (i) acquiring another’s trade secret by “improper means,” such as theft or in breach of contract, or (ii) disclosure or use of a trade secret without consent by a person who knew or had reason to know that it was a trade secret. UNIF. TRADE SECRETS ACT § 1(2) (1985).

(1) Not a Valid Trade Secret

If the plaintiff has actual knowledge that the trade secret is invalid, the claim is objectively baseless.⁶⁰ A trade secret may be invalid if the information is (a) not secret, (b) not valuable, or (c) not protected.⁶¹

For example, in *CVD, Inc. v. Raytheon Co.*, the court found that based on the evidence at trial, the jury could conclude Raytheon “knew it had no trade secrets, yet nevertheless asserted them in bad faith in order to restrain competition and monopolize [the relevant markets].” The evidence revealed “extensive public disclosure [the alleged secret], Raytheon’s failure to follow its own procedures for trade secret protection, [and] its refusal to specify trade secrets in asserting its claims” Likewise, in *Classic Limousine et al. v. Alliance Limousine LLC et al.*, the defendants successfully plead that the action was objectively baseless by alleging that the plaintiff knew it did not have a valid trade secret.⁶² Specifically, the defendant alleged that the plaintiff made statements “to the effect that [the plaintiff] did not possess any confidential information, trade secrets, or other proprietary information.”⁶³ In addition, the plaintiff principals “wrote numerous threats to the defendants’ attorney saying that ‘you will be barraged with an arsenal of extremely experienced litigators who will

make your head spin’ [and] ‘[the defendant] is going to need unlimited amounts of money to defend himself.’”⁶⁴ The court reasoned that if the plaintiffs knew that they did not have confidential information, then the claim would be objectively baseless.⁶⁵

The court will also likely find that the claim is objectively baseless if the plaintiff failed to take reasonable measures to protect the trade secret. In *Whitesell Int’l Corp. v. Whitaker*, the court upheld the jury’s finding that the plaintiff’s trade secret claims were objectively baseless because there was sufficient evidence that the plaintiff failed to secure the secrecy of its proprietary process.⁶⁶ Among other facts, defendant introduced evidence that hundreds of people had seen the process, employees were not required to sign confidentiality agreements, a published patent described the process, and documents describing the process were not treated as confidential. Given the general lack of security, the “jury could conclude that [plaintiff] did not reasonably believe that the Stamptech process was a trade secret and merely filed the instant suit to harass [defendant] or prevent him from competing.”⁶⁷

(2) Not Misappropriated

Alternatively, the defendant can show the claim is objectively baseless if the plaintiff

⁶⁰ See *CVD, Inc. v. Raytheon Co.*, 769 F.2d 842, 851 (1st Cir. 1985), cert. denied, 475 U.S. 1016 (1986) (“[A]n antitrust plaintiff [must prove] in addition to the other elements of an antitrust violation, by clear and convincing evidence, that the defendant asserted trade secrets with knowledge that no trade secrets existed.”).

⁶¹ See UNIF. TRADE SECRETS ACT § 1(4) (1985).

⁶² *Classic Limousine et al. v. Alliance Limousine LLC et al.*, No. CV990174911S, 2002 Conn. Super. LEXIS 2728, *18 (Conn. Sup. 2002).

⁶³ *Id.*

⁶⁴ *Id.*

⁶⁵ *Id.* at *22 (Conn. Sup. 2002).

⁶⁶ *Whitesell Int’l Corp. v. Whitaker*, No. 287569, 2011 Mich. App. LEXIS 99, *26-27 (Mich. App. 2011).

⁶⁷ *Id.* at *26-27. But see *Frosty Bites, Inc. v. Dippin’ Dots, Inc.*, No. 3-01-cv-1532-M, 2003 U.S. Dist. LEXIS 8472, *26 (N.D. Tex. 2003) (“ . . . DDI cannot prevail on its trade secrets claim because it did not use reasonable means to protect the secrecy of its alleged trade secrets. However, this does not necessarily make the claim ‘objectively baseless.’”).

knows that the defendant did not misappropriate any trade secrets. For example, the trade secret claim is baseless if the plaintiff knows that the allegedly infringing product does not incorporate or rely on the plaintiff's trade secret,⁶⁸ or if the plaintiff's evidence of misappropriation is too thin.⁶⁹ For example, in *Am. Chem. Soc. v. Leadscope, Inc.*, the plaintiff failed to identify any evidence upon which it relied to support its allegation of misappropriation and so the "jury could reasonably infer, based on the paucity of evidence presented, that the lawsuit was objectively baseless when filed."⁷⁰

(3) A Winning Lawsuit is Not a Sham

As a rule, a winning lawsuit is by definition not a sham.⁷¹ If a plaintiff successfully convinces a court or jury that the defendant misappropriated the plaintiff's trade secrets, the sham litigation counterclaim will fail.⁷² By contrast, a defendant cannot rely on

⁶⁸ Cf. *LocTite Corporation v. Ultraseal, Ltd.*, 781 F.2d 861 (Fed. Cir. 1985) (finding sham litigation could apply to patent infringement action where device was known not to be infringing).

⁶⁹ *Am. Chem. Soc. v. Leadscope, Inc.*, Slip Opinion No. 2012-Ohio-4193, ¶ 57, 2012 Ohio 4193, 2012 Ohio LEXIS 2236, *37-38 (Ohio Sept. 18, 2012).

⁷⁰ *Id.*

⁷¹ See *Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc.*, 508 U.S. 49, 61 n.5 (1993) ("A winning lawsuit is by definition a reasonable effort at petitioning for redress and therefore not a sham.").

⁷² *Id.*; *AvidAir Helicopter Supply, Inc., v. Rolls-Royce Corp.*, 663 F.3d 966, 976 (8th Cir. 2011) ("A lawsuit that leads to a jury award . . . is not objectively baseless, even if it did not succeed on each claim of the complaint."); *Eden Hannon & Co. v. Sumitomo Trust & Banking Co.*, 914 F.2d 556, 565 (4th Cir. 1990); *JPS Elastomerics Corp. v. Specialized Tech. Resources, Inc.*, 769 F. Supp. 2d 17, 18 (D. Mass. 2011) (finding an "egregious misuse of the 'sham litigation' theory of recovery where the plaintiff's

an unsuccessful lawsuit to prove a sham.⁷³ *Noerr-Pennington* immunity will protect the plaintiff so long as the plaintiff had a reasonable belief that the claim will succeed (probable cause).⁷⁴ In *Houston Mercantile Exchange*, the court found that the plaintiff was immune from antitrust claims because it was reasonable for the plaintiff to believe it would succeed on the trade secret claim after it succeeded in obtaining a temporary injunction and several settlement agreements in related litigation.⁷⁵

B. Subjective Anticompetitive Intent

Second, to state a sham litigation claim, the defendant must allege that the plaintiff subjectively had an anticompetitive intent in bringing the lawsuit. Here, the defendant should try to offer evidence of

underlying state court litigation was 'triumphantly successful, both before the jury and before the judge'); see also *Forro Precision, Inc. v. Int'l Business Machines Corp.*, 673 F.2d 1045, 1061 (9th Cir. 1982) (finding jury verdict proved merits of IBM's trade secrets claim and thus request for police assistance not objectively baseless).

⁷³ *Id.* ("[W]hen the antitrust defendant has lost the underlying litigation, a court must 'resist the understandable temptation to engage in *post hoc* reasoning by concluding' that an ultimately unsuccessful 'action must have been unreasonable or without foundation.'" (internal citations omitted)); see also *Monolithic*, 2007 U.S. Dist. LEXIS 22556, *22, 24 (finding that, after losing the infringement trial, the plaintiff's continued assertion of the patent against the defendant's customers was not objectively baseless because the plaintiff reasonably believed the decision would be reversed on appeal).

⁷⁴ See, e.g., *Houston Mercantile Exchange*, 1993 Tex. App. LEXIS 2358, *5-6 (Tex. App. 1993) ("[I]f a plaintiff has 'probable cause' to institute legal proceedings, then a finding of sham litigation is precluded.").

⁷⁵ *Houston Mercantile Exchange v. Daily Petroleum Servs. Corp.*, 1993 Tex. App. LEXIS 2358, *8-9 (Tex. App. 1993).

prelitigation statements made by or to the plaintiff that would put the plaintiff on notice that the lawsuit would prevent the defendant or other parties from competing. For example, in *Am. Chem. Soc. v. Leadscope, Inc.*, the evidence of wrongful intent included the plaintiff's knowledge, based on communications with Leadscope, that filing a lawsuit would "derail" potential investments in Leadscope, and that the plaintiff had withdrawn only those claims upon which Leadscope's defense insurance coverage was predicated, allegedly to bankrupt the defendant through litigation.⁷⁶ On that basis, the court found that the defendant had successfully established that ACS intended to use the misappropriation lawsuit to wrongfully interfere with Leadscope's business.⁷⁷

C. *Anticompetitive Harm*

Finally, the defendant must also prove an antitrust injury to have standing to bring the antitrust counterclaim.⁷⁸ Some courts have indicated that the costs of litigating the misappropriation action alone are sufficient to constitute an antitrust injury if the plaintiff brings the claim in bad faith.⁷⁹ In *Raytheon*, for example, the court found that the "legal expenses incurred in attempting to resolve Raytheon's bad faith claims, reflects the

⁷⁶ *Am. Chem. Soc. v. Leadscope, Inc.*, Slip Opinion No. 2012-Ohio-4193, ¶ 57, 2012 Ohio 4193, 2012 Ohio LEXIS 2236, *37-38 (Ohio Sept. 18, 2012).

⁷⁷ See also *Classic Limousine et al. v. Alliance Limousine LLC et al.*, 2002 Conn. Super. LEXIS 2728, *23, 29 (Conn. Sup. 2002).

⁷⁸ See, e.g., *Houston Mercantile Exchange*, 1993 Tex. App. LEXIS 2358, *5-6 (Tex. App. 1993).

⁷⁹ *CVD, Inc. v. Raytheon Co.*, 769 F.2d 842, 858 (1st Cir. 1985), cert. denied, 475 U.S. 1016 (1986) ("The injury to CVD, legal expenses incurred in attempted to resolve Raytheon's bad faith claims, reflects the anticompetitive effect of acts with an anticompetitive intent."); *Houston Mercantile Exchange*, 1993 Tex. App. LEXIS 2358, *5-6 (Tex. App. 1993).

anticompetitive effect of acts with an anticompetitive intent." However, whether litigation costs alone constitute a sufficient antitrust injury is unsettled.⁸⁰ To be safe, the defendant alleging sham litigation should link the litigation costs to an additional anticompetitive effect, such as how the litigation costs injured the defendant's participation in the market, depressed the defendant's stock or put pressure on the defendant's investors and shareholders.⁸¹

II. *Alternative Antitrust Counterclaims*

Although sham litigation is the most common theory alleged in trade secret counterclaims, a small number of creative defendants have tested other theories of antitrust violations. The following theories have yet to succeed in court, but under different facts, may become viable alternatives.

⁸⁰ Cf. *Bristol-Myers Squibb Co. v. Ben Venue Labs.*, 90 F. Supp. 2d 540, 543-46 (D.N.J. 2000) (patent infringement litigation fees may be an antitrust injury) with *Brotech Corp. v. White Eagle Int'l Techs. Group, Inc.*, Civ. No. 03-232, 2004 U.S. Dist. LEXIS 11552, 2004 WL 1427136, at *6-7 (E.D. Pa. June 21, 2004) (patent infringement litigation fees alone may not be an antitrust injury); see also *CVD, Inc. v. Raytheon Co.*, 769 F.2d 842, 858 (1st Cir. 1985) (finding antitrust injury from legal expenses incurred in resolving a misappropriation claim brought in bad faith).

⁸¹ See *Biovail Corp. Int'l v. Hoechst Aktiengesellschaft*, 49 F. Supp. 2d 750, 771 ("Biovail states that 'the specious threats [of patent infringement litigation] made by [defendants] were intended to weaken and damage Biovail's statute in the marketplace by keeping the price of Biovail's stock depressed and by putting pressure on Biovail's investors and shareholders.' That allegation suffices on a motion to dismiss." (internal citations omitted)).

A. Failure to Disclose Trade Secrets in a Patent Constitutes Fraud

Under this theory, a defendant argues that the failure to disclose the asserted trade secrets in a relevant patent either (a) constitutes a form of unfair competition,⁸² or (b) supports a finding that the trade secret has been maintained through fraud to the USPTO and is therefore invalid. The Seventh Circuit rejected the latter argument in *Christianson v. Colt*, finding that Colt's failure to disclose certain trade-secrets related to the manufacture of M16 rifles did not violate the "enablement" or the "best mode" requirements of the patent and so no fraud had occurred.⁸³ Accordingly, the court vacated the district court's determination that Colt was not entitled to trade-secret protection on the grounds that such trade-secrets should have been disclosed in the patent application.⁸⁴

B. Confidentiality Provisions Are a Restraint of Trade

Under this theory, confidentiality clauses that purport to protect an alleged trade secret improperly prevent competitors from using information that is already in the public domain. This theory fails, however, if the court finds that the plaintiff has a valid trade secret, because contracts are otherwise a valid method for protecting a trade secret. For example, in *Boeing Co. v. Sierracin Corp.*, Boeing sued its supplier Sierracin for

misappropriation of trade secrets based on Sierracin's breach of the supply agreement.⁸⁵ Sierracin counterclaimed that the confidentiality clauses in the agreements with Boeing violated state antitrust laws.⁸⁶ At trial, the jury found in favor of Boeing on the misappropriation claim.

On appeal, the court noted that the antitrust defense to the breach of contract claim would be valid "only if enforcement of the contracts would itself require unlawful conduct."⁸⁷ Ruling in favor of Boeing, the court reasoned that "confidentiality clauses in the Boeing/Sierracin contracts do not compel violation of antitrust laws, nor do they restrict Sierracin from lawfully competing by obtaining its own [FAA] authorization through an original design, reverse engineering, or information from the public domain."⁸⁸ To the contrary, the confidentiality provisions "protect what the jury found were Boeing's legitimate trade secrets," and therefore the contracts were not "in restraint of trade."⁸⁹ Therefore, because "Boeing knew its trade secrets were legitimate," Boeing's "protection of those secrets could not have been a sham."⁹⁰

⁸² See, e.g., *Monolithic Power Sys., Inc. v. O2 Micro Int'l Ltd.*, 2007 U.S. Dist. LEXIS 22556, *21 (N.D. Cal. 2007) ("MPS contends that O2 Micro withholding the best mode of practicing the alleged invention, and treating it as a trade secret, provides further evidence of O2's unfair competition.").

⁸³ *Christianson v. Colt Industries Operating Corp.*, 766 F. Supp. 670, 677-78 (C.D. Ill. 1991).

⁸⁴ *Christianson v. Colt Industries Operating Corp.*, 870 F.2d 1292 (7th Cir. 1989).

⁸⁵ *Boeing Co. v. Sierracin Corp.*, 738 P.2d 665, 671 (Wash. 1987)(en banc). Boeing had a contract with outside supplier Sierracin that prohibited Sierracin from using Boeings proprietary drawings "for any purpose other than exclusive Boeing manufacture." *Id.* Despite the contract, Sierracin used Boeing's drawings to obtain its own purposes. *Id.*

⁸⁶ *Id.* at 671-72.

⁸⁷ *Id.* at 676.

⁸⁸ *Id.*

⁸⁹ *Id.* at 676-677.

⁹⁰ *Id.* at 671.

C. Cease and Desist Letters to Third Parties Violate Section 1 of the Sherman Act

Under this theory, the trade-secret holder commits a *per se* antitrust violation by threatening to sever ties with suppliers or customers who also deal with the defendant. Such efforts could be stylized as an illegal tying arrangement or group boycott in violation of section 1 of the Sherman Act.⁹¹ In *Christianson v. Colt*, the trade secret plaintiff pressured the defendant's suppliers to avoid dealing with the defendant by threatening to revoke its business relationship with the suppliers.⁹² Although the plaintiff's efforts were "restraints" on trade, the court found that the restraints were "vertical restraints" rather than "horizontal restraints," and a vertical restraint is not illegal *per se* unless it includes some agreement on price.⁹³ Thus, without evidence of a horizontal conspiracy or price fixing among the trade secret plaintiff and defendant's customers or suppliers, the court was unwilling to find a violation.⁹⁴

The handful of cases that have considered trade secret sham claims show that the claim elements are straight forward, but rarely satisfied. The strongest trade secret antitrust counterclaim will be founded on evidence that the plaintiff knew the trade secret was invalid or not misappropriated. The weakest counterclaim will allege that the plaintiff's successful litigation on the merits was meritless. The spectrum in between, however, is relatively untouched and the boundaries remain available for creative defendants to explore.

⁹¹ "A tying arrangement is an agreement by a party to sell one product but only on condition that the buyer purchases a different (or tied) product, or at least agrees that he will not purchase that product from any other supplier." *Northern Pacific Railway Co. v. United States*, 356 U.S. 1 (1958).

⁹² *Christianson v. Colt Industries Operating Corp.*, 766 F. Supp. 670, 677-78 (C.D. Ill. 1991).

⁹³ *Id.* at 677.

⁹⁴ *Id.* at 678. Note, however, that the trade secret plaintiff does not necessarily deserve automatic immunity for refusing to deal either. The court in *Telecomm Tech. Servs., Inc. v. Siemens Rolm Commc'ns., Inc.*, 150 F. Supp. 2d 1365, 1370 (N.D. Ga. 2000), found that although patent and copyright-holders are immune from antitrust violation for refusal to sell their IP, such immunity did not apply to trade-secret holders. The court reasoned that "such an exception would swallow the rule. Given the [broad] definition of trade secret, virtually every

anticompetitive refusal to deal would be beyond the reach of antitrust law." *Id.*