Brian D. Coggio

Of Counsel

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Overview

About Brian

Mr. Coggio is of counsel to the New York office of Fish & Richardson P.C. He has extensive law firm experience as a senior trial attorney and counselor and has litigated disputes across a wide range of technologies with a particular focus in chemical, pharmaceutical, medical device, and biotechnology. He has also been involved in cases before the U.S. International Trade Commission and in various foreign countries including Germany, Great Britain, Switzerland, Italy, and the Netherlands. In addition, Mr. Coggio has also represented clients in numerous cases under the Hatch-Waxman Act and has written and lectured extensively on this and related topics in this country, Europe, Canada and Japan. He is presently an adjunct professor at Fordham Law School and, before that, at New York Law school, where he teaches a course in patent litigation.

Focus Areas

Services

- Litigation
- Hatch-Waxman
- Patent Litigation

Industries

- Chemicals

- Life Sciences
- Medical Devices

Education

LL.M., Trade Regulations, New York University School of Law (1980)

J.D. *cum laude*, Fordham University School of Law (1974) Editor, *Fordham Law Review*

B.S., Chemical Engineering, Manhattan College (1971)

Experience

Mr. Coggio consults various pharmaceutical companies on aspects of the Hatch-Waxman Act and prepares validity and infringement opinions on life sciences issues. For example, most recently, he was in charge of a worldwide patent analysis of hundreds of medical device patents dealing with drug delivery systems.

Hoffman-La Roche. He is lead counsel for Roche in four Hatch-Waxman actions involving the drug XELODA® against Mylan, Teva, Roxanne, and Accord respectively. The cases are pending in the District Court of New Jersey.

Boehringer Ingelheim. In *Novartis v. Ben Venue*, a Hatch-Waxman action he was lead counsel representing Ben Venue, a subsidiary of Boehringer Ingelheim. He secured a summary judgment of non-infringement, later affirmed by the Federal Circuit.

Bristol-Myers Squibb. He was lead counsel representing Bristol-Myers in *Zenith v. Bristol-Myers Squibb*, a declaratory action judgment involving the pharmaceutical cefadroxil and related to the Hatch-Waxman Act. The case established the principle of infringement by in vivo conversion of a non-patented product into patented pharmaceutical after ingestion.

Alcon Laboratories. He was part of a team representing Alcon in two Hatch-Waxman actions involving drugs for intraocular administration. Both litigations were successfully resolved on summary judgment in Alcon’s favor.

Marion Merrill Dow. In *Marion Merrill Dow v. Geneva* and *Marion Merrill Dow v. Par Pharmaceuticals*

, both Hatch-Waxman actions, he was lead counsel asserting infringement of the client's patent covering a metabolite of the antihistamine terfenadine (Seldane®). In the course of both litigations, various motions for summary judgment of invalidity and/or non-infringement were overcome. He was also involved in related litigations in the Supreme Court of Germany and in the House of Lords.

Bruker Daltonics. In *Extrel v. Bruker*, he was retained to prosecute the appeal from a decision in which Bruker had been found liable for infringement. Sales of the alleged infringing product, FTICR mass spectrometers, were enjoined, and awards of increased damages and attorney fees had been entered. On appeal, the Federal Circuit reversed the finding of infringement and vacated the injunction and all monetary awards against the client.

Hoechst Marion Roussel. In actions before the International Trade Commission and various district courts, he was lead counsel and led a large team that asserted that methods of producing diltiazen (Cardizem© CD) used by various defendants infringed a patent licensed to Hoechst by Tanaka Seiaku. The lengthy trial before ITC involved examination and cross-examination of witnesses who spoke Japanese, Finnish, Italian, German, or Hebrew.

Hoffmann-La Roche. He was lead counsel for Roche in a patent infringement action instituted by Chiron involving the latter's patents covering various aspects of the gene encoding the hepatitis C virus. In addition, he coordinated related litigations in the Netherlands, France, Germany, Switzerland, Italy and Japan. He and his team were instrumental in obtaining a favorable worldwide settlement of all the litigations.

Hewlett-Packard. In two district court trials and related appeals to the Federal Circuit in disputes between Hewlett-Packard and Bausch & Lomb involving X-Y plotters, he was part of a team that successfully represented Hewlett-Packard against accusations of patent infringement. Moreover, the team established willful infringement by Bausch & Lomb of Hewlett-Packard's own patent. As a result, Hewlett-Packard recouped all attorney fees from its adversary.

Hoffmann-La Roche. Throughout his career, he has been counsel to Roche and its foreign subsidiaries, including Nippon Roche and Roche GmbH, in various patent infringement litigations in which Roche has asserted patents covering alpha interferon. Recently, he was involved in related worldwide litigation involving a modified form of interferon (pegylated interferon) marked by Roche as Pegysys®. Most recently, in ICN Pharmaceuticals v. Hoffmann-La Roche, he was lead counsel representing Roche in a Hatch-Waxman action involving the pharmaceutical product ribavirin. That litigation was eventually settled. He was also lead counsel to Roche in a multi-defendant litigation instituted by Housey Pharmaceuticals against numerous pharmaceutical companies involving so-called research tool patents. After a successful result at a Markman hearing, the patentee conceded both invalidity and non-infringement. The ruling was affirmed by the Federal Circuit.

U.S. Biochemical. In *Harvard Medical School and U.S. Biochemical v. Pharmacia*, he was lead

counsel representing plaintiffs in a patent infringement action asserting infringement of a patent covering T7 DNA polymerase used in DNA sequencing. The successful result included the entry of a worldwide license agreement.

Bruker Daltonics. He was lead counsel representing Bruker and Agilent in *Finnigan v. Bruker* before the International Trade Commission. After a three-week trial, the Administrative Trial Judge held for Bruker. This decision was affirmed by the full commission and by the Federal Circuit. He also coordinated related litigations in U.S. district court and in Germany and Switzerland.

American Cyanamid. In *Ethicon v. American Cyanamid*, he was part of a team that represented the defendant-patentee who sued Ethicon (a division of Johnson & Johnson) for infringement of a patent covering synthetic absorbable sutures. After 72 days of trial, the case was settled in favor of Cyanamid. He also coordinated related litigations in England, France, and Germany, all of which were successfully resolved.

National Starch. In a patent/trade secret litigation instituted by Air Products, he was lead counsel for National Starch in the trade secret action and defeated claims that the client had misappropriate 13 separate trade secrets.

Insights

Teaching Positions

Adjunct Professor, Fordham Law School (1999-present).

Adjunct Professor, New York School of Law (1995-1998).

Presentations

“The Evolution of Safe Harbours and Patent Exemptions in Europe and the United States: Understanding the Expanding Reformation to Patent Infringement,” Panelist, C5’s Pharma & Biotech Patent Litigation in Europe Conference (February 23, 2021)

“Navigating to the Safe Harbor: What to Know in Advance,” Co-presenter, *Fish Life Sciences Webinar Series* (July 21, 2020).

“Antitrust Implications of Biologic Patent Settlements” Co-Presenter, Fish Life Sciences Webinar, (July 7, 2020)

“Biologics & Biosimilars: Innovator Versus Competitor,” Panelist, C5’s 10th Pharma & Biotech Patent

Litigation Conference (February 27, 2018)

“Litigating Biosimilars,” Presenter, C5’s Life Sciences IP Summit (October 11, 2017)

“Understanding the U.S. Safe Harbor, and Regulatory and Research Safe Harbors in the EU/Canada” Co-Presenter, Fish Litigation Webinar, (January 19, 2017)

Publications

Mr. Coggio is a contributing author to Fish’s IP Law Essentials.

“Users of Research Tools Take Note,” author, *Fish Litigation Blog* (June 4, 2021).

“First Circuit Finds Device Patent Improperly Listed in the Orange Book,” co-author, *IP Litigator* (September 2020).

“Attorneys for Branded Companies Should Carefully Review ANDAs for Admissions Regarding Generic Infringement,” co-author, *Fish Litigation Blog* (August 5, 2020).

“First Circuit Finds Device Patent Improperly Listed in the Orange Book,” co-author, *Fish Litigation Blog* (June 26, 2020).

“Generic Drug Labeling and Induced Patent Infringement,” co-author, *Fish Litigation Blog* (June 4, 2020).

“Overview of Approaches to Compulsory Licensing,” co-author, *Fish IP Law Essentials Blog* (May 21, 2020). Also published in Vol 40 (7) *The Licensing Journal* page 1 (Aug. 2020).

“Prodrugs – Federal Circuit Holds That A PTE Does Not Cover Their Metabolites,” author, *Fish IP Law Essentials* (May 12, 2020).

“Potential Ways for Avoiding the Presumption of Prosecution History Estoppel of an Allowable Dependent Claim Depending from a Rejected Independent Claim,” co-author, *Fish Patent Blog* (April 28, 2020).

“Biosimilars: Comparison between Canada, US and Europe,” co-author, Smart & Biggar’s “Rx IP Update” (November 2019).

“Ensnarement Defense To Doctrine of Equivalents Succeeds On Summary Judgment,” author, *Fish Litigation Blog* (November 22, 2019).

“The Doctrine of Equivalents and Its Limitations, Including ‘Ensnarement,’ a Particularly Potent Defense,” co-author, *IP Litigator* (September/October 2019).

“California Court Confirms that Venue Does Not Require a Nexus Between an ‘Act of Infringement’ and a ‘Regular and Established Place of Business,’

” *Fish Litigation Blog* (September 19, 2019).

“A District Court Split on Hatch-Waxman Venue Determinations,” co-author, *Law360* (August 30, 2019).

“Venue in Hatch-Waxman Actions is Governed by 28 U.S.C. § 1400(b) Not § 1391(b),” co-author, *Fish Litigation Blog* (May 3, 2019).

“Court Confirms ‘Unique’ Pleading Requirements in Hatch-Waxman Actions,” co-author, *Fish Litigation Blog* (April 12, 2019).

“Who can be a Defendant in Biosimilar Patent Litigation?” co-author, *Law360* (April 11, 2019).

“Comparison of the Hatch-Waxman Act and the BPCIA,” Fish Life Sciences (March 2019).

“Litigation-Related Issues Under the Biologics Price Competition and Innovation Act,” co-authored chapter with Dr. Tasha Francis and Ron Vogel, in Gutka H., Yang H., Kakar S. (eds) Biosimilars. AAPS Advances in the Pharmaceutical Sciences Series, vol 34. Springer, (January 2019).

“Canada’s New Linkage Litigation Scheme: A Comparison to Hatch-Waxman,” contributor, Smart & Biggar (January 2019).

“Should Stockpiling Be Protected by the Hatch-Waxman Safe Harbor?” co-author, *Fish Litigation Blog* (September 11, 2018).

“Ensnarement — A 2nd Bite At The Noninfringement Apple,” co-author, *Law360* (August 15, 2018).

“Searching For ‘Act Of Infringement’ Under Hatch-Waxman,” co-author, *Law360* (March 6, 2018).

“Canada’s New Linkage Litigation Scheme: A Comparison to Hatch-Waxman,” co-authored with Nancy Pei, *Lexology* (December 1, 2017).

“U.S. Supreme Court Provides Limited Guidance Regarding Biosimilar Patent Litigation,” co-authored with Tasha Francis, 16 BioScience Law Review, 153 (2017).

“The Unclear Scope Of ‘All Patent Rights’ In Patent Exhaustion,” *Law360* (September 27, 2017).

“A Review Of Willfulness Findings In Hatch-Waxman Actions,” co-author, *Law360* (September 19, 2017).

“Has Amgen Already Won Its BPCIA Dispute With Sandoz?” co-author, *Law360,* (August 2, 2017).

“Reviving ‘Regular And Established Place Of Biz’ Case Law,” co-author, *Law360*, (June 13, 2017).

Safe Harbor in the United States and Europe, co-author, Pharmaceutical Law & Industry Report, 14

PLIR 47 (December 2, 2016).

“Can Reference Product Sponsor Forfeit Right To Sue Under BPCIA?” *Law360* (July 25, 2016).

“What the Court Got Wrong About Hatch-Waxman in Alcon” co-author, *Law360* (February 1, 2016).

“Fed. Cir. Limits Safe Harbor for Post-Approval Conduct,” *Law360* (November 17, 2015).

“Safe Harbor Protects Supplier of Active Ingredient for ANDA,” co-author, *Law360* (September 29, 2015).

“Process Patents Are Vital In Biotech — Why Not Extend Them?” co-authored with Peter Ludwig, *Law360* (August 10, 2015).

“Hatch-Waxman Action: Who Do You (Can You) Sue?,” Pharmaceutical Compliance Montior (June 3, 2015).

“*Commil v. Cisco* – Who Really Won?” *IP Law360* (June 2, 2015).

“Personal Jurisdiction in Hatch-Waxman Actions in view of *Daimler*,” Pharmaceutical Compliance Monitor (June 1, 2015).

“Post-Approval Conduct and the Hatch-Waxman Safe Harbor,” Pharmaceutical Compliance Monitor (April 1, 2015).

“The Trouble with Commil is DSU,” *Law360* (January 29, 2015).

“Inter Partes Review by Hatch-Waxman Competitors Will Likely Increase Because of the Effect of IPR Decisions on the 30-Month Stay,” BioTechnology Rept. Vol 33, No. 6:249-51 (December 2014).

“Is Stockpiling Protected By Hatch-Waxman Safe Harbor?,” *Law360* (November 21, 2014)

“Drug Labels Can Provide Specific Intent for Inducement,” *IP Law 360* (October 3, 2014), cited in the Brief for the United States as Amicus Curiae supporting the Petition for Certiorari, in *Commil USA, LLC v. Cisco Systems, Inc.*, Nos. 13-896 and 13-1044.

“IPR’s and the Hatch-Waxman 30-Month Stay of FDA Approval” Fish Litigation Blog (August 12, 2014).

“A Common Sense Discussion of Patenting Medical Diagnostics,” Genetic Engineering & Biotechnology News (April 15, 2014).

“In Vivo Conversion as Inducement to Infringe,” Pharmaceutical Compliance Monitor (February 14, 2014).

“Hatch-Waxman Safe Harbor Expansion continues,” *Fish Litigation Blog* (February 12, 2014).

“Research Tools and the Hatch-Waxman Safe Harbor,” 22 Biotechnology Law Report 1 (November 1, 2014).

“License to Infringe on Research Tool Patents,” 33 Genetic Engineering & Biotechnology News 10 (October 1, 2013).

“The Patentability of Drug Enantiomers,” 190 N.J.L.J. 51 (October 1, 2007)

“Scope of the Safe Harbor Exemption of the Hatch-Waxman Act After *Merck v. Integra Lifesciences*,” 15 Fordham Intellectual Prop. L.J. (2005)

“Overview of Patent Litigation,” 11(1) IP Litigator 1 (2005)

“‘CREATE’ Act of 2004 Extends ‘Safe Harbor’ Aspects of Patent Laws,” N.Y.L.J. 4 (February 3, 2005).

“The Right to a Jury Trial in Actions for Patent Infringement and Suits for Declaratory Judgment,” 13 Fordham Intellectual Prop. L.J. 205 (2002), reprinted as Chapter 21, “Survey of Developments of Intellectual Property and Technology Law” (WebCredenza, Inc. 2004)

“New Horizons in Patent Litigation: Discovering Electronic Information,” N.Y.L.J. S4 (October 12, 2004).

“Recent Federal Circuit Decisions of Significance to Biotech/Pharmaceutical Practitioners”, appearing in “Biotechnology & Pharmaceutical Law 2004? (Practising Law Institute, October 2004)

“Electronic Discovery: Where We Are and Where We are Headed,” 16 Int’l Prop. & Tech. L.J. 16 (March 2004).

“Recent Developments Regarding The Hatch-Waxman Act,” N.Y.L.J. S2 (January 26, 2004).

“Can the Seventh Amendment Ever Require That the Defense of Inequitable Conduct be Presented to a Jury?,” 9 (7) IP Litigator 1 (2003).

“The Period of Liability for Patent Infringement,” 10(7) IP Today 36 (2003).

“Overview Of Patent Litigation” appearing in “What Every Litigator Must Know About Intellectual Property 2003? (Practising Law Institute, July 2003), updated July 2004

Contributor: “Patent Disputes: Litigation Forms and Analysis,” Battersby & Grimes (Aspen Pub. 2003)

Contributor: “Trademark & Copyright Disputes: Litigation Forms and Analysis,” Battersby & Grimes (Aspen Pub. 2003)

“Disqualification of Opinion Counsel as Trial Counsel When an Advice of Counsel Defense is Asserted,” 9(2) IP Litigator 11 (2003)

“*Integra Life Sciences I Ltd. v. Merck KGaA:* Exemptions For Research Tool Patents,” 9(3) IP Strategist 6 (2002)

“Court is Taking a Dim View of Best-Mode Defense,” 25(12) Nat’l L.J., Sec. C. (November 11, 2002).

“The Safe Harbor Provision of the Hatch – Waxman Act: Present Scope, New Possibilities, and International Considerations,” 57 Food Drug L.J. 161 (2002).

“The Right to a Jury Trial Under the Waxman-Hatch Act – The Question Revisited and Resolved,” 57 Food Drug L. J. 1 (2002).

“The Identification and Selection of Expert Witnesses,” 6(3) IP Litigator 1 (2000).

“Adequate Notice: The Key to Obtaining Pre-Suit Damages in Patent Infringement Actions,” 6(2) Met. Corp. Counsel 20 (1998).

“Arbitration of Patent Infringement Disputes,” 6(3) Metropolitan Corp. Counsel 13 (1998).

“Avoiding Patent Infringement During the Drug Approval Process,” N.Y.L.J. S4 (March 9, 1998).

“The Application of the Patent Laws to the Drug Approval Process,” 52 Food Drug L.J. 345 (1997).

“The Right to a Jury Trial in Actions Under the Hatch-Waxman Act,” 52 Food Drug L.J. 259 (1997).

“Developing Pharmaceutical Products Without Fear of Patent Infringement,” 5(6) Met. Corp. Counsel (1997).

“Are Clinical Trials Conducted to Obtain FDA Approval Fatal to Patent Validity?” 5(4) Met. Corp. Counsel (1997).

“The Utilization of U.S. Patents to Prevent the Importation and Sale of Gray Goods,” 83 Trademark Rptr. 481 (1993).

“The Exercise of Patent Rights Through Multiple Exclusive Field-of-Use Licensing,” 4 Rutgers Comp. & Tech. L.J. 383 (1985).

“History and Present Status of Gray Goods,” 75 Trademark Rptr. 433 (1985), reprinted in Hawk, B., United States, Common Market and International Antitrust: A Comparative Guide (Prentiss Hall 1986).

Mr. Coggio presented on life sciences issues and the world, including the U.S., Japan, Great Britain, Germany, the Netherlands, France, Japan, and Switzerland.

Recognition

Recognized as a 2013 Top Rated – AV® Preeminent™ Lawyers in Intellectual Property Law.