Overview of key recently filed cases and noteworthy rulings of relevance of the pharmaceutical and biotechnology industries

*Dnaform Co. Ltd. v. Eiken
Kagaku Co. Ltd.*

The IP High Court of Japan held a patent directed to a nucleic acid synthesis method, obtained by Eiken Kagaku Co. Ltd., one of the major biotechnology companies in Japan, is to be partially invalidated as being identical to a prior application filed in Japan, although such a prior application has failed to explicitly disclose the patented method in issue. Eiken has filed and obtained a patent directed to a method for the amplification of a nucleic acid. Dnaform, also a Japanese biotechnology company, challenged this patent as being not enabled under Art. 36(4)(i) of the Japanese Patent Act and identical to a prior application filed in Japan, which was published after the filing date of the patent in issue under Art. 29^{bis} of the Japanese Patent Act. With respect to the enablement requirement, upon judging an invention of a method, the Court held that in order that the enablement requirement and the sufficiency of support are satisfied, specific description to ‘use,’ or carry out the method, or equivalent, thereto in view of the common general knowledge in the art, must be described in the specification. The Court held that the method is enabled and the specification is sufficiently described in view of “*the common general knowledge.*” On the other hand, the Court invalidated parts of the claims (Claims 1-2) as being identical to a prior application filed in Japan, since although the prior application fails to describe the claimed invention in issue in a confirmatory manner but only describes vague, abstract prediction or possibility, the Court held that the prior application inherently discloses the claimed invention and, therefore has been identical to the prior application and thus been invalidated under Art. 29^{bis} of the Japanese Patent Act. It is known that the Art. 29^{bis} was introduced in 1970, as a part of ‘extending’ the first-to-file system. However, under current practice, ‘earlier’ application may be recognized to disclose an invention even if the description of the specification does not meet the description requirement such as enablement and clarity, and the like. The Court has confirmed such a practice in the subject case.

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Edwards Lifesciences AG v. Corevalve, Inc.

US Court of Appeals for the Federal Circuit, November 13

In this ruling, the Federal Circuit both affirmed and remanded the district court's rulings on validity, infringement, willfulness and damages. Edwards Lifesciences AG sued CoreValve, alleging that CoreValve's Generation 3 ReValving System infringed three of its patents. The only patent-at-issue in the appeal, however, was US Patent 5411552 (the '552 patent'), directed to a transcatheter heart valve. The claimed device is mounted on a collapsible stent and implanted into the heart via a balloon catheter. A jury determined that the '552 patent was valid and that CoreValve infringed Claim 1 willfully. Consequently, it awarded Edwards US\$72,645,555 damages for lost profits and \$1,284,861 in reasonable royalties. Although the district court entered judgment on the verdict, it declined to enhance the damages award for willful infringement or to issue injunctive relief against future infringement. Furthermore, the district court interpreted a litigation-agreed patent prosecution bar to preclude Edwards's litigation counsel and technical expert from participating in related patent reexamination proceedings. CoreValve's only challenge to the validity of the 552 patent was for lack of enablement. CoreValve pointed out that, at the time of filing, the claimed device had been implanted only in pigs. Moreover, some of those experiments were unsuccessful, prompting postfiling design changes. Edwards also stated that the device at that time was one "*to perform testing on,*" not "*to move in and treat patients.*" (Slip op. at 5). Based on a jury instruction on the issue of enablement, the jury found that the 552 patent was valid.

Source: www.cafc.uscourts.gov/images/stories/opinions-orders/11-1215.pdf

Novartis AG v. Kappos

US District Court for the District of Columbia, November 15

In this decision, Judge Ellen Segal Huvelle of the US District Court for the District of Columbia determined that Novartis AG and Novartis Vaccines and Diagnostics, Inc., had not satisfied the 180-day limitation of 35 U.S.C. §154(b)(4)(A) for challenging patent term adjustment (PTA) determinations of the USPTO with respect to 19 of 23 patents at issue; the Court also stated that the 180-day limitation should not be "*equitably tolled*". Novartis advanced two main claims. First, it argued that the USPTO acted improperly in refusing to apply the new standard for aggregating 'A-delay' and 'B-delay' PTAs from *Wyeth v. Kappos*. Second, Novartis argued that the calculation of the 'B-delay' should not exclude time consumed by requests for continued examination initiated after the 3-year window. The USPTO argued that the ordinary tolling rule – judicial review of agency actions is tolled during agency reconsideration – should not apply to §154(b)(4)(A). The court rejected this argument, holding that there was no indication that the statute was inconsistent with the normal tolling rule and allowing Novartis's claims to survive with respect to one additional patent. However, the court rejected Novartis's argument that its complaints not timely filed should be equitably tolled. On the remaining four patent complaints, the court granted summary judgment for Novartis.

Source: https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2010cv1138-49

Association for Molecular Pathology v. Myriad Genetics, Inc.

US Supreme Court, November 30

The US Supreme Court granted a certiorari in *Association for Molecular Pathology (AMP) v. Myriad* directed an invention of a human gene, whether such is patentable subject matter or not on 30 November 2012. The grant was directed to only the first question presented, whether human genes are patent-eligible. The certiorari was also concerned on additional two questions relating to screening methods using genetically transformed cells and a declaratory judgment plaintiff; however, the Supreme Court denied to hear and, thus, letting stand the Federal Circuit's determination to have standing. The case has long history. Initially, the US District Court for the Southern District of New York held that an invention directed to a gene is not a patentable subject matter under 35 U.S.C. §101 on 29 March 2010. Myriad filed a notice of appeal to the Court of Appeals for the Federal Circuit (CAFC) on 16 June 2010, seeking reversal of the decision, and the CAFC affirmed in part an reverse in part, but basically granted the Myriad's appeal on the patentable subject matter issue, and held that an invention of a gene is a patentable subject matter under 35 U.S.C. §101 on 29 July 2011. Thereafter, this first CAFC decision was appealed to the Supreme Court, and the Supreme Court of the USA granted the petition, vacated our decision, and remanded the case to us for further consideration in light of its decision in *Mayo Collaborative Services v. Prometheus, Inc.*, 566 U.S. ___, 132 S. Ct. 1289 (2012), on 26 March 2012. Thereafter, the CAFC has reevaluated and issued a decision on 16 August 2012. In the second decision, the CAFC held that: (1) the courts properly have jurisdiction over the declaratory judgment case; (2) composition claims to isolated DNAs, including cDNAs fall within the scope of Section 101 patentable subject matter; (3) method claims directed to comparing or analyzing gene sequences are not subject matter eligible; and (4) method claim to screening potential cancer therapeutics via *in vitro* changes is subject matter eligible. Thereafter, a Petition for a *writ of certiorari* filed on 25 September 2012. Subsequently, the Supreme Court granted the petition in which only Question 1 presented by the petition was granted. According to the Supreme Court, the time to file respondents' brief on the merits is extended to and including 7 March 2013.

Sources: www.supremecourt.gov/Search.aspx?FileName=/docketfiles/12-398.htm;
www.cafc.uscourts.gov/images/stories/opinions-orders/10-1406.pdf

Sandoz, Inc. v. Warner Lambert LLC

IP High Court of Japan, December 5

The IP High Court of Japan invalidated a patent directed to a specific crystal form of atorvastatin, one of the Pfizer's blockbusters, due to lack of enablement. Warner Lambert LLC, a Pfizer's subsidiary, has filed and granted a patent directed to a novel crystal form of atorvastatin, or Lipotol[®], thereby obtaining an 'extended' life cycle of exclusivity for the company's best-selling pharmaceutical product, whose basic patent has already expired. Sandoz challenged the patent by arguing that the patent in issue is not enabled for the entire scope of the crystal of atorvastatin. The Court has accepted Sandoz's arguments as the patent specification fails to describe specific parameters for preparing the crystals in issue and held that the patent in issue has been invalidated. Upon judging the enablement requirement, the Court stated that with respect to an invention of a product, in order that the enablement requirement is satisfied, specific description to produce the product, or equivalent thereto in view of the common general knowledge in the art, must be described in the specification. This criterion is different from that of the Examination Guidelines prepared by the Japan Patent Office, which requires how to use should be described in addition to how to make, for an invention of a product. Such a statement is repeatedly held by the IP High Court of Japan in a couple of recent cases and, thus, it is expected that the Court's position directed to the enablement requirement may be changed.

Source: www.courts.go.jp/hanrei/pdf/20121212115344.pdf

AstraZeneca AB, AstraZeneca Plc. v. European Commission, European Federation of Pharmaceutical Industries & Associations

Court of Justice of the EU, December 6

The Court of Justice of the European Union (CJEU) has dismissed the main appeal of the AstraZeneca group, which abused its dominant position by preventing the marketing of generic products replicating Losec (called Prilosec in the USA), in relation to misuse of the supplementary protection certificates (SPCs) system. The subject appeal is originated from the General Court, which judged the appeal from the European Commission. In the first instance at the European Commission, it was found that AstraZeneca had deliberately made ‘misleading representations’ to the patent offices of certain Member States in order to obtain or maintain SPCs for Losec. AstraZeneca’s purpose was to block generic competitors by extending patent protection to which it was not entitled, or alternatively, to which it was entitled but for a shorter period of time. The issue was about whether the interpretation of the first ‘pricing’ decision may be considered for SPC applications. Although AstraZeneca argued that a pricing decision is indeed necessary in certain Member States in order for a medicinal product to be marketed, AstraZeneca omitted the indication that the date indicated in the applications is the ‘pricing’ decision date. The Commission held that the lack of transparency constitutes ‘misleading representation’. Additionally, AstraZeneca *“was penalised for having submitted requests for deregistration of the marketing authorisations for Losec capsules in Denmark, Sweden and Norway in order to delay or make more difficult the marketing of generic medicinal products, and to prevent parallel imports of Losec.”* Thereafter, AstraZeneca appealed to the General Court for annulment of the Commission’s decision. On 1 July 2010, the General Court rejected most of the arguments put forward by AstraZeneca, except for the Commission’s decision so far as concerns the finding of the second abuse. AstraZeneca subsequently filed an appeal with the CJEU, seeking to have the General Court’s judgment set aside. AstraZeneca’s main arguments concerned errors of law by the General Court in its assessment of the two types of abuse and determination of the fine. In its decision, the CJEU dismissed AstraZeneca’s appeal. As for the misrepresentation, the CJEU recognized that: *“clearly ... AstraZeneca’s consistent and linear conduct ... which was characterised by the notification to the patent offices of highly misleading representations and by a manifest lack of transparency, inter alia as regards the existence of the French technical authorization, and by which AstraZeneca deliberately attempted to mislead the patent offices and judicial authorities in order to keep for as long as possible its monopoly on the PPI market, fell outside the scope of competition on the merits”* (paragraph 93). With respect to the second form of abuse, the Court held that this type of conduct *“...consisting in the deregistration, without objective justification and after the expiry of the exclusive right to make use of the results of the pharmacological and toxicological tests and clinical trials ... of the marketing authorisations for Losec capsules in Denmark, Sweden and Norway, by which AstraZeneca intended ... to hinder the introduction of generic products and parallel imports – does not come within the scope of competition on the merits”* (paragraph 130). The CJEU consequently reduced the fine from €60.0 million to €52.5 million.

Sources: <http://curia.europa.eu/jcms/upload/docs/application/pdf/2012-12/cp120158en.pdf>;
<http://curia.europa.eu/juris/documents.jsf?num=C-457/10>

Novartis AG v. Generics (UK)

England and Wales Court of Appeal,
December 12

Mylan sought to revoke their supplementary protection certificate (SPC) for the patent relating to rivastigmine, a drug for the symptomatic treatment of Alzheimer's disease. Novartis counterclaimed with an allegation that Mylan threatened to infringe the SPC with a generic version of rivastigmine. The patent in suit was for the (-) enantiomer of a compound referred to as RA7 in the prior art. The prior art disclosed RA7 and taught that it was effective against Alzheimer's disease. The question before the ruling was whether it was obvious to investigate the compound and resolve the mixture into its enantiomers. The Judge held that it was obvious, and the patent and its SPC were thus invalid. A counterclaim issued by Novartis argued on whether it was "*obvious to try*" to resolve the enantiomers. Novartis relied on evidence that there was no clear indication that resolving the enantiomers would be of use. The appeal by Novartis in respect of the error of the law was dismissed.

Source: www.bailii.org/ew/cases/EWCA/Civ/2012/1623.html

In re Rosuvastatin Calcium Patent Litig.

US Court of Appeals for the Federal
Circuit, December 14

In this ruling, the patent related to the cholesterol-lowering drug 'rosuvastatin', otherwise known as Crestor®, issued to Shionogi Seiyaku Kabushiki Kaisha and licensed to AstraZeneca UK and its US subsidiary IPR Pharmaceuticals Inc., (the Plaintiffs) was called into question. The Plaintiffs alleged infringement of the patent against several generic producers, including Apotex US (the Defendants), when they filed an Abbreviated New Drug Application under the Hatch–Waxman Act. The district court held the patent valid, enforceable and infringed where: patent invalidity on the ground of obviousness had not been shown for the compound rosuvastatin; unenforceability based on inequitable conduct was not established; reissue was available, and that the scope of the reissue was in accordance with law. All Defendants appealed the rulings of validity and enforceability, whilst Apotex US, claimed that it was not a proper defendant because their agency for Apotex Canada did not qualify them as a legal 'submitter' of an ANDA. The Court rejected these claims and Apotex US was named as a formal legal defender.

Source: www.cafc.uscourts.gov/images/stories/opinions-orders/10-1460.pdf

Dr Reddy's Laboratories (UK) Ltd & Another v Warner–Lambert Company LLC

Patents Court of England and Wales,
December 20

The Patents Court of England and Wales have rejected a challenge brought by Dr Reddy's Laboratories against the 6-month pediatric extension of the supplementary protection certificate (SPC) for Pfizer's cholesterol-lowering product atorvastatin (Lipitor). This was the Court's first judgment on a challenge to a pediatric extension under the Pediatric Regulation. Atorvastatin was covered in the UK by an SPC that originally extended patent protection until November 2011. However, in July 2008, the European Medicines Agency agreed on a Pediatric Investigation Plan (PIP) for atorvastatin. That PIP required two studies to be completed and a third to be started (and then completed as part of a separate Risk Management Plan). Pfizer completed the first two studies, started the third, and applied for an indication for pediatric use. Pfizer then obtained a 6-month pediatric extension of the SPC, lasting until May 2012. Dr Reddy's Laboratories challenged the extension, claiming that the first two studies under the PIP were not significant, and the third study had to be completed before

any entitlement arose to the 6-month extension. The Court, however, ruled in favor of Pfizer, rejecting Dr Reddy's Laboratories claims against unlawful procurement of the 6-month extension.

Source: www.bailii.org/ew/cases/EWHC/Patents/2012/3715.html

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