

INDUSTRY

Pharmaceutical

The attorneys in Benesch's Pharmaceutical Industry Team represent companies in a variety of legal issues throughout the entire pharmaceutical industry supply chain, including manufacturers, licensors, distributors and sellers of both generic and branded drugs.

These issues include compliance, contracting (CMO agreements, licensing, distribution and supply agreements, 3PL agreements), DSCSA compliance, fraud and abuse counseling, government investigations, and intellectual property matters. We also handle product liability, mergers and acquisitions, labor and employment, and real estate issues.

A Full-Service Experience

- Intellectual Property
- Product Liability
- Government Investigations
- Corporate
- Labor & Employment
- Real Estate
- Transportation & Logistics

Representative Clients

- Abbott Laboratories
- Accord BioPharma
- Alkem Laboratories
- Annora Pharma
- Apotex Inc.
- Baxter International
- BioXcel Therapeutics
- Encube Ethicals
- Gan & Lee Pharmaceuticals
- Gland Pharma
- Hetero Drugs
- INTAS Pharmaceuticals
- Torrent Pharma

Industry Recognition



Nationally Recognized

by Best Law Firms® in Intellectual Property Litigation



Trade Secret Powerhouse

by IAM Patent 1000



Recognized

by Chambers in Intellectual Property

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Dedicated attorneys

including many with backgrounds in life sciences, offering nuanced insights across various therapeutic areas and drug delivery methods

Therapeutic Areas

- Oncology
- Dermatology
- Immunology
- Endocrinology
- Ophthalmology
- Cardiovascular Disease
- Infectious Disease
- Respiratory Disorders
- Pain Management
- Women's Health
- Arthritis Disorders
- Neurological Disorders

Dosage Forms & Devices

- **Oral dosage forms**
(suspensions, tablets, capsules, films)
- **Topicals**
(sprays, creams, transdermal patches)
- **Injectables**
- **Inhalation solutions**
- **Ophthalmic solutions**
- **Dry powder inhalers**

Recent **Products**

- Apixaban (ELIQUIS)
- Apremilast (OTEZLA)
- Axitinib (INLYTA)
- Buprenorphine/Naloxone (SUBOXONE FILM)
- Bupropion HCl (WELLBUTRIN)
- Cefuroxime Axetil (CEFTIN)
- Crisaborole (EUCRISA)
- Dapagliflozin (FARXIGA)
- Dapagliflozin Metformin (XIGDUO)
- Desmopressin Acetate (DDVAP)
- Efinaconazole (JUBLIA)
- Empagliflozin (JARDIANCE)
- Erlotinib HCl (TARCEVA)
- Famotidine (PEPCID)
- Fentanyl (SUBSYS)
- Ferric Citrate (AURYXIA)
- Ferumoxytol (FERAHEME)
- Infliximab (REMICADE)
- Melphalan (EVOMELA)
- Memantine/Donepezil (NAMZARIC)
- Methylphenadate (DAYTRANA)
- Naltrexone HCl (CONTRAVE)
- Palonosetron (ALOXI)
- Pegfilgrastim (NEULASTA)
- Pemetrexed (PEMFEXY)
- Pierfenidone (ESBRIET)
- Regadenoson (LEXISCAN)
- Tavorole (KERYDIN)
- Teriflunomide (AUBAGIO)
- Ticagrelor (BRILINTA)
- Tiotropium Bromide (SPIRIVA)

Representative **Matters**

- ▶ Represented clients as trial counsel in a Hatch-Waxman ANDA case relating to a leading A2A adenosine receptor agonist and coronary vasodilator, Lexiscan[®] (regadenoson), resulting in settlement on behalf of both clients during trial on three polymorph patents.*
- ▶ Represented a client in a patent litigation regarding a biosimilar version of Amgen's blockbuster drug Neulasta[®] (pegfilgrastim). The litigation was successfully terminated when the client obtained an order dismissing Amgen's related declaratory judgment.*
- ▶ Represented a client in litigation in federal court related to a biosimilar version of Janssen's multibillion-dollar drug Remicade[®] (infliximab), resulting in two highly publicized motions for summary judgment that invalidated one of Janssen's patents related to the infliximab antibody.*
- ▶ Represented a client as counsel in a Hatch-Waxman litigation in a first-to-file (FTF) opportunity related to a leading iron replacement product, Feraheme[®] (ferumoxytol), used to treat iron deficiency anemia in patients with chronic kidney disease (CKD), resulting in settlement at trial and permitting the client to launch its product prior to expiry of patents-in-suit.*
- ▶ Argued an appeal before the Federal Circuit on behalf of an appellee seeking reversal of summary judgment of noninfringement based on prosecution history estoppel in a Hatch-Waxman ANDA litigation.
- ▶ Represented a leading manufacturer of women's health products in multiple litigations related to extended regimen oral contraceptives and a hormone replacement therapy.
- ▶ Secured a favorable claim construction for a patent relating to a cyclodextrin carrier for a melphalan injectable (Evomela[®]) that led to a successful settlement.
- ▶ Obtained summary judgment on behalf of the filer of an ANDA for a generic version of DDAVP[®] Tablets (desmopressin acetate) for noninfringement and unenforceability claims based on inequitable conduct. The summary judgment was affirmed on appeal.
- ▶ Forced a covenant not to sue and a unilateral motion to dismiss in a case involving formulation patents for a dronabinol oral solution (Syndros[®]) that led to the possibility of an entry date prior to expiration of the Orange Book-listed patents.
- ▶ Represented a client in Hatch-Waxman patent litigation in a first-to-file (FTF) opportunity related to a methylphenidate transdermal patch sold by Noven as Daytrana[®]. Obtained partial summary judgment rulings of noninfringement and invalidity due to an inadequate written description. The parties' settlement permitted the client to launch its product three years before expiration of the patent-in-suit.

*These matters were completed prior to the attorney joining Benesch.