IAM

PATENT LITIGATION REVIEW 2024

The *IAM Patent Litigation Review* offers a wealth of expert knowledge and analysis for patent owners and litigators on the most urgent issues when it comes to taking intangible assets to court in the key regions of the Americas, the Asia-Pacific, and Europe, the Middle East and Africa.

All articles come complete with footnotes and relevant statistics

Specialist chapter: Trends and strategies in global pharma and biotech patent litigation

Michael A Davitz, **Jordan G Garner** and **Vera Glonina** | Leason Ellis LLP
Jason T Murata and **Alexander S Krois** | Axinn, Veltrop & Harkrider LLP

In summary

International patent protection is now part-and-parcel for any significant drug or therapeutic, and, as a result, disputes over patent ownership and infringement now regularly implicate a myriad of related laws across international venues. In this article, we analyse a handful of recent global patent disputes in pharma and discuss how differing local laws can affect litigants and substantive outcomes, and how parties can leverage international patent disputes.

Discussion points

- Leveraging local patent laws for disparate results
- Leveraging litigation to drive favourable settlement

Referenced in this article

- CRISPR-Cas9
- Amgen v Sanofi & Regeneron cases
- Ultomiris litigation
- Biktarvy litigaition

Introduction

Because biotechnology and pharmaceutical companies market their products worldwide, patent protection – which operates on national level – must be sought globally. This approach requires an appreciation of the subtle, but often important differences between countries about what inventions can be protected by patents. Companies often seek patent protection for blockbuster therapies or drugs, in a wide range of markets. As a consequence of worldwide patent protection and product markets, patent litigation has increasingly gone international. One has to act locally to secure patent protection, but companies must think globally about litigation and how it can be used strategically in an offensive and defensive fashion.

In this article, we review several recent biotechnology and pharmaceutical patent disputes about how parties have approached global patent litigation.

Leveraging local patent laws for disparate results

Because of differences in local patent and procedural laws, the same set of facts may lead to dramatically different outcomes across jurisdictions. Although international agreements have harmonised many aspects of patent law,[1] there remain substantive variations. These differences present not only opportunities to leverage local laws to obtain an outcome that would have been out of reach elsewhere, but also dangers, as compliance with one country's laws does not mean compliance with another's. Moreover, many of the nuances of a given jurisdiction's laws will not become evident until well into litigation, and thus parties should think carefully even in early patent prosecution.

CRISPR-Cas9

The CRISPR-Cas9 dispute, which has raged in the United States and Europe, illustrates how differing patent prosecution rules can lead to different substantive outcomes in the control of patent rights.

For nearly a decade there has been an ongoing international disagreement over who has priority rights for the patents related to CRISPR-Cas9 technology, a revolutionary discovery that allows for efficient and reliable gene editing.[2] In 2012, the University of California, Berkeley[3] and the University of Vienna[4] (collectively CVC) filed a patent application directed to the CRISPR-Cas9 technology. Soon after their initial discovery, the Broad Institute[5] filed a patent based on additional

1 *See, eg*, WIPO, *Patent Law Harmonization*, https://www.wipo.int/patent-law/en/patent_law_harmonization.htm (last visited 28 November 2023).
2 *See, eg*, Susan Krumplitsch, *The CRISPR patent wars*, DLA Piper Intellectual Property and Technology News (16 November 2022), https://www.dlapiper.com/en-co/insights/publications/intellectual-property-and-technology-news/2022/the-crispr-patent-wars.
3 Based on research led by Nobel laureate Jennifer Doudna.
4 Based on research led by Nobel laureate Emmanuelle Charpentier.
5 Based on research led by Feng Zhang.

modifications to the CRISPR-Cas9 system that enabled the technique to work in eukaryotic cells – a classification of cells that includes all animal and human cells. Both parties filed patents covering the method that included claims using the technique in eukaryotic cells (ie, mammalian cells), and, inevitably, there was a dispute between the two parties about which one was entitled to a patent. The stakes were enormous – a Nobel prize and likely billions in licensing revenue.[6]

Beginning in 2014, in the United States, the CVC group attempted to use interference proceedings to establish that the CVC group was the first to invent the CRISPR-Cas9 technology as applied to eukaryotes.[7] To date, the CVC group has filed two interference proceedings. In both cases the USPTO ruled in favour of the Broad Institute – ie, that the Broad Institute's use in eukaryotic cells is a separate invention and that the CVC group was not the first to invent it.[8] The first of these interferences was affirmed by the Federal Circuit in 2018,[9] and the second interference resulted in a 2022 USPTO decision also in favour of the Broad Institute.[10] While the appeal for the latter is ongoing, it appears that the Broad Institute has secured patent rights of the use of CRISPR-Cas9 in eukaryotic cells, and thus in humans and animals, in the United States.[11,12] Thus, and because the CVC group still holds foundational patents directed to the underlying basis of the technology, both the Broad Institute and the CVC group have patent rights covering the application of CRISPR-Cas9 to eukaryotic cells in the United States.

In Europe, however, the Broad Institute was less successful. There, the CVC group was able to use the differences in patent rules to drive a different outcome. Specifically, during patent prosecution, the Broad Institute relied on a claim of priority to earlier US applications that named an inventor, Luciano Marraffini, who did not appear on the European patent filing.[13] Inventor Marraffini had transferred his right to priority to a third party, Rockefeller University. As a result of strict European rules on priority claims, the European Patent Office (EPO) ruled that the Broad Institute could not rely on its US priority date, because it

6 Broad Institute, *For journalists: Statements and background on the CRISPR patent process* (28 February 2022), https://www.broadinstitute.org/crispr/journalists-statement-and-background-crispr-patent-process.

7 Because the patents-at-issue were filed before 16 September 2012, the USPTO applied the pre-AIA first-to-invent patent law.

8 *See supra* note 3; Leanna Tilitei, *CRISPR Technology and Patent Ownership*, Penn Carey Law News & Events (2 May 2023), https://www.law.upenn.edu/live/news/15802-crispr-technology-and-patent-ownership.

9 *See generally Regents of the Univ of Cal v Broad Inst, Inc*, 903 F.3d 1286 (Fed. Cir. 2018).

10 *See generally Regents of the Univ of Cal v Broad Inst, Inc*, Patent Interference No. 106, 115 (P.T.A.B. 28 February 2022).

11 Ultimately, the Noble Prize only went to the CVC group.

12 The use of a patent pool is being explored to solve the licensing issue. *See* Patrick Neville, *MPEG LA's Use of a Patent Pool to Solve the CRISPR Industry's Licensing Problems Licensing Problems*, 2020 Utah L. Rev. 535 (2020), https://dc.law.utah.edu/cgi/viewcontent.cgi?article=1259&context=ulr.

13 *See* Kelly Servick, *Broad Institute takes a hit in European CRISPR patent struggle*, ScienceInsider (18 January 2018), https://www.science.org/content/article/broad-institute-takes-hit-european-crispr-patent-struggle (Stating that the difference in authorship arose because of a disagreement between the Broad Institute and The Rockefeller University (Luciano Marraffini's institution)).

did not own all of the priority rights. This loss of priority resulted in a win for the CVC group and the revocation of the Broad Institute's patents – a ruling that was later affirmed by the Board of Appeals at the EPO.[14] Challenges to priority rights are a major issue in Europe as many US companies have discovered to their unending heartache.[15] Despite these setbacks, the Broad Institute still holds additional patents and patent applications, and disputes regarding these are ongoing.

It is evident from the CRISPR-Cas9 example that the differences in governing law between the United States and the EPO allowed the CVC group to reach a favourable outcome in Europe that they were unable to achieve in the United States. The dramatically different outcomes illustrate that careful attention must be paid to the rules in each jurisdiction, and while your patent may be 'safe' in one jurisdiction, a slight difference in the law can completely change the result upending your 'safe' patent protection elsewhere.

Amgen v Sanofi & Regeneron, anti-PCSK9 abs

Amgen Inc, Sanofi, and Regeneron Pharmaceuticals Inc have fought a patent battle over anti-PCSK9 monoclonal antibodies in the United States, Europe, Japan and Australia. Amgen markets one such antibody product under the brand name Repatha, which is covered by patents directed to the antibody itself. Sanofi and Regeneron have partnered to market a competing antibody product under the brand name Praluent. As a result of the patent battle, several of Amgen's patents were invalidated, including through a recent high-profile US Supreme Court case,[16] but invalidation of Amgen's patent rights in this case has not been universal or consistent.

In 2014, Amgen sued Sanofi and Regeneron in a US district court for infringement of patents directed to monoclonal antibodies that target PCSK9 and that are used to treat high cholesterol. The claims recited antibodies that were functionally claimed.[17] Unsurprisingly, the parties disputed whether this functional claiming satisfied the US written description and enablement requirements.[18] The case proceeded to trial, where a first jury found that the claims were not invalid for lack of written description and enablement. Following a reversal at the Federal

14 id.; *see also* Clara Rodríguez Fernández, *Broad Institute Loses Appeal on European CRISPR Patent,* Labiotech (27 January 2020), https://www.labiotech.eu/trends-news/crispr-patent-europe/.

15 *See* Rachel Wallis & Lee Chapman, *Priority – Still a Challenge at the EPO* (17 February 2022), https://greavesbrewster.co.uk/priority-still-a-challenge-at-the-epo/.

16 *See generally Amgen Inc v Sanofi*, 598 U.S. 594 (2023).

17 For instance, one claimed recited '1. An isolated monoclonal antibody, wherein, when bound to PCSK9, the monoclonal antibody binds to at least one of the following residues: S153, I154, P155, R194, D238, A239, I369, S372, D374, C375, T377, C378, F379, V380, or S381 of SEQ ID NO:3, and wherein the monoclonal antibody blocks binding of PCSK9 to LDLR.' U.S. Patent No. 8,829,165 at claim 1. Thus, the claim recites two separate functions of the antibody – (1) binding to certain residues, and (2) blocking binding of PCSK9 to LDLR.

18 AIPLA, *Supreme Court Unanimously Upholds Federal Circuit's Decision in Amgen Inc v Sanofi* (15 June 2023), https://www.aipla.org/detail/news/2023/06/15/supreme-court-unanimously-upholds-federal-circuit-s-decision-in-amgen-inc.-v.-sanofia.

Circuit because of faulty jury instructions, a second jury again found that the claims were not invalid. Despite two jury rulings, the district court ultimately ruled, via a judgment as a matter of law, that the claims were invalid as not adequately enabled. The Federal Circuit affirmed, and Amgen appealed to the US Supreme Court, leading to the recent *Amgen v Sanofi*[19] decision wherein the US Supreme Court held that claiming all antibodies that bind to a specific target, potentially numbering in the millions, while only disclosing 26 examples, did not satisfy the enablement requirement of section 112. The decision did not purport to change the basic law of enablement and relied on century-old precedent, but it has cast a pall on the validity of broad genus claims, particularly in the pharmaceutical and biotechnology industries.[20]

But, as noted, Amgen pursued an aggressive patent enforcement strategy internationally, including suits in Japan, Europe and Australia.

In Europe, Sanofi and Regeneron have generally won out, but local procedural rules meant that Amgen was able to temporarily block competing sales. Specifically, in an initial win for Amgen, the Regional Court at Düsseldorf found infringement and issued an injunction against infringing sales of Sanofi and Regeneron's commercial product in 2019.[21] Unlike the United States, Germany bifurcates infringement and invalidity proceedings. Thus, Amgen was able to leverage this bifurcated procedure to block sales before a ruling on validity of the relevant European patent.[22] A 2020 opposition proceeding before the EPO's Technical Boards of Appeal resulted in amendments to the patent that meant it no longer covered the relevant products.[23] The parties continue to litigate various related patents, and the parties have moved to the Unified Patent Court (UPC), where they brought both infringement and revocation actions.[24] The UPC actions are still in their infancy, but to date have resulted in the first-ever UPC Court of Appeals decision, which dealt with procedural deadlines.[25]

19 598 U.S. 594 (2023), *aff'g* 987 F.3d 1080 (Fed. Cir. 2021).

20 *See, eg*, Dennis Crouch, *Enabled to Claim the Unknown? Federal Circuit applies Amgen v Sanofi to invalidate broad antibody claims*, PatentlyO (20 September 2023), https://patentlyo.com/patent/2023/09/enabled-invalidate-antibody.html.

21 Amy Sandys, *EPO revokes Amgen antibody patent amid ongoing battle with Sanofi*, Juve Patent (22 March 2023), https://www.juve-patent.com/cases/epo-revokes-amgen-antibody-patent-amid-ongoing-battle-with-sanofi/.

22 *See id.* ('Sanofi and Regeneron were unable to obtain a compulsory license for their product, meaning they could no longer sell and produce [their product] in Germany.').

23 id.

24 Amy Sandys, *Amgen and Sanofi's race to file UPC actions ignites bifurcation question*, Juve Patent (1 September 2023), https://www.juve-patent.com/cases/amgen-and-sanofis-race-to-file-upc-actions-ignites-bifurcation-question/.

25 Mathieu Klos, *First UPC Court of Appeal decision clarifies deadline for defendants*, Juve Patent (18 October 2023), https://www.juve-patent.com/legal-commentary/first-upc-court-of-appeal-decision-clarifies-deadline-for-defendants/.

In Japan, Amgen saw initial success. In 2018 the Japanese IP High Court ruled that Amgen's patent was valid in the face of a challenge by Sanofi and that Sanofi infringed.[26] Regeneron, however, was able to bring a separate, later action that included additional evidence and experimental data, and in 2023, the Japanese IP High Court issued a decision opposite to its first.[27] Specifically, the Japanese IP High Court invalidated Amgen's claims for reasons similar to those the US Supreme Court would later use (ie, that the patent's specification did not support claiming all antibodies that bound to a target and inhibited PCSK9 binding). Further, the Japanese IP High Court differentiated Regeneron's case from Sanofi's because Regeneron presented new arguments and evidence.[28] Thus, by bringing a second action and introducing new evidence, Regeneron was able to effectively take a second bite at the apple and succeed where Sanofi had not. These types of subsequent challenges may be more difficult in countries outside of Japan, such as the United States.

Amgen saw more success sustaining the validity of the PCSK9 patent in Australia. Specifically, in 2022, Amgen defeated opposition actions to several of its patent applications, even though these applications had claims that were similar to those invalidated elsewhere[29] (ie, functionally defined claims).[30] These applications, however, were examined under Australian law that existed before the Intellectual Property Laws Amended (Raising the Bar) Act of 2012. The Raising the Bar amendments came into effect in April 2013 and heightened disclosure requirements from a 'full description' and 'fair basis' standard[31] to instead requiring that the scope of the claims be commensurate with the technical contribution and be enabled for their full scope. While it is an open question as to whether these applications would have survived under modern law, Amgen was nonetheless able to successfully leverage Australia's local laws to obtain claims that had been found unpatentable elsewhere.

---

26 Mami Hino, Naho Ebata, *Amgen v Sanofi and Regeneron: Japan IP High Court overrules its own decision on validity of Amgen patent*, Kluwer Patent Blog (15 May 2023), https://patentblog.kluweriplaw.com/2023/05/15/amgen-v-sanofi-and-regeneron; Aoyoma & Partners, *IP High Court Case Summary:2021 (Gyo-ke) 10093* (Sept. 20, 2023), https://www.aoyamapat.gr.jp/en/news/3761.

27 id.

28 This new evidence included 'expert declarations and experiments' and cast doubt on the premise that antibodies competing with one another would necessarily bind to the same binding site on PCSK9. id.

29 Michael Christie, *Sanofi unsuccessful in its opposition to Amgen's Australian patent applications* (29 September 2022), https://www.spruson.com/patents/sanofi-unsuccessful-in-its-opposition-to-amgens-australian-patent-applications/; Grant Fisher et al., *Australia: Therapeutic antibody patent claims*, Mondaq (22 November 2022), https://www.mondaq.com/australia/patent/1246112/therapeutic-antibody-patent-claims.

30 For instance, one challenged claim recited '1. An isolated neutralizing antigen binding protein that binds to a PCSK9 protein comprising the amino acid sequence of SEQ ID NO: 1, wherein the neutralizing antigen binding protein decreases the LDLR lowering effect of PCSK9 on LDLR.' Australian Patent Application No. 2013/2036771.

31 Christie, *super* note 29 ('Under the 'old' Act, . . . [t]o meet the full description requirement, the specification needs only to enable the skilled addressee to produce something within each claim without new inventions or additions or prolonged study of matters presenting initial difficulty. To meet the fair basis requirement, the specification must provide a 'real and reasonably clear disclosure' of the claimed invention.').

The multinational litigation saga of PCSK9 illustrates how patent practitioners can leverage success in some jurisdictions (here Europe and Australia) to offset set-backs in others.

Leveraging litigation to drive favourable settlement

In addition to leveraging the nuances of local law, litigants can also use the pressure of litigation itself, and its associated costs, to drive settlement and licensing. Below, we detail two global disputes that ultimately resulted in high-value agreements.

Ultomiris litigation[32]

In 2022, Roche's Chugai Pharmaceutical (Chugai) and AstraZeneca's Alexion (Alexion) settled their major global patent dispute regarding the prescription drug Ultomiris (ravulizumab) used for the treatment of adults and children with paroxysmal nocturnal hemoglobinuria (PNH), a rare blood disorder.[33]

From 2009 to 2013, Chugai patented its invention related to methods of removing an antigen from plasma in the United States, the European Union and Japan.[34] However, beginning in 2016, when Alexion developed Ultomiris with the alleged use of certain similar molecules and methods as Chugai's invention, Alexion challenged the validity of Chugai's patents in the European Union and Japan.

In the European Union, Alexion challenged five of Chugai's patents, four of which were revoked by the EPO. For example, on 19 December 2019, the Opposition Division of the European Patent Office revoked European Patent No. 2552955 pursuant to article 101(3)(b) EPC (based on the novelty and inventive step grounds).[35]

In Japan, the IP High Court invalidated four Chugai's Japanese patents challenged by Alexion.[36] In particular, on 26 June 2019, the Japanese IP High Court invalidated Chugai's patent titled 'Antigen-Binding Molecule Capable of Binding to Two or More Antigen Molecules Repeatedly,' since the Court

32 *See generally* AstraZeneca reaches settlement agreement resolving patent litigation related to *Ultomiris*, AstraZeneca (17 March 2022), https://www.astrazeneca.com/media-centre/press-releases/2022/astrazeneca-reaches-settlement-agreement-resolving-patent-litigation-related-to-ultomiris.html (hereinafter AstraZeneca Press Release); *see also Chugai Pharm Co, Ltd v Alexion Pharms, Inc*, No. 1:18-cv-01802-MN (D. Del. filed 15 November 2018); *Chugai Pharm Co, Ltd v Alexion Pharms, Inc*, No. 1:19-cv-02120-MN (D. Del. filed 12 November 2019), .

33 AstraZeneca Press Release.

34 The patented technology is titled 'Antigen-binding molecule capable of binding to two or more antigen molecules repeatedly'. Chugai's patents include the US patents Nos. 9,890,377 and 10,472,623 and Japanese Patent Nos. 4,954,326 and 641,743.

35 Specifically, the EPO found that certain claim of the invention extends the subject matter beyond the content of the application as filed within the meaning of article 123(2) EPC. This Decision was further affirmed by the Board of Appeal of the EPO. *See* case number: T 0509/20 - 3.3.04. Decision of Technical Board of Appeal of 28 July 2022 (EU), https://legacy.epo.org/boards-of-appeal/decisions/pdf/t200509eu1.pdf.

36 *See* AstraZeneca Press Release.

has determined that the description of this invention does not conform to the enablement requirements of Japanese Patent Law.[37] According to the Japanese IP High Court, the 'Detailed Description of the Invention fails to describe the constitution of the invention to the extent that allows a person ordinarily skilled in the art to implement the case where a plurality of sites are substituted with histidines.'[38] Subsequently, the Supreme Court of Japan dismissed Chugai's appeal against this invalidity decision.[39]

In 2018, Chugai took the offensive and initiated the patent infringement litigation in Japan and the United States.

Specifically, Chugai sued Alexion in the Tokyo District Court alleging that Alexion's product Ultomiris infringed two patents in Japan. One of the two asserted patents had already been invalidated.[40] Therefore, Chugai filed a correction to the claims of this patent-in-suit.[41] Alexion countered that the corrected claims are still invalid and not infringed.

Chugai also sued Alexion in the United States in November 2018 in the District Court for the District of Delaware alleging that Ultomiris infringed its US Patent No. 9,890,377.[42] Upon issuance of the US Patent No. 10,472,623 in November 2019, Chugai filed a second lawsuit in the US, which was consolidated.[43] Chugai asked for injunctive relief and unspecified damages.[44] The parties litigated the case until December 2021, when after claim construction proceedings, discovery, filing requests for jury instruction and several delays with trial, the parties initiated a global settlement process.[45]

Under the terms of the 2022 settlement agreement, Alexion agreed to pay Chugai US$775 million in exchange for the Japanese firm withdrawing the patent infringement lawsuits it filed in various courts in Europe, Japan, and the United States.[46] This case clearly illustrates how one company can use foreign patent invalidation proceedings to gain leverage in US and global patent infringement disputes to force a settlement on reasonable terms. Although substantive patent law varies from country to country, the factual findings and admissions in foreign

37 Case Number: 2018 (Gyo-Ke) 1004, Decision of Court Intellectual Property High Court, Third Division (26 June 2019) (JP), https://www.ip.courts.go.jp/app/files/hanrei_en/469/002469.pdf.
38 id.
39 *See* AstraZeneca Press Release.
40 *See* Chugai Files Lawsuit against Alexion for Infringement of its Proprietary Antibody Engineering Technology in Japan, News, Chugai Pharmaceutical Co, Ltd, (5 December 2018), https://www.chugai-pharm.co.jp/news/cont_file_dl.php?f=181205eALXN1210_JP_IP.pdf&src=%5b%250%5d,%5b%251%5d&rep=130,570.
41 *See* Vanessa Doctor, *Alexion Settles Patent Infringement Lawsuits Against Ultomiris for $775M* (17 March 2022), https://www.biospace.com/article/alexion-pays-77m-to-settle-patent-infringement-lawsuits-against-ultomiris/#:~:text=In%202018%2C%20Chugai%20sued%20Alexion%20Pharma%20GK%20in,correction%2C%20but%20the%20patent%20office%20found%20these%20invalid.
42 *See Chugai*, No. 1:18-cv-01802-MN.
43 *See Chugai*, No. 1:19-cv-02120-MN.
44 Complaint, *Chugai*, No. 1:18-cv-01802-MN, Dkt No. 1 (15 November 2018).
45 id.
46 *See* AstraZeneca Press Release.

invalidation decisions may be used globally. Moreover, patent vulnerabilities and strengths in commercially significant jurisdictions may provide leverage to negotiate reasonable settlements of worldwide litigations. The threat of a patent infringement ruling and the associated risk to a company's ability to market its product, however, provides a compelling justification for a substantial licence fee or upfront payment, or both, particularly for companies without diversified income streams from multiple products.

Biktarvy litigaition[47]

Biktarvy (bictegravir, emtricitabine, and tenofovir alafenamide) is a single-tablet regimen used to treat HIV-1 infection developed by Gilead Sciences, Inc (Gilead).[48]

In February 2018, ViiV Healthcare, GSK and Shionogi (collectively ViiV) filed a lawsuit against Gilead in the US District Court of Delaware, alleging that the commercialisation of Biktarvy infringes on ViiV's US Patent No. 8,129,385 (the '385 patent) covering ViiV's dolutegravir under the doctrine of equivalents, as the bictegravir in Biktarvy was alleged to be 'not substantially structurally different' from the claimed dolutegravir.[49,50] However, Gilead raised several counterarguments, including invoking the 'dedication-disclosure rule', arguing that the '385 patent described, but did not claim, the formulation used in Biktarvy, and, therefore, there could not be an infringement under the doctrine of equivalents.[51]

In November and December 2019, ViiV filed similar patent infringement related to Biktarvy lawsuits against Gilead in France, Germany, Ireland and the United Kingdom (asserting the European Patent No. 3,045,206); in Australia (asserting Australian patent No. 2,006,239,177); in Japan (asserting Japanese patent No. 4,295,353); and in Korea (asserting Korean patents Nos. 1,848,819 and 1,363,875).

In August 2019, ViiV also filed a similar lawsuit against Gilead in the Federal Court of Canada, alleging that Gilead infringed the ViiV's Canadian patent No. 2,606,282 (compound patent covering ViiV's dolutegravir). In April 2020, the Federal Court of Canada determined that Biktarvy does not infringe on the claims of the ViiV's

47 *See* GSK announces settlement between ViiV Healthcare and Gilead Sciences, Inc resolving litigation relating to Biktarvy and ViiV's dolutegravir patents and entry into a patent license agreement (2020), https://viivhealthcare.com/hiv-news-and-media/news/press-releases/2022/january/gsk-announces-settlement-between-viiv-healthcare-and-gilead-sciences/ (hereinafter ViiV Press Release); *see also* Gilead Sci, Inc Forms 10-K (2018-2020), https://www.sec.gov/Archives/edgar/data/882095/000088209520000013/q120form10-q.htm; https://www.sec.gov/Archives/edgar/data/882095/000088209518000022/q218form10-q.htm; *see also ViiV Healthcare Co v Gilead Sciences*, Inc, No. 1:18-cv-00224-CFC-CJB (D. Del. filed 7 February 2018).

48 *See* ViiV Press Release.

49 *See* Complaint, *ViiV*, No. 1:18-cv-00224-CFC-CJB, Dkt. 1 (7 February 2018).

50 *See ViiV Healthcare Co v Gilead Sci Inc*, 437 F. Supp. 3d 395 (D. Del. 2020).

51 id.; *see also* Gilead and ViiV Healthcare Settle Global Patent Dispute for Over $1B USD, IPOSGOODE (22 April 2022), https://www.iposgoode.ca/2022/04/gilead-and-viiv-healthcare-settle-global-patent-dispute-for-over-1b-usd/.

Canadian patent No. 2,606,282 and dismissed the case after holding a summary trial.[52] The court found that 'bictegravir does not fall within any of the asserted claims' of the patent No. 2,606,282.[53] On 16 June 2021, Canada's Federal Court of Appeal (FCA) upheld this decision and specifically noted that 'the Federal Court's finding that the patent, properly construed, did not cover bictegravir.'[54]

This case was globally settled in 2022, with Gilead agreeing to make an upfront payment of US$1.25 billion as well as a 3 per cent royalty on all future US sales of Biktarvy (about US$6 billion in 2020) and in respect of the bictegravir component of any other future bictegravir-containing products sold in the United States.[55] However, Gilead received a worldwide licence to relevant patents relating to dolutegravir and a covenant not to enforce any patents controlled by ViiV against Gilead in connection with any past or future claims of infringement relating to Biktarvy and any future product containing bictegravir.[56] Considering the expiration date of the '385 patent is estimated to be in 2027, and the risks of significant damages calculated based on the revenue from Biktarvy in the US litigation, this settlement agreement could be considered favourable for Gilead.[57]

Overall, this case illustrates how pharmaceutical and biotechnology companies use foreign proceedings to leverage favourable resolution of US and global patent disputes. In particular, certain determinations made by foreign courts, especially key factual determinations, might be helpful in negotiating a better settlement in global patent litigation. Careful consideration about breadth during prosecution of ViiV's patent was also significant to allow ViiV to obtain additional licensing revenue from a drug molecule that was structurally similar to its patented dolutegravir molecule.

Trends and strategies

In recent years, there has been a trend towards more complex and high-stakes global patent disputes in the pharmaceutical industry, including parallel litigation across multiple jurisdictions. Although the United States has historically been the leading jurisdiction of patent litigation, other jurisdictions, such as the European Union, Canada, Japan and Australia, are becoming increasingly important. The above disputes highlight that differences in law across jurisdictions can result in differing substantive outcomes and that potential litigants need to prepare and account for these possibilities. Moreover, the lessons above show that these

52 *ViiV Healthcare Co v Gilead Sci Canada, Inc,* (4 June 2020), https://decisions.fct-cf.gc.ca/fc-cf/decisions/en/item/468790/index.do.
53 id.
54 *ViiV Healthcare Co v Gilead Sci Canada, Inc*, 2021 FCA 122, (16 June 2021), https://decisions.fca-caf.gc.ca/fca-caf/decisions/en/499020/1/.
55 *See* ViiV Press Release.
56 id.
57 Based on the information available in the Complaint and the Gilead's Form 10-K (2020), including Gilead's statement: ('In addition, should a court find that we are liable for infringement, we expect ViiV will seek a royalty on sales after the trial. ViiV calculates these damages based on the cumulative US revenues from Biktarvy since launch, which have totaled $11.46 billion through December 31, 2020.'). See https://s29.q4cdn.com/585078350/files/doc_financials/2020/q4/2020-q4.pdf.

concerns are not exclusive to those actively engaged in litigation, as even during patent prosecution parties must consider the downstream consequences as they gather and produce assignments records or draft support and enablement positions, consider seeking to invalidate certain patents of third parties and use factual findings from foreign administrative proceedings and litigation in the patent disputes litigated in the United States. Accordingly, any global patent litigation strategy has to start early in a technology's lifecycle as minor – or at least what seems minor or not directly relevant at the time – issues early on can have dramatic consequences down the line.

Michael A Davitz
Leason Ellis LLP

Michael Davitz, a partner at Leason Ellis, is a registered US patent attorney and physician with over 15 years in biomedical research, and over 20 years providing strategic counselling to clients in all aspects of intellectual property law. His practice focuses on creating value for clients through the development and effective enforcement of intellectual property rights. He has counselled clients in the pharmaceutical, medical device and biotechnology area working with a diverse array of clients ranging from start-ups to multinational companies and universities. He has extensive international experience in Europe and Asia handling intellectual property problems ranging from cross-border licensing deals, acquisitions, to patent litigation. Michael has represented clients before the Patent Trial and Appeal Board, the European Patent Office in oppositions and the Chinese Re-examination and Invalidation Department.

Michael received his JD from New York University, his MD from the College of Physicians and Surgeons at Columbia University and his BA from Yale University. Prior to law school, he was an assistant professor of pathology and environmental medicine at New York University School of Medicine, where he was a Lucille P Markey Scholar in the biomedical sciences. Michael has published over 25 papers in peer-reviewed scientific journals such as *Science and Nature*. He is a regularly invited speaker on patent issues with the American Conference Institute, the Practicing Law Institute and the Commercial Law Development Program of the US Department of Commerce. He is also a trustee for the conservation group Save the Elephants.

Jordan G Garner

Leason Ellis LLP

Jordan G Garner is a partner in the patent practice, Japan practice and litigation practice groups at Leason Ellis. Jordan works with individuals, start-ups and established companies to obtain patents and to manage their patent portfolios, from acquisition through enforcement or monetisation. Jordan excels at managing the IP aspects of complex financial transactions that involve a heavy IP component. During his time at Leason Ellis, Jordan has provided advice and IP diligence expertise on financial deals totalling more than a billion dollars. In providing IP diligence services, Jordan routinely works with venture capital, private equity and commercial law firms to assess IP risks and devise timely and effective solutions. He also provides opinions on patentability and patent infringement as well as trade secret misappropriation. During frequent travels to Japan and China, Jordan advises Japanese and Chinese companies on US patent law. His domestic and foreign clients operate in a wide range of industries including pharmaceuticals, bioinformatics, aeronautics, e-commerce, lighting, medical devices, chemical and university research.

Jordan enjoys teaching and speaking on IP law and can often be found giving presentations in China, Japan and New York about various aspects of patent law. Jordan is a member of the Hon William C Conner Inn of Court. He has been listed in New York Super Lawyers and the Business Council of Westchester Rising Stars 40 Under 40. Jordan received his LLM in IP Law from the Benjamin Cardozo Law School and his JD from Brooklyn Law School where he was a judicial intern for Judge Randal Rader of the Court of Appeals for the Federal Circuit. Jordan received his undergraduate degree from Cornell University.

Vera Glonina

Leason Ellis LLP

Vera is a law clerk/intern in the trademark and copyright practice group. Vera has an international background and experience in handling trademark, copyright, advertising, trade secret, data protection and litigation matters as a foreign attorney (admitted to practice law in Russia) as well as an intern with a technology company and as a law clerk with law firms in the United States.

Vera actively participates in professional organisations including INTA, AIPLA, NYIPLA and NYCBA. In particular, she serves as a student member of the NYCBA Council on Intellectual Property. Vera is also a Certified Information Privacy Professional (CIPP/US).

Vera is currently a JD candidate at Benjamin N Cardozo, School of Law. She received her master of laws degree at the University of Illinois at Urbana-Champaign School of Law. In addition, Vera received her bachelor of laws and master of laws degrees from Lomonosov Moscow State University, School of Law.

Leason Ellis is home to attorneys and staff professionals who love intellectual property law. Sound funny? Go ahead and laugh – we do it all the time. IP law is an art that comes with years of practice rooted in dedication, experience, and even a bit of humour. Are we talking to you? Then read on to learn about our roots, the values we live by, and view the opportunities to join our team.

Our roots

In 2008, David Leason and Ed Ellis left Darby & Darby, a large and venerable intellectual property firm in New York City, seeking to establish a new kind of IP boutique. Like them, almost all of our attorneys practiced at large firms in Manhattan before joining us here in White Plains, NY. Since we are located just north of the Big Apple, we gain significant savings in operating expenses that we are able to utilise in other areas of our business. In addition to offering significantly lower billing rates, we are able to invest in the latest technology, train our staff on the latest industry advances, and, when we find someone we really want to work with, hire all-stars from other top IP practices.

Our unique approach to building a business has allowed us to be more sensitive to our clients' needs as well as responsive to their communications. Our strategic size encourages collegiality among attorneys and staff and works to the benefit of our clients, who gain the most from the teamwork we foster.

Today, we are one of the largest IP firms in the state outside of Manhattan and rated among the top New York law firms for our patent, trademark, and copyright services. Our broad array of clients range from Fortune 100 companies, to midsize and small companies, to start-ups, inventors and entrepreneurs. We protect the IP rights of domestic clients in the US and abroad and, in turn, we directly represent many global companies in protecting their rights in the US. We also work on behalf of foreign law firms to develop and enforce their clients' patent, trademark and copyright rights here.

You may be wondering about the meaning behind our apple tree logo. To us, it represents the perfect confluence of the three pillars of our practice. The falling apple connotes the insight of Sir Isaac Newton, whose spirit of inventiveness in conceiving the laws of gravity while seeing an apple fall from a tree infuses our patent practice. The distinctiveness of the logo serves as a unique source identifier for our trademark services, and the artistic originality of the design speaks to our copyright capabilities.

At Leason Ellis, we are inspired by insight. Whether you want to join our team or learn more about how we can apply original thinking to your IP needs, we invite you to contact us.

1 Barker Ave
White Plains, NY 10601
United States
Tel: +1 914 288 0022

www.leasonellis.com

Michael A Davitz
davitz@leasonellis.com

Jordan G Garner
jgarner@leasonellis.com

Vera Glonina
glonina@leasonellis.com

Jason T Murata

Axinn, Veltrop & Harkrider LLP

Jason Murata is a partner in the intellectual property litigation group and chair of Axinn's diversity, equity and inclusion committee. Jason's practice involves all aspects of pre-trial, trial and appeals, with a particular focus on the pharmaceutical and biopharmaceutical, technology, consumer products and food industries. He also brings extensive litigation experience to bear on complex issues relating to managing a company's IP risks and freedom to operate.

Alexander S Krois

Axinn, Veltrop & Harkrider LLP

Alexander Krois is an associate in the intellectual property group in Axinn's San Francisco office.

Prior to joining Axinn, Alexander was a judicial clerk to the Honorable Judge Raymond Chen of the US Court of Appeals for the Federal Circuit and was an associate at an international law firm. In law school, Alexander was a judicial extern to the Honorable Judge Lucy Koh of the US District Court for the Northern District of California, as well as a member of the editorial board for the *Berkeley Technology Law Journal*.

Alexander received his law degree from the University of California, Berkeley, School of Law, where he graduated Order of the Coif. Prior to law school, Alexander received a PhD in biophysics from The Scripps Research Institute, where he conducted biochemistry and biophysics research on proteins critical in suppressing cancer, resulting in multiple peer-reviewed publications. Alexander also received a BS degree with Highest Honors in Chemistry and a BA degree in Anthropology from the University of North Carolina at Chapel Hill.

Axinn combines the skills, experience and dedication of the world's largest firms with the focus, responsiveness, efficiency and attention to client needs of the best boutiques. The firm was established in the late 1990s by lawyers from premier Wall Street firms with a common vision: provide the highest level of service and strategic acumen in antitrust, intellectual property and high-stakes litigation. Axinn's lawyers have served as lead or co-lead counsel on nearly half a trillion dollars in transactions and, in the last 10 years alone, have handled more than 300 litigations.

Global Competition Review named Axinn 'Firm of the Year – Americas' twice. The firm was nominated by Global Competition Review for Lawyer of the Year, Litigator of the Year, Litigation of the Year, Litigation of the Year – Cartel Defense, Deal of the Year and Dealmaker of the Year.

Axinn has numerous seasoned IP trial lawyers and is a go-to firm for IP matters of strategic importance. The IP group typically has several dozen pending patent and trade secret cases, and tries multiple cases annually. Axinn has served as lead trial counsel in some of the most significant recent patent cases for the world's leading pharmaceutical, medical device, diagnostics, biologics and consumer products companies, including Johnson & Johnson, Thermo Fisher Scientific, Teva Pharmaceuticals and Unilever. On numerous occasions, the firm has been asked to take over cases during or after discovery and serve as lead counsel at trial, including the defense of a multibillion dollar jury trial.

Axinn litigators try cases and win. They have tried cases before juries, judges and arbitrators alleging breach of contract, business torts, breach of fiduciary duty, unfair competition, antitrust violations, employment discriminations, fraud and theft of intellectual property. Axinn litigators also understand their clients, their businesses and products, their goals and governance issues, and what keeps their GCs up at night. Axinn has particular expertise in serving financial institutions with dozens of insurer hedge funds, mutual funds, and other financial industry clients. Axinn litigators are frequently involved in litigation on behalf of international clients and have successfully represented clients in forums from the Cayman Islands and Jersey to ICC arbitrations.

55 Second Street
San Francisco, CA 94105
United States
Tel: +1 415 490 2000

www.axinn.com

Jason T Murata
jmurata@axinn.com

Alexander S Krois
akrois@axinn.com