

Gunars Gaikis

Partner

Toronto

Barrister and Solicitor,
Patent and Trademark Agent



CONTACT

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YEAR OF CALL

Ontario Bar 1983

QUALIFICATIONS

- University of Toronto
B.Sc.Pharm. (Pharmacy) 1977
- Residency in Hospital
Pharmacy 1978
- Osgoode Hall Law School of
York University J.D. 1981
- Registered Trademark Agent
1983
- Registered Patent Agent
1987
- Registered to practise
before the United States
Patent and Trademark Office

PRACTICE AREAS

Pharmaceutical
Litigation
Patents
Life Sciences
Trademarks
Chemical & Industrial
Biotechnology
IP Management & Strategic
Counselling
Licensing & IP Transactions
Life Sciences — Regulatory &
Compliance

LANGUAGES SPOKEN

English
Latvian

PROFILE

**Globally heralded life sciences litigator and
"seasoned gladiator"**

A pre-eminent and pioneering leader in life sciences intellectual property, Gunars is consistently recognized by his peers and clients for his expertise and contributions over the past 25 years in the highly specialized field of pharmaceutical patent, trademark and related litigation. Among his many accolades, Gunars has been listed as one of the top thirty patent attorneys globally and named as one of the world's leading life sciences patent litigators. Known for his unrelenting client commitment and fierce courtroom advocacy, clients praise Gunars as an "IP star" and "seasoned gladiator."

One of Canada's most experienced life sciences IP litigators, Gunars has been at the forefront of the pharmaceutical patent litigation field since its emergence in the early 1990's. In counselling clients, he strives for practical, cost-effective and often creative solutions that consider client needs, financial implications and the IP rights at stake.

**Ground-breaking court successes protect critical
pharmaceutical innovations**

A strong proponent of protecting pharmaceutical innovation, Gunars acted as counsel in many ground-breaking court decisions on behalf of innovators seeking protection in Canada. This includes his win for AstraZeneca when the Supreme Court "wholly rejected the promise doctrine" and clarified the requirement for patent utility. He has appeared as lead counsel in numerous intellectual property cases before the Ontario, Federal and Supreme courts. His successes earned him recognition by legal publications as a "skilled fighter and lifecycle strategist for original drugs companies."

**Licensed pharmacist with first-understanding in
medical, biotech and pharmaceutical issues**

As a licensed pharmacist with experience in clinical pharmacy, Gunars offers first-hand understanding of medical, biotechnology and pharmaceutical matters, including the relevant regulatory issues, in addition to his exceptional legal experience. He regularly counsels clients in pharmaceutical patent procurement, data protection, PMPRB, IP lifecycle management and drug regulatory matters, and provides invaluable pre-litigation advice and due diligence. Gunars also has extensive expertise in pharmaceutical trademark and passing off cases, and has succeeded in obtaining preliminary injunctions in such trademark cases in both the Ontario Superior and Federal Courts.

Gunars joined Smart & Biggar in 1985 and was instrumental in the growth and expansion of the Toronto office.

Rankings and recognition

- Named the Canadian Patent Litigation Attorney of the Year by *LMG Life Sciences* 2015 and 2018
- Named 2018 Outstanding IP Practitioner of the Year in Canada by *Managing Intellectual Property*
- Nominated for 2018 IP Litigation Lawyer of the Year in Canada by *Benchmark Canada*
- *Benchmark Litigation Canada* - 2019 IP litigator of the year
- Named one of the 'Top 50 Trial Lawyers' in Canada by *Benchmark Canada* 2018 and 2019
- Recognized as a *World IP Review Leader* since the inaugural edition in 2016
- Recognized by *Best Lawyers* as the Biotechnology Law "Lawyer of the Year" in Toronto for 2013 and 2017
- Recognized as one of the top thirty patent attorneys in the world by *Expert Guides: Best of the Best* 2014, 2016 and 2018
- Recognized annually since the inaugural edition in 2006 of *Chambers Global* – The World's Leading Lawyers for Business under Intellectual Property: Litigation
- Recognized annually since the inaugural edition in 2016 of *Chambers Canada* as a leading lawyer for Intellectual Property Litigation and as a recognized practitioner for Life Sciences in 2019
- Recognized as a 'Thought Leader' for Patents and Life Sciences by *Who's Who Legal: Thought Leaders* 2018 and 2019 for obtaining one of the highest number of

- nominations from peers and corporate counsel
- Recognized annually since the inaugural Canada Chapter in 2013 of *LMG Life Sciences* as a 'Life Science Star' under Intellectual Property
- Recognized annually since the inaugural edition in 2012 as a 'Local Litigation Star' in *Benchmark Canada* under Intellectual Property
- Recognized as a 'Leading Lawyer' in Intellectual Property Law in *The Legal 500 Canada* since 2016
- Recognized annually since 2006 in *The Best Lawyers* in Canada under Intellectual Property Law and under Biotechnology Law since 2009
- Recognized annually as an 'IP Star' since the inaugural edition in 2014 of *Managing Intellectual Property's* IP Stars Handbook: Patents
- Featured in Lexpert's Special Edition on Litigation and *The Globe and Mail's Report on Business Magazine* as a Leading Canadian Litigator since 2008
- Recognized annually since the inaugural edition in 2012 of *IAM Patent 1000 - The World's Leading Patent Practitioners* under Litigation
- Recognized in each edition of *Euromoney's Expert Guides: Patents* since 2007
- Recognized annually in *Who's Who Legal: Life Sciences* since the inaugural edition in 2008 ("Most Highly Regarded" for 2017)
- Recognized annually in *Who's Who Legal: Patents* since 2010
- Listed in *The Canadian Legal LEXPERT® Directory* under Intellectual Property, Litigation — Intellectual Property and Biotechnology
- Recognized annually in the *Lexpert® Guide* to the Leading US/Canada Cross-Border Litigation Lawyers in Canada under Intellectual Property Litigation since 2008
- Listed in *The Lexpert®/American Lawyer Guide* to the *Leading 500 Lawyers in Canada* as "Most frequently recommended" under Biotechnology, Intellectual Property and Intellectual Property Litigation
- Recognized in *IAM Life Sciences 250 - The World's Leading Life Sciences Patent Litigators* 2010
- Recognized in the 2015 edition of *Who's Who Legal 100* under Intellectual Property
- Listed in *Life Sciences Specialist 500*
- Recognized annually in *PLC Which Lawyer?* under IP: patent litigation since 2006 and Life sciences: patent litigation since 2003
- Listed in *World Intellectual Property Review - 2018 Leaders Patent & Trademarks Guides* as leader in Biotech, Life Sciences, Patent, Technology and Trademark areas
- Listed in the 2018 *Life Sciences Expert Guide*
- Fellow, Litigation Counsel of America

EXPERIENCE

Proceedings under the *Patented Medicines (Notice of Compliance) Regulations*

- AstraZeneca Canada Inc v Apotex Inc*, [2010 FC 714](#) (esomeprazole)
- Aventis-Pharma Inc v Pharmascience Inc*, [2009 FC 915](#) (ramipril)
- AstraZeneca Canada Inc v Apotex Inc*, [2008 FC 1316](#) (esomeprazole)
- sanofi-aventis Canada Inc v Laboratoire Riva Inc*, [2008 FC 291](#) (ramipril)
- sanofi-aventis Canada Inc v Canada (Health)*, [2008 FC 129](#) (ramipril)
- sanofi-aventis Canada Ltd v Laboratoire Riva Inc*, [2007 FC 1317](#) (ramipril)
- sanofi-aventis Canada Inc v Pharmascience Inc*, [2007 FC 1057](#) (ramipril)
- sanofi-aventis Inc v Laboratoire Riva Inc*, [2007 FC 532](#) (ramipril)
- AB Hassle v Apotex Inc*, [2008 FC 184](#) (omeprazole)
- sanofi-aventis Canada Inc v Novopharm Limited*, [2006 FC 1547](#) (ramipril)
- sanofi-aventis Canada Inc v Novopharm Limited*, [2006 FC 1473](#) (ramipril)
- AstraZeneca AB v Apotex Inc*, [2006 FC 7](#) (omeprazole)
- Aventis Pharma Inc v Apotex Inc*, [2005 FC 1504](#) (ramipril)
- Aventis Pharma Inc v Apotex Inc*, [2005 FC 1461](#) (ramipril)
- Aventis Pharma Inc v Apotex Inc*, [2005 FC 1381](#) (ramipril)
- Aventis Pharma Inc v Apotex Inc*, [2005 FC 1283](#) (ramipril)
- AstraZeneca Canada Inc v Apotex Inc*, [2005 FCA 216](#) (omeprazole)
- Aventis Pharma Inc v Pharmascience Inc*, [2005 FC 340](#) (ramipril)
- AB Hassle v Apotex Inc*, [2005 FC 234](#) (omeprazole)
- AstraZeneca AB v Apotex Inc*, [2004 FC 71](#) (omeprazole)
- AB Hassle v Genpharm Inc*, [2003 FC 1443](#) (omeprazole)
- AB Hassle v Apotex Inc*, [2003 FC 903](#) (omeprazole)

AB Hassle v Apotex Inc, [2003 FCT 771](#) (omeprazole)
AstraZeneca Canada Inc v Apotex Inc, [2002 FCT 1250](#) (omeprazole)
Wyeth-Ayerst Canada Inc v Faulding Canada Inc, [2002 FCT 969](#) (piperacillin)
AB Hassle v Apotex Inc, [2002 FCT 931](#) (omeprazole)
AB Hassle v Rhoxalpharma Inc, [2002 FCT 780](#) (omeprazole)
Rhoxalpharma Inc v AB Hassle, [2002 FCA 147](#) (omeprazole)
Hassle v Apotex Inc, [2002 FCT 222](#) (omeprazole)
Hassle v Canada (Minister of National Health and Welfare), [2001 FCT 1264](#) (omeprazole)
AB Hassle v Canada (Minister of National Health and Welfare), [9 CPR \(4th\) 79](#) (omeprazole)
Merck Frosst Canada Inc v Canada (Minister of Health), [8 CPR \(4th\) 87](#) (timolol)
AB Hassle v Canada (Minister of National Health and Welfare) [190 FTR 264](#) (omeprazole)
Bayer AG v Canada (Minister of National Health and Welfare), [77 CPR \(3d\) 129](#) (ciprofloxacin)
Hoffmann-La Roche Limited v Apotex Inc, [72 CPR \(3d\) 480](#) (ketorolac)
AB Hassle v Canada (Minister of National Health and Welfare), [72 CPR \(3d\) 318](#) (metoprolol)
Pharmacia Inc v Ben Venue Laboratories Inc, [72 CPR \(3d\) 229](#) (doxorubicin)

Interim/interlocutory injunctions

AstraZeneca Canada Inc v Apotex Inc, [2011 FC 505](#) (esomeprazole)
Aventis Pharma SA v Novopharm Ltd, [2005 FC 815](#) (enoxaparin)
Zeneca Ltd v Apotex Inc (1997), [79 CPR \(3d\) 399](#) (Ont. Ct. Gen. Div.) (lisinopril)
Ciba-Geigy Canada Ltd v Novopharm Ltd (1994), 56 CPR (3d) 289 (FCTD) (diclofenac)
Ciba-Geigy Canada Ltd v Novopharm Ltd (1993), 52 CPR (3d) 497 (FCTD) (diclofenac)
Sklar-Pepler Inc v Decor-Rest Furniture Ltd (1990), 34 CPR (3d) 76 (FCTD) (industrial design, sofa)

Pharmaceutical patent infringement/validity/section 8 actions

Apotex Inc v AstraZeneca Canada Inc, [2018 FC 181](#) (esomeprazole)
AstraZeneca AB v Apotex Inc, [2018 FC 185](#) (esomeprazole)
AstraZeneca Canada Inc v Apotex Inc, [2015 FC 322](#) and [2017 FCA 9](#) (Omeprazole)
AstraZeneca Canada Inc v Apotex Inc, [2014 FC 638](#), [2015 FCA 158](#) and [SCC 36654](#)(esomeprazole)
Apotex Inc v AstraZeneca Canada Inc, [2012 FC 559](#) (omeprazole)
Apotex Inc v sanofi-aventis, [2012 FC 553](#) (ramipril)
sanofi-aventis Canada Inc v Teva Canada Limited, [2012 FC 552](#) (ramipril)
sanofi-aventis Canada Inc v Teva Canada Limited, [2012 FC 551](#) (ramipril)
Apotex Inc v Syntex Pharmaceuticals International Inc, [2010 FCA 155](#) (naproxen)
sanofi-aventis Canada Inc v Apotex Inc; sanofi-aventis Canada Inc v Novopharm Inc, [2009 FC 676](#) (ramipril)
Apotex Inc v Syntex Pharmaceuticals International Ltd and Hoffmann LaRoche Limited, [2009 FC 494](#) (naproxen)
Merck & Co Inc v Apotex Inc, [2006 FC 524](#) (lisinopril)
Apotex Inc v Syntex Pharmaceuticals International Ltd, [1 CPR \(4th\) 22](#) (naproxen)

Judicial review

Bayer Schering Pharma Aktiengesellschaft v Canada (Attorney General), [2010 FCA 275](#) (patent claims)
Bayer Schering Pharma Aktiengesellschaft v Canada (Attorney General), [2009 FC 1249](#) (patent claims)
Bayer Inc v Canada (Health), [2009 FC 1171](#) (estradiol)
sanofi-aventis Canada Inc v Canada (Health), [2009 FCA 169](#) (ramipril)

Bayer Inc v Canada (Health), [2009 FCA 133](#) (estradiol)
Immunex Corporation v Canada (Health), [2008 FC 1409](#) (etanercept)
sanofi-aventis Canada Inc v Canada (Health), [2008 FC 1062](#) (ramipril)
Bayer Inc v Canada (Health), [2008 FC 857](#) (estradiol)
Ferring Inc v Canada (Health), [2007 FCA 276](#) (ramipril)
Ferring Inc v Canada (Health), [2007 FC 300](#) (ramipril)
sanofi-aventis Canada Inc v Canada (Minister of Health), [2006 FC 1559](#) (ramipril)
Hoffmann-La Roche Ltd v Canada (Minister of Health), [2004 FC 1547](#) (trastuzumab)
AstraZeneca Canada Inc v Canada (Minister of Health), [2004 FC 1278](#) (omeprazole)
AstraZeneca Canada Inc v Canada (Minister of Health), [2004 FC 1277](#) (omeprazole)

Appeals

Federal Court of Appeal

Apotex Inc v AB Hassle, [2008 FCA 416](#) (omeprazole)
Hässle v Apotex Inc, [2008 FCA 88](#) (omeprazole)
Novopharm Limited v sanofi-aventis Canada Inc, [2007 FCA 167](#) (ramipril)
Apotex Inc v sanofi-aventis Canada Inc, [2007 FCA 7](#) (ramipril)
sanofi-aventis Canada Inc v Apotex Inc, [2006 FCA 357](#) (ramipril)
sanofi-aventis Canada Inc v Apotex Inc, [2006 FCA 328](#) (ramipril)
Apotex Inc v Merck & Co, [2006 FCA 323](#) (lisinopril)
Apotex Inc v Merck & Co, [2006 FCA 324](#) (lisinopril)
Apotex Inc v Merck & Co Inc, [2006 FCA 198](#) (lisinopril)
Aventis Pharma Inc v Apotex Inc, [2006 FCA 64](#) (ramipril)
AstraZeneca Canada Inc v Canada (Minister of Health), [2005 FCA 208](#) (omeprazole)
AstraZeneca Canada Inc v Canada (Minister of Health), [2005 FCA 189](#) (omeprazole)
AstraZeneca AB v Apotex Inc, [2005 FCA 183](#) (omeprazole)
Hoffman-La Roche Ltd v Canada (Minister of Health), [2005 FCA 140](#) (trastuzumab)
Merck & Co Inc v Apotex Inc, [2003 FCA 488](#) (lisinopril)
Apotex Inc v AB Hassle, [2003 FCA 409](#) (omeprazole)
Apotex Inc v AB Hassle, [2003 FCA 87](#) (omeprazole)
AstraZeneca AB v Novopharm Ltd, [2003 FCA 57](#) (felodipine)
AB Hassle v Canada (Minister of National Health and Welfare), [2002 FCA 421](#) (omeprazole)
Novopharm Ltd v AstraZeneca AB, [2002 FCA 387](#) (felodipine)
Hoffmann-La Roche v Canada (Minister of National Health and Welfare), [9 CPR \(4th\) 90](#); aff'd 85 CPR (3d) 67 (flunisolide)

Ontario Court of Appeal

Apotex Inc v Sanofi-Aventis, et al, [2018 ONCA 890](#) (ramipril)

Supreme Court of Canada

AstraZeneca Canada Inc v Apotex Inc, [2017 SCC 36](#) (esomeprazole)
AstraZeneca Canada Inc v Canada (Minister of Health), [2006 SCC 49](#) (omeprazole)

PROFESSIONAL INVOLVEMENT

Memberships

- Fellow, Litigation Counsel of America
- Fellow, Intellectual Property Institute of Canada
- Member, Pharmaceutical Trade Marks Group
- Member, American Intellectual Property Law Association
- Past long-time Chair of the Patent Committee of the IP Section, Canadian Bar

- Association
- Editorial board member of LSIPR Newsletter

Speaking engagements

- "What Pharmacists Need to Know about Cannabis", (co-speaker: Alice Tseng), Pharmacy Experience Pharmacie (PxP) conference, Toronto, Ontario, June 4, 2019
- "A Focus on the Utility Doctrine" (co-presenter: Yoon Kang), The Canadian Institute's 13th Forum on Pharma Patents, October 2016
- "Canada: Is Case Law Moving Sideways? The Utility & the "Promise" issue" presentation at C5's Life Sciences IP Summit, October 2016
- "Navigating Jurisdictional Challenges and Quantifying Damages in s. 8 Cases: Critical Views from Both Sides" panel discussion at the Canadian Institute's 11th Annual Forum on Pharma Patents, Toronto, October 2012
- "Damages in Patent Infringement and Section 8 Cases: The View from Both Sides" panel discussion at the Canadian Institute's 10th Annual Forum on Pharma Patents, Toronto, October 2011
- "Strategies in Pharma Patent Litigation," Insight Information's 9th conference on Drug Patents in Canada, Toronto, May 2010
- "Pharma Patents Litigation: Year in Review," panel discussion at The Canadian Institute's 8th Annual Forum on Pharma Patents, Toronto, October 2009
- "Pharma Patent Trials Within Two Years," Insight Information's Drug Patent and Legal Forum, Toronto, May 2009
- "Year in Review – Regulatory Developments" (co-presenters: Nancy P. Pei and Daphne C. Lainson) and "Year in Review – Litigation" (co-presenters: J. Sheldon Hamilton and Yoon Kang), Smart & Biggar's Pharma Patents 2008, Mississauga, ON, November 2008
- "Pharma Patents and Competition Law Issues: Patentee's Perspective," Insight Information's Drug Patents and Legal Forum, Toronto, February 2008
- "Successfully Maximizing Product Life Cycle: What Every Innovator Needs to Know," "The Canadian Institute's National Business and Legal Guide to Life Sciences Business and Legal, Ottawa, April 2008
- "Pharma Patents – The Year in Review" (co-presenters: J. Sheldon Hamilton, Yoon Kang, Nancy P. Pei and Denise L. Lacombe) and "Pharmaceutical Product Life Cycle Management – Patents and the Regulatory Environment, Including Data Protection and the *Patented Medicines (Notice of Compliance) Regulations*" (co-presenter: Nancy P. Pei), Smart & Biggar's Pharma Patents 2007, Mississauga, ON, November 2007
- "Authorized Generics and Relevant Licensing Issues," The Canadian Institute's 6th Annual Forum on Pharma Patents, Toronto, October 2007
- "Changes to *Patented Medicines (NOC) Regulations* – Industry Perspective" (co-presenter: Nancy P. Pei), Canadian Association of Professional Regulatory Affairs symposium From Product Monograph to Promotion and Other Emerging Initiatives, Toronto, November 2007
- "Successfully Protecting Exclusivity in the New Regulatory Framework," The Canadian Institute's Summit on Pharmaceutical & Biotech Regulatory Compliance, Toronto, March 2007
- "Preventing, Defending, and Financing IP Litigation," Insight/ALM conference Intellectual Property: Building, Protecting, and Profiting From Your IP Portfolio, Toronto, November 2006
- "Pharma Patents and the Regulatory Environment" (co-presenter: Nancy P. Pei), "Litigating Pharma Patents" (co-presenters: John R. Morrissey and Steven B. Garland) and "Hot Topics and Discussion" (co-presenters: A. David Morrow and J. Sheldon Hamilton), Smart & Biggar's Pharma Patents 2006, Mississauga, ON, November 2006

MEDIA

Publications

- Quoted in "[Decision resurrects disputed patent principle](#)", *Law Times*, November 26, 2018
- "[Process for Choosing and Vetting an Expert Witness in Patent Cases](#)", (co-authors Andrew Mandlsohn and Shirley Liang Komosa), *Canadian Intellectual Property Review*, June 2016, Volume 32
- "Clarification of the 'promise' of utility doctrine in Canada," *Expert Guides: Patent 2015*, March 2015, pp. 88-89
- "[The race for market exclusivity](#)," *Life Sciences Intellectual Property Review Quarterly*, Vol. 2, Issue 2 (2015)
- "[Cold Feet in Canada](#)," *Life Sciences Intellectual Property Review Quarterly*, Vol. 2, Issue 1 (2015)
- "[Supreme Court of Canada: VIAGRA patent "void" for insufficient disclosure](#)" (co-authors: J. Sheldon Hamilton and Colin B. Ingram), *IP Update – Canada*, November 8, 2012
- "Pharmaceutical Patent Litigation is Inevitable — Typically Overlooked Licensing Terms" (co-authors: Junyi Chen, Jeff J. Kang and Rebecca B. Rodal), presented at the Federated Press conference titled "Negotiating & Drafting Bio Pharma Contracts," June 2011

- "The Patentability of Pharmaceutical Dosage Regimes in Canada" (co-author: David E. Schwartz), *26 Canadian Intellectual Property Review* 2, December 2010
- "Minimizing the Risk of Section 8 Damages" (co-authors: Andrew Mandlsohn, Patrick M. Roszell and Alain Laplume), presented at the 9th Annual Forum on Pharma Patents, November 2010
- "Analyzing the Latest Developments in the Law to Identify Emerging Trends, Opportunities and Threats" (co-authors: Andrew Mandlsohn, Urszula Wojtyra and Jordan D. Scopa), presented at the 8th Annual Forum on Pharma Patents, October 2009
- "Understanding Key Issues Impacting the Industry Today: Recent Developments in the Law of Patents" (co-authors: Andrew Mandlsohn and Jayda A. Sutton), presented at the 7th Annual Forum on Pharma Patents, October 2008
- "Unique IP Issues in Canada's Pharmaceutical and Biotechnology Industry" (co-authors: Daphne C. Lainson and David E. Schwartz), *The 2006 LEXPERT Guide to the Top 100 Industry Specialists in Canada*, October 2006, pp. 125-129
- "Proposed Amendments to the Patented Medicines (Notice of Compliance) Regulations and Data Protection Provisions of the Food and Drug Regulations" (co-author: Junyi Chen), presented at the Canadian Institute's Pharmaceutical & Biotech Regulatory Compliance Conference, March 2006
- "Recent Jurisprudence Under the NOC Regulations" (co-author: Junyi Chen), presented at the Canadian Institute's 4th Annual Forum on Pharma Patents: The Legal and Strategic Guide, October 2005
- "Listing Patents on the Patent Register" (co-author: Junyi Chen), presented at Drug Patents: The Latest Legal, Regulatory, and Litigation Developments, March 2005