

Recent Life Sciences Representations

- We represented **Celgene Corporation** in connection with a petition seeking Inter Partes Review of Celgene's U.S. Patent No. 7,968,569 that was filed by Alvogen Pine Brook and Lotus Pharmaceuticals. Quoting liberally from our preliminary response, the Patent Trial and Appeals Board denied institution, soundly rejecting Alvogen's position on the merits and upholding the validity of Celgene's patent, which covers methods of using Celgene's Revlimid drug product for the treatment of multiple myeloma. The patent expires in October of 2023.
- We represented **The Broad Institute, Inc.** in a patent interference (Interference No. 106,048) suggested by the University of California and Emmanuelle Charpentier challenging key Broad patents directed to use of CRISPR in eukaryotic cells, humans, other mammals, and plants. CRISPR technology has been widely hailed in the press as one of the most important scientific breakthroughs of this century. We, along with co-counsel, obtained a victory for the Broad, MIT and Harvard as the PTAB declared there was no interference in fact and dismissed the interference with our client's patents. On September 10, 2018, the Federal Circuit issued its decision in favor of our client, affirming the PTAB's ruling.
- We won a complete victory for our client **Celgene Corporation** in an *inter partes* review challenging U.S. Patent No. 8,741,929, which expires in 2028. The patent covers methods of using Celgene's Revlimid drug product for the treatment of mantle cell lymphoma ("MCL"), a deadly and hard-to-treat blood cancer. Apotex is seeking to market a generic version of Revlimid with a label indication for MCL. The PTAB rejected Apotex's positions in their entirety, upholding the validity of the '929 patent.
- QE won three complete victories for our clients **Celgene Corporation** and **Abraxis BioScience, LLC**, in inter partes reviews challenging U.S. Patent Nos. 7,820,788, 7,923,536, and 8,138,229. These patents cover aspects of Celgene's Abraxane drug product, which is approved to treat metastatic breast cancer and other aggressive cancers. Inter partes review of all three of these patents had previously been instituted based on identical prior art, arguments, and expert testimony in a related case that had settled. We prevailed in these IPRs by obtaining key admissions from the opposing parties' expert during his deposition. The PTAB relied on these fatal admissions in denying institution of each IPR, despite having previously instituted on the same grounds. We had previously successfully defended against another IPR covering an unrelated patent related to Abraxane, U.S. Patent No. 8,853,260.
- We represent biopharmaceutical company **Theravance Biopharma US, Inc. and certain of its affiliates** against its former Senior Vice President of Technical Operations, Junning Lee. Prior to his resignation in February 2017, Lee downloaded hundreds of thousands of confidential, proprietary, and trade secret documents from Theravance's servers, then attempted to cover his tracks when Theravance discovered the downloading. We asserted claims for trade secret misappropriation under state and federal law, as well as claims for breach of contract and breach of Lee's fiduciary duty and duty of loyalty. The court (Judge

Vince Chhabria in the Northern District of California) granted our motion for preliminary injunction with only minor modification, ordering Lee to return dozens of devices, to provide access to his email accounts, and to identify any third parties who might have received Theravance data. Theravance was not required to post a bond.

- We achieved a significant appellate victory for our long-time client **Merck (US)** in connection with its NuvaRing® contraceptive product. On October 19, 2017, the United States Court of Appeals for the Federal Circuit reversed the district court's finding that Merck's patent covering NuvaRing® was obvious. The decision prevents generic competition for NuvaRing® until after the patent expires
- In the federal multidistrict litigation, *In re Zolofit*, several hundred plaintiffs alleged that use of Zolofit, an antidepressant sold by Pfizer, during pregnancy caused children to be born with birth defects. We, as national and lead counsel for **Pfizer**, led a defense team that secured an important appellate ruling in the U.S. Court of Appeals for the Third Circuit, in which the court unanimously affirmed the exclusion of the plaintiffs' key causation expert evidence under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and entry of summary judgment in favor of Pfizer.
- In *Porter v. SmithKline Beecham Corp.*, the plaintiffs alleged that use of Zolofit, an antidepressant sold by Pfizer, during pregnancy caused their child to be born with a birth defect known as omphalocele. We, as national and lead counsel for **Pfizer**, led a defense team that secured an important appellate ruling in the Pennsylvania Superior Court, in which the court unanimously affirmed the exclusion of the plaintiffs' key causation expert evidence under the Pennsylvania Rules of Evidence (which adopts the standard for expert evidence set forth in *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923)) and entry of summary judgment in favor of Pfizer.
- We represented **Gilead Sciences, Inc.** against two generic companies in a Hatch-Waxman patent dispute concerning Gilead's life-extending, \$800 million/year cardiovascular drug, Letairis. With the final Pretrial Order filed and trial about to be scheduled, we achieved a very favorable, confidential settlement. The client was thrilled with the result.
- We represented **Jazz Pharmaceuticals, Inc.** in a Hatch-Waxman patent litigation involving Jazz's Xyrem® (sodium oxybate) drug product, which is indicated to treat cataplexy and excessive daytime sleepiness in narcolepsy patients. After more than six years of litigation, we obtained a favorable settlement for Jazz that does not permit generic entry until 2023, after the majority of the 20 patents covering Xyrem have expired.
- We represent **Pfizer** in litigation alleging that use of Zolofit during pregnancy has caused birth defects in some children. On December 23, 2016, the Mass Litigation Panel of West Virginia entered an order granting summary judgment in the last two West Virginia cases. At the outset, there were almost 40 cases pending before the Panel, filed by a Texas attorney seeking to avoid the federal multidistrict litigation. In 2014, we had successfully obtained dismissal on grounds of forum non conveniens of 29 cases, while others were voluntarily dismissed, leaving only 4 cases remaining in West Virginia state court. Earlier this year, we successfully moved for summary judgment in two of those cases. The remaining two were scheduled for trial in mid-January, but as a result of consistent pressure applied by us during discovery, Plaintiffs withdrew their liability expert and we moved for summary judgment. Rejecting the Plaintiffs' arguments that an expert witness on the adequacy of the Zolofit label was not required, the Panel granted our motion for summary judgment.

- We secured a 9-figure settlement for a **pharmaceutical company** in several contract disputes arising out of drug and device development collaboration and licensing agreements, without having to file suit or request arbitration. This was a prime example of the “Quinn Emanuel Effect,” where our appearance, reputation, and initial strategic initiatives resulted in an early and highly favorable outcome.
- We represented **Celgene Corporation** in a Hatch-Waxman patent litigation involving Celgene’s Revlimid® (lenalidomide) drug product, which is indicated to treat multiple myeloma and other types of cancer. After more than five years of litigation, we obtained a favorable settlement for Celgene that does not permit full generic entry until 2026, after all but one of the nearly 30 patents covering Revlimid have expired.
- We represented **Celgene Corporation** in connection with an IPR petition filed by Hedge fund manager Kyle Bass and patent troll Erich Spangenberg (and related funds and other entities) against Celgene Corporation’s U.S. Pat. No. 5,635,517, which covers the active ingredient in Celgene’s blockbuster cancer therapy, Revlimid®. The Patent Trial and Appeal Board denied institution of the IPR, adopting nearly all of Celgene’s arguments against institution.
- We secured a key victory at the Federal Circuit for our client **Avanir Pharmaceuticals, Inc.**, an innovator pharmaceutical company, in a “bet-the-company” Hatch-Waxman patent litigation relating to Avanir’s flagship Nuedexta® product. Chief Judge Leonard P. Stark of the District of Delaware had previously issued a well-reasoned and thorough 63-page opinion in Avanir’s favor. Our adversary appealed, and oral argument was held on Friday, August 7, 2015. The morning of Monday, August 10, 2015—less than one business day later—the Federal Circuit issued a Rule 36 affirmation of the District Court’s decision, thereby ensuring patent protection for Nuedexta® until 2026.
- We represented **Abbott Laboratories** and **Third Wave Technologies** in litigation in the Western District of Wisconsin against Innogenetics relating to Innogenetics’ patents related to Hepatitis C in which we obtained a favorable resolution by way of settlement.
- We are representing **AccessClosure** in a patent case involving vascular closure devices.
- We defended **ALZA** in a patent inventorship dispute in which two individuals alleged that they were the inventors of an ALZA patent covering liposomes used for the targeted delivery of pharmaceuticals. After a one-week bench trial, the court rejected the claim of inventorship and entered judgment for ALZA.
- We are defending **Ambu A/S** in the international patent litigation battle against LMA relating to laryngeal masks necessary for anesthetic purpose in the trial and appellate court in Düsseldorf and in the EPO (opposition proceedings, also appeal).
- One of our partners acted as trial counsel for **ArthroCare Corp.** in a patent infringement litigation involving medical devices for spine surgery.
- We represented **Becton Dickinson & Company** against Syntron Bioresearch in a patent case involving home pregnancy test kits, winning claim construction and obtaining a favorable settlement. In a similar patent action against Inverness Medical, our lawyers defeated summary judgment and obtained a favorable claim construction and settlement.

- We represented **Bio-Rad Laboratories, Inc.** as lead counsel in multiple patent infringement suits regarding microplate, electroporation, and multiporation technology. Multiple cases were settled on favorable terms for Bio-Rad.
- We achieved a complete defense victory for **Bio-Rad Laboratories** in a biotech patent case relating to genetic testing for an iron disorder. We obtained a ruling that one patent was invalid for failing the written description requirement of the patent laws, and another patent was invalid over prior art. This successful judgment was affirmed in a precedential opinion in the Court of Appeals for the Federal Circuit on April 29, 2011.
- One of our attorneys defended **Bio-Rad Laboratories**, which had been charged with infringing a patent covering a confocal microscope. Although the patent had been upheld in an earlier suit before the same judge, the court was convinced to not only find the patent invalid, but that it was procured through inequitable conduct. These findings resulted in a complete victory in which Bio-Rad received its attorney's fees.
- We represented **Boston Scientific** in multiple patent cases involving coronary stents, balloon angioplasty catheters, and microcatheters.
- Plaintiffs **Catalina Marketing Corporation** and its wholly owned subsidiary, **Catalina Health Resource** (collectively “Catalina”), retained us to take over as lead counsel in an action alleging infringement of U.S. Patent No. 6,240,394 (“the '394 patent”) shortly before the *Markman* hearing. The '394 patent disclosed and claimed a novel method and computer system for generating targeted messages for pharmacy patients at the point of sale. Catalina alleged that LDM Group LLC's “Carepoint” product and related services infringed the '394 patent. The parties resolved the case informally pursuant to a confidential settlement agreement.
- We are representing **Celgene Corporation** in several intellectual property matters, including a 26-patent Hatch-Waxman patent litigation against three defendants in the District of New Jersey in connection with Celgene’s REVLIMID® drug product. We have successfully defended Celgene’s patents for more than four years since the case was filed in October 2010.
- Several of our attorneys represented **Celgene Corporation** in a 10-patent Hatch-Waxman patent litigation against a generic drug company in the District of New Jersey in connection with Celgene’s THALOMID® drug product. We successfully defended Celgene’s patents for more than three years, at which point the generic company withdrew its application to market generic THALOMID® and its counterclaims were dismissed with prejudice.
- We are representing **Centocor Ortho Biotech**, a Johnson & Johnson subsidiary, in a patent inventorship dispute involving a patent on an anti-cancer drug.
- We represented **Connetics** in Paragraph IV patent infringement litigation involving Olux® clobetasol propionate foam. The case settled following a favorable claim construction and after the defendant's motion for summary judgment of no infringement was denied.
- We represented plaintiffs **Connetics Corporation** and **Stiefel Laboratories** (now a GSK Company) in Paragraph IV patent infringement litigation involving Luxiq® betamethasone valerate foam.

- We represented **Cornell** against Zeiss in a patent case involving two-photon microscopy for medical research, winning claim construction and obtaining a favorable settlement.
- We won summary judgment of non-infringement for **Covidien** against Applied Medical Resources Corp., obtaining a judgment that Covidien's VERSAPORT™ PLUS surgical trocar products do not infringe Applied's patent.
- We represented **Dyax** in a patent infringement case involving phage display libraries. After successfully moving to dismiss for lack of personal jurisdiction in the Southern District of New York, we obtained summary judgment of no infringement in the District of Massachusetts.
- We obtained summary judgment in favor of our client **EKR Therapeutics, Inc.** in a Hatch Waxman dispute involving infringement of EKR Therapeutics' patent covering the manufacturing formula for its brand name drug Cardene® I.V. Cardene® I.V. is one of the leading therapies for the treatment of acute hypertension in emergency settings. Generating sales of about \$360 million per year, Cardene® I.V. came under attack from the generic drug company Sun Pharmaceuticals Industries, Ltd., which was threatening to launch a generic copy of Cardene® I.V. prior to expiration of the patent-in-suit. Believing that it would prevail on a theory that it characterized as “unavoidable,” Sun Pharmaceuticals filed an early motion for summary judgment of noninfringement in July 2008. The firm's decision to oppose that motion by having EKR Therapeutics file its own cross-motion for summary judgment paid off. On March 31, 2009, the Court issued an order and opinion finding that Sun Pharmaceuticals' generic copy of Cardene® I.V. infringes the patent-in-suit, both literally and under the doctrine of equivalents.
- After a three-week patent infringement jury trial, one of our partners won a jury verdict in favor of **Ethicon Endo-Surgery** (“EES”), which triggered an eight-figure payment and ongoing royalties to EES under the parties' settlement agreement.
- We secured a win for **Forest Laboratories** when the U.S. Court of Appeals for the Federal Circuit issued its mandate affirming the U.S. District Court for the Southern District of New York's JMOL of obviousness. The district court, Judge Lewis A. Kaplan presiding, had ruled that no reasonable jury could fail to find the asserted patent claim invalid due to obviousness by clear and convincing evidence. The Federal Circuit affirmed, and did so decisively, issuing a Rule 36 affirmance three days after the appellate oral argument. The district court JMOL and Federal Circuit affirmance eliminated a claim for damages and ongoing royalties of over \$600 million, and removed the possibility of an injunction barring the sale of Lundbeck and Forest's antidepressant drugs CELEXA® and LEXAPRO®, which have over \$2 billion in annual U.S. sales.
- We represented **Forest Laboratories** and **ONY** in a declaratory judgment case involving lung surfactants used to treat premature infants. We obtained judgment of equitable estoppel and no infringement following a twelve-week jury trial.
- We helped innovator pharmaceutical companies **Forest Laboratories, Inc.**, **Forest Laboratories Holdings, Ltd.**, and **H. Lundbeck A/S** protect their multi-billion-dollar blockbuster antidepressant LEXAPRO® in a lawsuit brought by generic drug company Apotex Inc. in the Eastern District of Michigan. Through early motion practice, we made the case unwinnable for Apotex, which voluntarily dismissed the case only six months after filing it.

- **Forest Laboratories** and **Merz Pharmaceuticals** brought multiple actions against over 20 defendants under the Hatch-Waxman Act to protect its anti-Alzheimer's drug NAMENDA®. NAMENDA® generates annual U.S. sales of over \$1 billion. After two years of litigation, we negotiated settlements that included consent judgments with injunctions against all defendants, preventing generic competition with NAMENDA® until 2015, and protecting over \$5 billion in revenue.
- We are currently representing **Forest** and **Merz** in a Hatch-Waxman patent litigation involving its extended release NAMENDA XR® drug product against thirteen defendants.
- We successfully defended **Genentech, Inc.** in high-stakes patent litigation brought by Sanofi-Aventis Deutschland in the Eastern District of Texas. Sanofi sought damages on Genentech's Rituxan® and Avastin® products, which earn billions of dollars in revenues each year. After we secured a writ of mandamus from the Federal Circuit transferring the case to the Northern District of California—in an opinion now routinely cited in transfer motions—the district court granted summary judgment of non-infringement of all asserted claims, which the Federal Circuit subsequently affirmed.
- When Columbia demanded that **Genentech** license a “new” patent on co-transformation—a widely used recombinant DNA technique for producing protein in a host cell—we sued for obviousness-type double patenting. With our summary judgment motion looming, the university filed a broad covenant not to sue Genentech for past, current, or future infringement of the “new” patent or any reissued patent with the same or similar claims.
- We are representing **Gilead Sciences** in several intellectual property matters, including an antitrust action brought by a generic pharmaceutical company seeking to force Gilead to provide samples of its drug product Letairis® for use in bioequivalence studies.
- We represented **General Electric Medical Systems** as plaintiff and as defendant in matters regarding digital medical image storage and display technologies.
- We are representing **General Electric Medical Systems** in separate matters regarding the alleged infringement of medical image compression and progressive transmission patents and the alleged infringement of an MRI pulse sequence patent.
- One of our attorneys was trial counsel for **Generation II Orthotics/Ossur** in a jury trial in Seattle, WA. The patents covered an adjustable knee brace for treating osteoarthritis. The jury found the patents valid and willfully infringed. Damages and interest amounted to approximately \$8 million and the defendant was enjoined from offering the infringing product.
- We represented **IDX** and **Cerner Software** (the largest medical software developer in the U.S.) in a medical provider business method patent suit in the Northern District of Texas. The case settled on very favorable terms for our clients.
- We are representing **Jazz Pharmaceuticals** in several intellectual property matters, including a 15-patent Hatch-Waxman patent litigation against four defendants in the District of New Jersey in connection with Jazz's Xyrem® successfully defended Jazz's patents for more than four years since the case was filed in November 2010.
- We represent **Keryx Biopharmaceuticals** in pre-litigation counseling on its tetraferrous tricitrate decahydrate product, including: (1) patent portfolio strategy; (2) FDA regulatory

strategy; (3) counseling for obtaining New Chemical Entity status; (4) counseling for obtaining Patent Term Extension; and (5) counseling on optimal positioning for any future litigation.

- We represented **Kos Pharmaceuticals** in three related Paragraph IV patent infringement litigations regarding Kos' sustained release niacin product, Niaspan®. The lawsuits settled favorably.
- One of our attorneys represented **Lexicon** and enforced two sets of patents covering technology for creating knock-out mice. Mario Capecchi, the named inventor on one set of patents, and Oliver Smithes, a key witness on the other set of patents, shared the 2007 Nobel Prize in Physiology for technology covered by the patents. The cases ultimately settled for 8 figures.
- We represented **LifeCycle Pharma** and **Shionogi Pharma** in Hatch Waxman action related to the cholesterol lowering drug Fenoglide® and obtained a favorable settlement.
- We represented **LifeScan** in multiple patent cases involving blood glucose monitoring devices and test strips.
- We represented **McNeil-PPC** in a patent case involving teeth whitening strips.
- We represented **Medicis Pharmaceutical** in series of Hatch Waxman actions related to Loprox® shampoo and obtained a favorable settlement.
- We represented **Medicis Pharmaceutical** in series of Hatch Waxman actions related to the topical steroid Vanos® and obtained a favorable settlement.
- We represented **Merz** in a patent infringement case involving Merz's Cuvposa drug product brought by Classen Immunotherapies. We successfully had the Complaint dismissed in the early stages of the case, avoiding costly litigation and potential damages for Merz.
- We represent **Molnlycke Healthcare AB** on a regular basis in patent infringement actions protecting their wound care technology, inter alia before the trial and appellate courts in Düsseldorf, the trial and appellate courts in Mannheim and Karlsruhe, and the Federal German Patent Court. Molnlycke Healthcare, owned by Nordic Capital, is a global leader in the field of wound care technology.
- We defended **Monsanto** when the plaintiff patentee alleged that Monsanto's recombinant bovine growth hormone product infringed its patent. The plaintiff sought \$1.8 billion in treble damages and a permanent injunction. After we won summary judgment eliminating one of the two accused products, the case settled favorably the day before trial.
- We obtained a nonsuit for **Optical Radiation Corporation** after a three-week jury trial in a whistleblower case.
- We secured an important victory for **Ortho-McNeil**, a Johnson & Johnson subsidiary, against Affymax in an arbitration involving inventorship and ownership of two patent families related to new biological drugs for the production of red blood cells. In 2004, Affymax initiated litigation in the United States and Germany to obtain ownership of Ortho's solely-filed patents on the second invention. Ortho counterclaimed for joint inventorship and ownership of the patents issued from the first set of applications. Based on procedural limitations in the German litigation, Ortho moved to compel arbitration and

dismiss the court actions. Judge Kennelly of the Northern District of Illinois granted the motion and ordered Affymax to dismiss the German action. After two sets of hearings, the arbitration panel granted Ortho a complete victory—sole inventorship/ownership over the second set of patents, and joint inventorship/ownership on the first set of patents.

- We represented **Ortho-McNeil**, a Johnson & Johnson subsidiary, in a unanimous Seventh Circuit victory that made new law narrowing “manifest disregard of the law” as a ground for district court vacatur of arbitral awards and reversed a partial vacatur of an award that had favored Ortho in a dispute over ownership of two patent families relating to new biological drugs for the production of red blood cells.
- We represented **Pharmacia** in a patent case involving purification of monoclonal antibodies.
- We represented **Reliant Pharmaceuticals** in a patent litigation related to competing branded fenofibrate products. We sought a declaratory judgment of non-infringement, invalidity, and unenforceability due to inequitable conduct. The case settled on terms favorable to Reliant.
- We successfully defended **Roche Molecular Systems** against claims of infringement of Stanford HIV patents related to viral load and therapy decisions. At the trial court, we obtained summary judgment of invalidity due to obviousness, and a favorable ruling on appeal to the Federal Circuit regarding standing to enforce the patents-in-suit. The United States Supreme Court affirmed the Federal Circuit in a 7-2 decision, confirming a complete victory for the firm’s clients. Quinn Emanuel’s client, Roche, now owns a portion of the patent rights asserted against it by Stanford, allowing Roche to continue to make and sell its life-saving HIV kits free from Stanford’s claims. The Supreme Court upheld Roche’s position that universities must adhere to their contracts and not rely on the Bayh Dole Act to void their prior commitments.
- We obtained a 7-2 victory in the U.S. Supreme Court for **Roche** against Stanford University in a suit involving patents related to HIV treatment that had been developed in a collaboration between Stanford and Roche’s predecessor, Cetus Corporation. The Court held that Roche was a co-owner of the patents in suit and rejected Stanford’s effort to void its prior contracts based on its receipt of federal funding, reasoning that the Bayh Dole Act—the statute governing federal research funding—does not give automatic ownership of patents to universities.
- We represent **Roche Diagnostics** on a regular basis in patent infringement actions in the bio-tech field. Roche Diagnostics is a global leader in the field of diagnostics.
- We obtained a victory in the United States Court of Appeals for the Ninth for **Sequus Pharmaceuticals, Inc.**, a subsidiary of Johnson & Johnson. The appeal decided a question of first impression: whether a district court has removal jurisdiction under the Convention on the Recognition and Enforcement of Foreign Arbitral Awards, 9 U.S.C. § 201 et seq., over a case in which the defendant raises an affirmative defense related to a foreign arbitral award. In a unanimous published opinion, the Ninth Circuit agreed with Sequus that the removal provision of the New York Convention should be construed broadly (unlike most removal provisions) so that it provides a meaningful shield against litigation that seeks an end run around foreign arbitration. Since Sequus had raised an Israeli arbitral award as part

of its affirmative defense of collateral estoppel, the court upheld removal of the case to federal court.

- We represented **Tyco Healthcare Group LP** in a suit against Applied Medical Resources Corp. to enforce its patents against certain of Applied's surgical trocar products. The jury returned a verdict of infringement by Applied and awarded Tyco \$4,810,389 in damages, out of Applied's total profit of \$6,734,544 on the infringing sales.
- We are representing **Varian** in a patent case involving nuclear magnetic resonance technology.
- We achieved a victory in arbitration for our clients **Vermillion, Inc.** and **Bio-Rad Laboratories, Inc.** We obtained rulings of no liability with respect to claims including breach of contract, tortious interference with contract, and fraud regarding the use and licensing of rights to surface-enhanced laser desorption technology.
- We represented **Vertex Pharmaceuticals** in a declaratory judgment case involving patents related to neuroregenerative compounds. We successfully obtained judgment on the pleadings, dismissing plaintiff's inventorship and inequitable conduct claims, and the case was settled on terms favorable to Vertex.
- We are representing **Vivus** in a Hatch-Waxman patent litigation in the District of New Jersey in connection with its only commercial drug product, Qsymia®.
- We secured an important victory for **Wyeth LLC** (whose parent is Pfizer Inc.) in the U.S. Supreme Court, which held that a federal statute preempts state-law causes of action based on theories of defective design in governmentally-approved child vaccines. The opinion attracted the support of six justices, and adopted many of the arguments advanced in Wyeth's brief. For Quinn Emanuel and counsel of record Kathleen Sullivan, the win represented the third in as many terms at the Supreme Court. The decision has significant implications for public health and the vaccine supply, as it removes design-defect claims that, if permitted, would have increased manufacturers' costs and depressed vaccine supply and development.