



# IPAB Allowed an Appeal and Granted A Patent to Pfizer For Tofacitinib and its Salts

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The IPAB allowed an appeal and granted a Pfizer Tofacitinib patent in India and its salts (application 991/MUMNP/2003). an appeal and granted a patent to Pfizer for its application 991/MUMNP/2003.

This application claimed the compound 3-((3R, 4R)-4-Methyl-3-[methyl-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-amino]-piperidin-1-yl)-3-oxo-propionitrile and pharmaceutically acceptable salts thereof (Tofacitinib and its salts) and was refused by the patent office on various grounds, including anticipation by prior claiming and section 3(d).

The main prior art cited by the controller for novelty was Document WO 0142246(D1) that claimed and disclosed the compound 3-(4-methyl-3-[methyl-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-amino]-piperidin-1-yl)-3-oxo-propionitrile. The ground of anticipation by prior claiming was not raised in the hearing notice and for section 3(d) no known substance was identified.

The appeal was filed on various grounds including that the order was against principles of natural justice as the objection of anticipation by prior claiming was never raised, and “known substance” was not identified for section 3(d) but also on various substantive grounds like non-applicability of such grounds to the present invention.

It was also submitted that during the prosecution of present invention, before the hearing in 2015 the Appellant submitted comparative data to support the surprising efficacy of the compound claimed in the present application, Tofacitinib monohydrate, compared to the compound disclosed in the alleged prior art document D1.

The appeal was allowed by the Hon’ble IPAB and the main findings in the decision are as follows: –

## Section 3(d):

- it is against the principles of natural justice that an application is rejected without clearly communicating an objection to the Appellant.
- The applicant must be aware as to what the known substance is, and against which an enhancement of efficacy is to be shown to show patentability.
- As D1 is not a prior published documents, the hon’ble IPAB held that for section 3(d), prior art has to be known to the public and not the inventor/ applicant of the patent specification. Inventor’s knowledge is immaterial in patentability analysis.



- The document cited- D1 was filed earlier, however, was not published before the priority date, it was not a prior public document and therefore the compound disclosed therein, in particular compound of Example 14 was published after the priority date of the present application and is not a “known compound”.
- The controller admits that a data comparing Tofacitinib and example 14 of prior art can overcome section 3(d), however, still rejects the application on grounds of section 3(d), even in the presence of such data.

The board therefore held that Section 3(d) is not applicable to the present case as there is no “Known compound”. D1 was not publically available at the priority date of the present application. Further, even if Section 3(d) is applied without prejudice, the applicant by evidence has established the superiority of claimed form over 3-[4-methyl-3-[methyl-(7H-pyrrolo[2,3-d] pyrimidin-4-yl)amino]-piperidin-1-yl]-3-oxopropionitrile, and other enantiopure forms of compound of D1.

## Anticipation by Prior Claiming

- It is settled law and principle of anticipation that a generic disclosure does not take away the novelty of a claim of a specific disclosure, or else several provisions of the Indian Patents Act including section 3(d) would be rendered otiose
- The party/ applicant is to only establish that 3R, 4R has not been specifically claimed in the cited art.
- It is a legally established principle that no data, establishing superiority of unexpected results is required to overcome the objection of anticipation be it anticipation by prior claiming or anticipation by prior publication.

After the order in the appeal was orally announced, a third party filed a pre grant opposition and made representation of the opposition before the board. The board also dismissed the representation and held that in the present case the application for registration was rejected though no opposition was filed.

Once the application was rejected, the question of filing opposition in the rejected application does not arise. The board also discouraged the filing of oppositions to delay grant of the application and held that:

- Once the infringers become aware that it is a valid, genuine and commercially successful invention/patent and if any action is taken or likely to be taken before the Court for infringement, they make all efforts and see that the life of the genuine patentee must become miserable by raising all types of false and frivolous objections.
- the practice of filing of Benami opposition by the Benami opponent and crooked imposter has to be stopped.



- It is the duty of the respondent/controller of patents that such person(s) may not be allowed to take the advantage of multiple layers of opposition.
- If any opposition is filed either under Section 25(1) or 25(2), which is bogus and without any merit, the same is to be thrown out at the earliest with heavy costs and penalty. Only the genuine oppositions are to be entertained.

