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## Contents

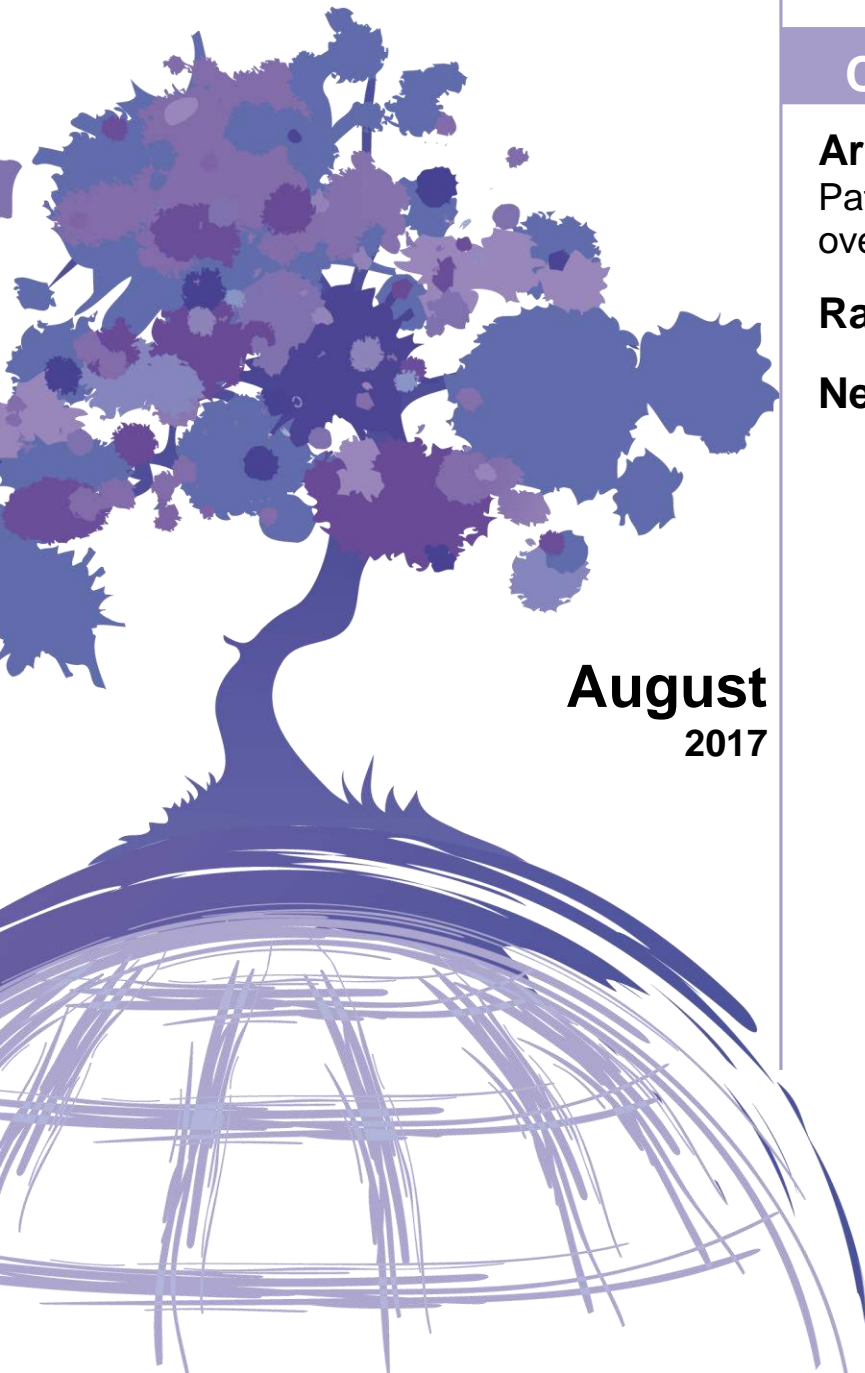
### Article

Patent refusal for Enzalutamide: An  
overview .....2

**Ratio Decidendi**.....5

**News Nuggets** .....6

**August**  
2017





## Article

### Patent refusal for Enzalutamide: An overview

By Dr. Prosenjit Chattopadhyay & Archana Viswanathan

Enzalutamide, marketed by the name 'Xtandi', is a prescription medicine for treating men with metastatic castration-resistant prostate cancer<sup>1</sup>. Enzalutamide was invented at the University of California, Los Angeles (UCLA). UCLA has patent rights for Enzalutamide in 50 jurisdictions. The drug is marketed in India by a Japanese company, Astellas. Recently, in November 2016, the Indian Patent Office ('IPO' hereinafter) refused to grant a patent to the Regents of University of California, for Enzalutamide (Application number 9668/DELNP/2007), on the ground that the

invention lacked inventive step and was not patent eligible under Sections 3(d) and 3(e) of the Indian Patents Act ('Act' hereinafter). Five pre-grant oppositions had been filed against the Application; two of which were by pharmaceutical companies, Fresenius Kabi Oncology Limited (FKOL) and BDR Pharmaceutical International Pvt. Ltd. (BDR), one by the Indian Pharmaceutical Alliance (IPA) and two others by two individuals. Concise description of grounds raised by various opponents can be found in the following table.

Opponent	Relevant Sections of the Act	Grounds raised
FKOL (Opponent 1)	25(1)(e)	Lack of inventive step
	25(1)(f)	Not an invention
	25(1)(g)	Lack of clarity and sufficiency
	25(1)(h)	Section 8 requirement not complied
BDR (Opponent 2)	25(1)(b)	Lack of novelty
	25(1)(e)	Lack of inventive step
	25(1)(f)	Not an invention
	25(1)(h)	Section 8 requirement not complied
Mr. Umesh Shah (Opponent 3)	25(1)(b)	Lack of novelty
	25(1)(e)	Lack of inventive step
	25(1)(f)	Not an invention
	25(1)(g)	Lack of clarity and sufficiency

<sup>1</sup> <https://www.xtandi.com/>

Opponent	Relevant Sections of the Act	Grounds raised
IPA (Opponent 4)	25(1)(b)	Lack of novelty
	25(1)(e)	Lack of inventive step
	25(1)(f)	Not an invention
Ms. Sheela Pawar (Opponent 5)	25(1)(i)	Application not filed in the prescribed time period
	25(1)(h)	Section 8 requirement not complied

### *Detailed analysis of the IPO's order*

**Lack of novelty:** Opponents cited US 5441981 (US'981), US6087509 (US'509), 2440/DEL/1996, US 5434176 (US'176) and US 5750553 as the novelty destroying documents. These documents disclose Markush structures claiming a multitude of compounds. However, none of the documents disclose specific structure of Enzalutamide. The Ld. Controller held that for a prior art document to be novelty destroying, it should explicitly disclose the specific structure of the compound and a generic disclosure in form of Markush representations will not suffice. This is also in consonance with point 08.03.02 (g) of the Manual of Patent Office Practice and Procedure, which states that, "A *generic disclosure in the prior art may not necessarily take away the novelty of a specific disclosure.*" The objections against novelty were, thus rejected.

**Lack of inventive step:** A combination of documents was cited by the opponents to substantiate the argument for lack of inventive step. Opponent 1 sought to further the arguments against the inventive step by mosaicing US'981, US 6518257 (US'257), US4636505 (US'505), and J. Med. Chem. 2004, 47(15), 3765-16 (D1 hereinafter). D1 discloses quantitative structure activity relationship (QSAR) study of a group of, primarily, synthetic compounds for androgen receptor. Opponent 1 argued that US'981

discloses a Markush structure, wherein values for various substituents can be selected from different functional groups. When the list of these possible substituents on the main Markush structure is viewed in the light of the teachings in D1, Enzalutamide becomes an obvious choice for a person skilled in the art. For instance, US'981 delineates nitro, halogen and cyano as groups from which substituent R1 can be selected. D1 teaches that a hydrogen bond acceptor is favoured at this position, which hints towards possible use of a group like a cyano group. Opponent 1 presented similar arguments in case of other substituents too, drawing parallels between substituents listed in US'981 and findings of D1 in this regard. Other Opponents too put forth similar arguments. The Applicant in his defence reasoned that the arguments of the Opponents amounted to a hindsight analysis, wherein prior art documents were chosen with structure of Enzalutamide in mind; something which becomes possible only after disclosure of Enzalutamide by the Applicant. However, the Ld. Controller took cognizance of the opponents' arguments and reached the conclusion that the impugned disclosure lacked inventive step when US'981 was viewed in combination with D1, and US'257 was viewed in combination with D1.

**Not an invention:** The Opponents submitted that the structural similarity between Enzalutamide and the compounds disclosed by the

above-mentioned prior arts (cited for lack of novelty and inventive step arguments) made Enzalutamide a derivative of these compounds. Enzalutamide, according to the Opponents, was thus a derivative of a known substance and hence did not qualify as an invention according to Section 3(d) of the Act, unless the Applicant presents data for enhanced efficacy. Such data being unavailable, the impugned disclosure falls under the purview of Section 3(d) of the Act. The Ld. Controller concurred with this view of the Opponents. Further, the Opponents also argued that the composition claims of the impugned Application could not be considered inventive under Section 3(e) of the Act, as the composition was a mere admixture which did not exhibit any synergistic increase in activity over that of the individual components (Enzalutamide). Having acknowledged the lack of inventiveness of Enzalutamide, the Ld. Controller accepted Opponents' arguments with regards Section 3(e) too. The Ld. Controller opined that, as Enzalutamide itself lacked inventiveness, any composition comprising Enzalutamide could not be considered inventive, unless there was data to unequivocally prove that the composition exhibited activity, which was substantially higher than the sum of activities of the constituents comprising the composition, i.e., Enzalutamide and other excipients, carriers etc.

**Lack of clarity and sufficiency:** The Application was also opposed on the ground that it did not disclose the invention in a sufficiently detailed manner to enable a person skilled in the art to practice the invention without undue experimentation. The Opponents argued that, details pertaining to efficacy of Enzalutamide were missing in the specification. However, the Ld. Controller found these grounds untenable and observed that the disclosure was detailed enough to meet the requirements laid down by the Act.

**Non-compliance with Section 8:** The opponents further contended that the Applicant had failed to comply with the requirements of Section 8, by not disclosing the details of applications filed in foreign jurisdictions from time to time, for the same or substantially the same application. However, based on facts presented by the Applicant as a rebuttal to this ground for opposition, this ground too was found inadmissible by the Ld. Controller.

Therefore, the Application was refused by the IPO for the lack of inventive step and the disclosure not being an invention according to Sections 3(d) and 3(e) of the Act.

### *IPO rejection challenged*

The patent Applicant filed a writ in the Delhi High Court and the matter is now pending before the High Court. Ordinarily, the rejection is appealable to the Intellectual Property Appellate Board (IPAB), which unfortunately has not been functional for more than a year now. In March of this year, the Delhi High Court issued a notice in this challenge to the IPO, which is now entitled to file its reply in the matter. The High Court will now have to hear it on merits once all the pleadings are completed. The next date of hearing in said matter is 7th December, 2017. There is, at present, no stay on the IPO's rejection.

### *Conclusion*

The IPO's decision to refuse the grant of a patent for Enzalutamide will enable generic drug manufacturers to make and market generic versions of 'Xtandi'. This is, of course, subject to appropriate regulatory approvals. According to some reports, 'Xtandi' is currently priced at ₹ 3.35 lakhs for 112 tablets to be taken over a span of 28 days<sup>2</sup>, translating into ₹ 11,000 / day and for obvious reasons, generics may be able to market the drug at much lower prices.

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<sup>2</sup> <http://health.economictimes.indiatimes.com/news/pharma/new-twist-in-fight-over-patent-on-cancer-drug/58938215>

One danger for the patent applicant here is that even if the High Court finally allows the writ and the patent is also granted, the fact that, in the meantime, other generics have already started selling the product in the market may result in denial of an injunction if the patent is enforced at a later point in time. This is not a rule set in stone, but this is what happened in *Roche v.*

*Cipla*, with respect to Erlotinib, where a permanent injunction was denied on the basis, among others, that Cipla had already been selling the infringing product for a long time.

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## Ratio decidendi

### Trademarks – Phonetic similarity when word used as suffix in one mark and as prefix in another

Observing that there existed high degree of phonetic similarity between the mark of the plaintiff “FEVIKWIK” and the mark of the defendant “KWIKHEAL”, Bombay High Court has issued an interim injunction in favour of the Plaintiff in a suit for trademark infringement & passing off and copyright infringement. It was held that the word “KWIK” is a dominant part of the trademark of the plaintiff and that the mark used by the defendant is *prima facie* deceptive or misleading. The Court observed that the defendant could not point out any dictionary meaning of the word “KWIK”, and no document was produced in support of the submission that the word mark “KWIK” is common.

The contention that there was no likelihood of any deception or confusion as the mark “KWIK” is used by the plaintiff as suffix whereas the defendant used the said mark as prefix, was also rejected by the Court. The photographs *prima facie* indicated that the label containing trademark of the plaintiff and that of defendant on the products displayed side by side by dealers indicated the similarity of the two products to the last decimal. Hence the product of the defendant was a colourable imitation of the plaintiff’s product. It was also held that overall structural

and phonetic similarity between two products is likely to cause confusion in the mind of the customers. The court was also of the view that the plaintiff was not precluded from raising plea of fraud in the suit alleging infringement of the registered trademark, even though no such allegation was made by it in its application under Sections 47 and 57 of the Trade Marks Act, 1999 for rectification of the mark filed before the Appellate Authority. [*Pidilite Industries Limited v. Poma-Ex Products* - Notice of Motion no. 2695 of 2016 in Suit No. 653/2014, decided on 2-8-2017, Bombay High Court]

### Copyright in literary work authored by director of a company

Delhi High Court has granted an interim injunction in favour of the plaintiff in a case pertaining to a suit for copyright infringement in a literary work, wherein the defendant contended that the literary work was produced by the plaintiff during the course of her employment as a director of the defendant company. The Court in this regard observed that the defendants had not placed on record any material to show that the literary work was authored as a part of the duties and obligations of a director. The Single Judge also noted that neither any agreement nor the articles or memorandum of association of the company was placed on record to prove otherwise. The fact that copyright registration in

favour of the plaintiff was granted when the plaintiff was the director with the defendant, was also taken into consideration by the Court while granting interim injunction. [*Neetu Singh v. Rajiv Saumitra* - IA 8803/2016 & IA 13791/2016 in CS(COMM) 935/2016, decided on 4-8-2017, Delhi High Court]

### Patent revocation application when not to be heard

The Bombay High Court, by its recent judgment dated June 19, 2017, has allowed the Writ petition filed by Chemtura Corporation of Delaware, USA (Writ Petition no. 1919 of 2014), and set aside the order of the Intellectual Property Appellate Board (IPAB), dated August 24, 2012, whereby the IPAB revoked the writ petitioner's patent directed to the invention titled "Improvement in drop-wires for warping-machines," under Section 64 of the Patents Act,

1970 (Act), on the ground of non-compliance of Section 8, and lack of inventive step. The Bombay High Court referred to the decision of the Hon'ble Supreme Court in the case of *Shiv Prasad v. Durga Prasad* [1975 1 SCC 405] and held that the IPAB erred in proceeding with the hearing of the Revocation Application, despite the pending Miscellaneous petitions seeking "unconditional withdrawal" of the revocation application and the Memorandum of understanding signed between Chemtura and VRC Continental, the original Applicant seeking revocation, existing on record. The Bombay High Court thus directed that the Patent No. 213608 be restored on the Register of patent under Section 117(D)(2) of the Act. [*Chemtura Corporation v. Union of India* - Writ Petition No. 1919/2014, decided on 19-6-2017, Bombay High Court]



## News Nuggets

### Global injunction on display of search engine results

Google has on 24th of July brought an action before the US District Court (Northern District of California-San Jose Division) to prevent enforcement of the Canadian Supreme Court Order that prohibits Google from publishing within the US, search result information about the contents of the internet. The Canadian Supreme Court in the case of *Google Inc. v. Equustek Solutions Inc.*, had upheld the Order issued to Google to execute a worldwide injunction to globally de-index the defendant's websites (Datalink), which the defendant, in breach of several court orders, was using to unlawfully sell the intellectual property of the plaintiff company (Equustek). The Canadian

Court had dismissed, as theoretical, Google's concerns about the injunction violating U.S. law.

According to the petitioner, removing a website link from the search index neither prevents public access to the website, nor removes the website from the internet at large. It was also contended that the petitioner is not a publisher and the fact that Google's search results may contain snippets from third-party websites, does not transform those snippets into content created by petitioner-Google. Violation of Communications Decency Act, providing legal immunity to providers of interactive computer services in respect of content created by others, and other US provisions is alleged in the dispute.

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