SEPTEMBER/OCTOBER 2017
VOLUME 23 NUMBER 5

IP Litigator®

DEVOTED TO INTELLECTUAL PROPERTY LITIGATION & ENFORCEMENT

Edited by Gregory J. Battersby and Charles W. Grimes

Wolters Kluwer

International Litigation

David Puleo and Dr. Anthony Sabatelli

UK Supreme Court Redefines Patent Infringement

Although there always are ongoing developments pertaining to US patent law, there is occasion to report on patent litigation developments of note from abroad. One such patent case decided last month in Great Britain deserves the attention of all patent practitioners. On July 12, 2017 the United Kingdom Supreme Court (UKSC) redefined patent infringement laws as related to infringement by equivalents, that is, under what is known here in the United States as the "Doctrine of Equivalents." To elaborate, under this doctrine, a party can be found liable for patent infringement even though the accused item or process does not fall within the literal scope of a patent claim. The current legal test in the United States determines whether the difference between the accused item or process and the patent claim is "insubstantial" so that it is equivalent to an invention falling within the scope of the claim. [*See Warner-Jenkinson Co. v. Hilton Davis Chem. Co.* (1997).] Although well established in the United States, the doctrine has been anathema under UK law.

In the case of *Actavis UK Limited and others v. Eli Lilly and Company* ([2017] UKSC 48), Eli Lilly held a patent on pemetrexed disodium salt (marketed as Alimta®) as a lung cancer treatment. However, the generics division of Teva Pharmaceuticals, Actavis Generics, filed patents for different variants of pemetrexed, including pemetrexed diacid, pemetrexed ditromethamine, and pemetrexed dipotassium. Since their variants do not contain disodium ions, as Lilly's pemetrexed does, Actavis sought declarations of non-infringement for their compounds in the United Kingdom, as well as in France, Italy, and Spain.

The UKSC previously had developed a set of questions, known as the Improver/Protocol Questions, which had been used to decide whether infringement had in fact occurred. Based on these Questions, the High Court and Court of Appeal originally ruled that since the Lilly patent specifically claimed the disodium version of pemetrexed, Actavis' pemetrexed variants did not infringe upon the Lilly patent. However, the UKSC intervened and re-vamped the Improver/Protocol Questions, citing that they only covered the specific claims of a patent and were too narrow in scope. The UKSC also invoked two new questions: (1) Does the variant infringe any of the claims as a matter of normal interpretation?; and (2) If not, does the variant nonetheless infringe because it varies from the invention in a way or ways which is or are immaterial? If the answer to either question is yes, then infringement has occurred. This directly parallels the "insubstantial" standard in the US doctrine.

In the context of the current case, the UKSC cited that although the Lilly patent only claimed pemetrexed disodium, it also should be inclusive of other pemetrexed variants because these variants are obvious to those skilled in the art. Using these new metrics, the UKSC ruled that Actavis did in fact infringe upon the Lilly patent. The UKSC court ruling also applies to Actavis' patents in France, Italy, and Spain as well. As an aside, the extension of the UK decision to other courts previously was determined in another case. This British ruling and the expanded interpretation by which infringement is interpreted under the Doctrine of Equivalents have vast potential for the future of UK patent protection and litigation.

Anthony Sabatelli, PhD, JD is an experienced patent practitioner and former biotech executive and research scientist, who provides insightful, practical, and business-oriented service to his clients. He is currently the Chairperson of the Pharmaceutical and Biotech practice group at Dilworth IP. Having spent most of his career in-house, as both a research scientist and as a patent attorney, he appreciates the needs and perspective of the inventors in the lab and the in-house attorneys who seek to protect those inventions. Dr. Sabatelli has a strong interest in and commitment to education and currently is an Adjunct Professor of Chemistry at the University of New Haven. He is a Member of the Board of Governors of Yale University and of the Board of Directors of Connecticut United for Research Excellence (CURE). Dr. Sabatelli can be reached at asabatelli@dilworthip.com.

David Puleo, a technology specialist at Dilworth IP and PhD candidate in the Pharmacology Department at Yale University, combines extensive research and leadership experience to provide a unique approach to biotechnology and the law. Prior to attending Yale, Mr. Puleo graduated from Boston College with a BS in Biochemistry. His interest in drug discovery prompted him to work in the Center for Proteomic Chemistry at Novartis Institutes for BioMedical Research in Cambridge, MA for two years. During his time at Yale, David has collaborated with Gilead Sciences on an early stage drug discovery project to develop novel targeted therapies for immune-related diseases. He can be reached at dpuleo@dilworthip.com.