

Determination of novelty in organic chemistry for patentable inventions

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Patents are the primary motivation behind investment in the pharmaceutical R&D. There are four requirements to get invention patented that are novelty, inventive steps, industrial application, and should not be excluded from being patented. Novelty, particularly in organic synthesis, is one of the essential criteria to determine whether inventions are patentable or not. In the specific area of chemical synthesis in drug discovery, it is very critical to analyze novelty. There are various reasons: 1, one Markush structure (Fig. 1) has many atoms such as C, H, O, N, F, I, C etc. and elimination, addition or exchange of any atom can make a completely new molecule. Therefore, one general formula of a class of compounds can be transformed into millions of compounds with different permutations and combinations. 2, change in a single atom can result in a considerable shift in the physical and chemical properties of the molecule. Hence, it is not easy to enjoy a patent monopoly in drug development because the highly variable potential of chemical structure has made it easier for a competitor to invalidate or overcome protected inventions in drug synthesis on the grounds of novelty and inventive steps. This can be seen in Dr. Reddy (UK) Limited vs Eli Lilly's case where the claimant drug company Dr. Reddy UK (DR-UK), sought revocation of a European patent owned by the defendant, Eli Lilly (Lilly). The patent was about an anti-psychotic drug, olanzapine, used to treat schizophrenia under the brand 'Zyprexa.' Lilly had filed a provisional application in Great Britain in 1974 and disclosed a broad class of compounds. The exact olanzapine (Fig. 2a) was not mentioned in the provisional application. Also, Lilly's research leader published three research papers for several compounds with the general formula (Fig. 2a) with neuroleptic properties in 1980, 1982, and 1989 without mentioning olanzapine. After a few years of provisional application, Lilly patented olanzapine compounds in 1990.

DR-UK opposed Lilly's patent being invalidated because it lacked novelty and would be obvious to a person skilled in the art based on their previous provisional application and published papers that disclosed a general formula. A decision was made by Judge Mr. Floyd at England and Wales High Court on October 13, 2008, in favour of Lilly. As such, no prior art was available about olanzapine during the patent application by Lilly. The decision was significant in the evolution of patent law related to chemical structure. In addition, many other court cases in pharmaceutical drug discovery were resolved based on Lilly's case outcome.

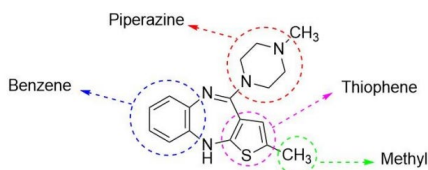


Fig. 1 Basic terminologies used in the chemical structure of olanzapine

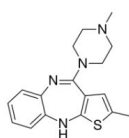


Fig 2a Olanzapine

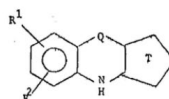


Fig 2b General Formula of compound
Where R¹, R², Q, and T are variables

Biography

Sunil Kumar received his PhD in Pharmacy (Medicinal Chemistry) from Punjab Technical University Jalandhar, India in 2012. He worked a scientist-IPR (Intellectual Property Rights) at Arch Pharmed Labs Ltd, Navi Mumbai, India in 2012-2013. He was employed as an Assistant professor from 2008 to 2011 at ISF College of Pharmacy, Moga, India. The National Science Council (NSC), Taiwan, awarded him a postdoctoral fellowship. He performed his postdoctoral research at Taipei Medical University from 2013 to 2016 and at National Taiwan University (QS world ranking # 68) in 2017-2018. He also conducted research as a postdoctoral researcher at Chang Gung University, Taiwan. His research is based on medicinal and natural product chemistry, specializing in anti-inflammatory and anti-cancer drug design. He has cleared the prestigious GATE exam organized by IIT (Indian Institute of Technology) three times (in 2005, 2006 and 2009). To his credit, he has various publications in reputed journals like PLoS One, the Journal of Natural Products, the European Journal of Medicinal Chemistry, etc. He has the expertise to run the analytical instrument such as NMR, and LC/MS. To understand drug discovery's novelty and patent aspects, he pursued LLM-IPR from Nottingham Trent University, England. Currently, He is working as a scientist/developmental chemist at ThermoFisher Scientific, Loughborough, England. He also has joined SGT University, Delhi-NCR, Haryana, India as an adjunct faculty at School of Pharmacy.

Received: October 07, 2024; **Accepted:** October 09, 2024; **Published:** December 14, 2024