The European Union launches a WTO case against Turkey's measures forcing foreign producers of pharmaceuticals to relocate their productions

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On 2 April 2019, the European Union initiated a case before the World Trade Organisation (WTO) against Turkey targeting national measures on pharmaceuticals that oblige foreign producers to relocate their production in the country.

The pharmaceutical industry is a key player in the Turkish economy, in particular for innovative products, for which Turkey represents an important strategic market and a gateway between Europe and the Middle East. The country is considered one of the top export markets for European pharmaceuticals, and over 50% of Turkey's pharmaceutical imports come from the EU[1].

However, the Turkish Government has recently made resort to localisation policies, market access barriers and discriminatory measures to increase the domestic production of medicines in

[1] For further information, see the following LINK.

order to respond to an upsurge in domestic demand. These measures concern the production, importation and marketing of pharmaceutical products and, therefore, have a direct impact on the pharmaceutical industry. Moreover, they are in breach of the existing commitments under the EU-Turkey Customs Union[2]. It is to target these measures that the European Union launched a WTO dispute against Turkey. As stated by Commissioner for Trade, *Cecilia Malmström*, "*… Turkey is discriminating against EU pharmaceuticals producers by forcing them to move production there. This is a clear violation of WTO rules and puts many EU jobs at risk...*"[3]. The targeted measures include localisation and technology transfer requirements, an import ban on localised products and prioritization measures.

More particularly, the Turkish authorities adopted measures that require foreign producers to commit to localise in Turkey their production of certain pharmaceutical products. The 64th Action Plan of the Turkish Government[4], as well as other legal instruments such as Presidency Decision No. 108 on the New Economy Program for the period 2019- 2021[5], the Social Security Institution Law Number 5502 of 16 May 2006[6], and the SSI Regulation on Alternative Reimbursement for Universal Health Insurance[7], introduced provisions threatening to disqualify imported products from reimbursement of pharmaceuticals sold by pharmacies to patients, a scheme operated by Turkey's social security system. Since such scheme covers the vast majority of sales of pharmaceuticals by pharmacies, the exclusion of imported products from the reimbursement list may impair their competitive opportunities in the Turkish market, as compared with domestically produced comparable products. The localisation requirement is designed to apply on an ongoing basis, or at least until the localisation objectives established by the Turkish Government are achieved. Moreover, Turkey applies technology transfer requirements, whereunder foreign producers may be obliged to transfer technology, including patent rights, to a producer established in Turkey, as well as an import prohibition of pharmaceutical products whose production has been localised in Turkey in accordance with the localisation requirement. Such import prohibition is applied in conjunction with the Turkish rules for approving the importation and marketing of pharmaceuticals[8]. Finally, even in cases where imported products are not disqualified from the reimbursement scheme, the Turkish authorities give priority to the review of applications for inclusion of domestic pharmaceuticals in the list of products covered by the reimbursement scheme, as well as with respect to any pricing and licensing policies and processes, over the review of the applications for imported products.

The estimated value of pharmaceutical exports likely to be affected by these measures is about 460 million Euro and, if further implemented, they could potentially affect all EU exports to Turkey, worth more than 2.5 billion Euro.

[2] Decision No 1/95 of the EC-Turkey Association Council of 22 December 1995 on implementing the final phase of the Customs Union (96/142/EC).
[3] See the following LINK.
[4] 2016 Action Plan of the 64th Government, of 10.12.2015. See in particular Action 46, according to which: "*… The reimbursement, pricing and licensing processes of medical devices and strategic and domestic medicines shall be improved…*".
[5] Presidency Decision, of 20.09.2018, n. 108, on the New Economy Program for the period 2019-2021.
[6] Social Security Institution Law of 16.05.2006, n. 5502, as amended by Article 88 of Decree Law of 02.07.2018, n. 703, Amending Certain Laws and Decree Laws for the Purposes of Compliance with the Amendments to the Constitution.
[7] SSI Regulation, of 10.02.2016, on Alternative Reimbursement for Universal Health Insurance.
[8] European Union Permanent Mission to the World Trade Organization, 02.04.2019, *Request for Consultations by the European Union.* Available at the following LINK.

Such measures compromise patients' access to appropriate treatments and are in contrast with the WTO obligations to treat foreign companies on an equal footing with domestic players and to protect the intellectual property of foreign companies in national territory.

According to the European Union, the localisation requirement and the prioritization measures are in breach of Article III, paragraph 4, of the 1994 GATT Agreement[9], since they accord to imported pharmaceuticals a less favourable treatment than that granted to like products of national origin. Moreover, by imposing an import ban of localised products, the national measures also violate Article XI, paragraph 1, of the GATT Agreement[10], since they provide for a prohibition or restriction, other than duties, taxes or other charges, on the importation of products of other contracting States. In addition, the European Union argues that the technology transfer requirement is in breach of both Article 27, paragraph 1, and Article 28, paragraph 2, of the TRIPS Agreement[11]. Such requirement does not apply to domestic pharmaceutical producers, and therefore patents are not available and patent rights are not enjoyable without discrimination regardless of whether products are imported or locally produced. Moreover, it restricts the right of patent owners to assign, or transfer by succession, the patent and to conclude licensing contracts, and may require foreign producers of pharmaceutical products to transfer undisclosed information protected by Article 39 of the TRIPS Agreement[12] to a Turkish producer.

[9] WTO General Agreement on Tariffs and Trades of 15.04.1994. Article III of the Agreement, named "National Treatment on Internal Taxation and Regulation", at paragraph 4 asserts: "*… The products of the territory of any contracting party imported into the territory of any other contracting party shall be accorded treatment no less favourable than that accorded to like products of national origin in respect of all laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution or use. The provisions of this paragraph shall not prevent the application of differential internal transportation charges which are based exclusively on the economic operation of the means of transport and not on the nationality of the product…*".

[10] Article XI of the Agreement, named "General Elimination of Quantitative Restrictions", at paragraph 1 asserts: "*… No prohibitions or restrictions other than duties, taxes or other charges, whether made effective through quotas, import or export licences or other measures, shall be instituted or maintained by any contracting party on the importation of any product of the territory of any other contracting party or on the exportation or sale for export of any product destined for the territory of any other contracting party…*".

[11] WTO Agreement on Trade-Related Aspects of Intellectual Property Rights of 15.04.1994. Article 27 of the Agreement, named "Patentable Subject Matter", at paragraph 1 asserts: "*… Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced...*".
Under Article 28, paragraph 2, of the Agreement, named "Rights Conferred", "*… Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts…*".

[12] Article 39 of the TRIPS Agreement provides that: "… *1. In the course of ensuring effective protection against unfair competition as provided in Article 10bis of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3.*
2. Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices so long as such information:
(a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;
(b) has commercial value because it is secret; and

The localisation requirement and the import ban on localised products are also incompatible with the commitments of the EU-Turkey Customs Union[13]. Although imports, exports or goods in transit may be prohibited or restricted on grounds of public morality, public policy or public security[14], quantitative restrictions on imports, exports and all measures with an equivalent effect are prohibited[15]. Furthermore, Turkey should make sure that "*… no discrimination regarding the conditions under which goods are procured and marketed exists between nationals of the Member States and of Turkey…*"[16].

The dispute settlement procedure is governed by the WTO Understanding on Rules and Procedures Governing the Settlement of Disputes[17]. In particular, once a request for consultations is made, *"…* [i]*f the consultations fail to settle a dispute within 60 days after the date of receipt of the request for consultations, the complaining party may request the establishment of a panel…*"[18]. The panel will be composed by well-qualified governmental and/or non-governmental individuals, and in order to assist the Dispute Settlement Body[19] *"… in discharging its responsibilities…*", it will *"… make an objective assessment of the matter before it, including an objective assessment of the facts of the case and the applicability of and conformity with the relevant covered agreements…*"[20].

It remains to be seen if this unprecedented event in EU-Turkish trade relationships will result in a negotiated settlement and agreed solution, or develop into a dispute in proper sense within the WTO legal framework.

(c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.
3. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use…".

[13] Decision of the EC-Turkey Association Council, of 22.12.1995, n. 1, on implementing the final phase of the Customs Union (96/142/EC). Under Article 5 of the Decision, Turkey committed to the obligation that quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between the Parties. Turkey has not fulfilled that obligation.

[14] Article 7 of the Decision asserts: "*… The provisions of Articles 5 and 6 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between the Parties…*".

[15] See Articles 5 and 6 of the Decision.

[16] See Article 42 of the Decision.

[17] WTO Dispute Settlement Rules, of 15.04.1994, Understanding on Rules and Procedures Governing the Settlement of Disputes.

[18] Article 4, paragraph 4, of the Understanding.

[19] The WTO Dispute Settlement Body is composed by all of the representatives of the member governments, and it is charged with deciding the outcome of a trade dispute on the recommendation of a Dispute Panel. In deciding, the WTO Dispute Settlement Body employs a 'reverse consensus' procedure, meaning that the recommendation of the Panel should be adopted unless there is a consensus of the members against its adoption.

[20] Article 11 of the Understanding.

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