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**In Strides Shasun Limited*,
the Mumbai Bench of ITAT
held that the activity of
preparation of 'Dossier'
should be treated as
manufacture or production of
an article or thing and is
eligible for deduction under
section 10B of the Act.**

*ITA No. 8614/Mum/2011

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Facts of the case

- Strides Shasun Limited (formerly known as Strides Arcolab Limited) [assessee] was engaged in the business of manufacturing and marketing of pharmaceutical products.
- The assessee had filed its return of income for AY 2007-08 claiming deduction under section 10B of the Act, in respect of the profits arising out of activities carried out, which included the Strides Technology and Research (STAR) unit, amongst others.
- STAR unit was engaged in the development of the generic version of products by re-formulating an existing innovator product. This re-formulated generic version of the product was initially produced/manufactured in the R & D facility as a 'prototype'. Subsequently, all data relating to such product was compiled in the form of a 'dossier' and submitted to the regulatory authorities for approval. On receipt of approval, the dossier was sold to the customers.
- During the course of assessment proceedings, the tax officer in the draft order had denied the claim of 10B deduction on the grounds that the activity undertaken in STAR unit comprises of development of a 'process' which is neither an article nor a thing, but only a method of manufacturing a product. The tax officer further held that the assessee is not selling the 'process of manufacture' but is merely granting a license to manufacture and sell the product within a territory, using the process developed by the assessee. The same can by no stretch of imagination be treated as 'manufacture or production of an article or thing and export thereof'.
- The DRP also rejected the assessee's objections on the basis that the preparation of dossier is only a regulatory and intermediary process and not an end-product in itself and that the assessee is not selling the dossier, but granting the license by utilising the process. It further held that to be eligible for deduction and exemptions 'first degree of nexus' with the eligible income is sine-qua-non.
- The tax officer in the final assessment order confirmed the disallowance of deduction under section 10B of the Act on profits earned by STAR unit in accordance with the directions of the DRP. Aggrieved by the order of the tax officer, the assessee filed an appeal with the Hon'ble Mumbai Tribunal (ITAT).

Key issue under consideration

Whether the assessee is eligible for claiming deduction under section 10B of the Act in respect of the profits of STAR unit?

Ruling of ITAT

- The product development activity is a process-related activity and the final outcome of the activity is presented in the form of a 'dossier'. The dossier explains how the

development activity is carried out along with details of production of a product at every stage.

- Although the end product is a dossier, the major activity involved in creating it is manufacturing, which starts from the R&D facility and ultimately takes place in the plant. The production normally takes place at the R&D unit up to the development batches and thereafter, the exhibit batch manufacturing takes place in the regular production plant under the supervision of the R&D team.
- The dossier is a culmination of various activities which are primarily manufacturing/development of exhibit batches supported by data collection, stability studies, and bio-equivalent studies. The dossier explains how the development activity is carried out along with the details of production of a product at every stage.
- The process of preparing the dossier cannot be completed without completing the process of manufacture of exhibit batches. The exhibit batch is a commercial size batch which is a final product and is in a finished form capable of being sold and belongs to the customers.
- The fundamental requirement in all the agreements is the creation of a dossier, which is a compilation of all the relevant technical education to manufacture a product.
- For each market, a separate dossier is prepared and is generally required to be supported by additional activity and data besides manufacturing of exhibit and commercial batch.
- The ITAT observed that the creation of dossier in fact entails the actual production of the formulation initially in the laboratory. In this regard, the ITAT also relied on the decision of Supreme Court in the case of Scientific Engineering House Pvt. Ltd. (157 ITR 86) wherein it was held that the compilation of technical know-how is an article to be considered as capital asset eligible for deduction for depreciation.
- The ITAT also relied on the decision of Bangalore Bench of ITAT in the case of ISBC Consultancy Services Ltd. (64 taxmann.com 222) wherein it was held that processing of data or information tantamount to manufacture or production of article or thing.
- On above facts and decisions, the ITAT held that a dossier has all the attributes of product being an article or thing and its creation specifies the requirement of a production and accordingly allowed deduction under section 10B of the Act.

Conclusion

The Mumbai Bench of ITAT has held that a dossier, which *inter-alia* explains the development activity along with details of production, has all the attributes of a product being an article or thing. Its creation entails actual production of the formulation, initially in the laboratory, and thereafter up to the batch size, and is eligible for claiming deduction under section 10B of the Act.

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