Would the proposed “manufacturing waiver” really pass the TRIPS test?

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As most readers will know, yesterday the European Commission published a proposal to amend Regulation 469/2009 concerning the supplementary protection certificate for medicinal products (the “SPC Regulation”) aimed at introducing a so-called “manufacturing exemption for export purposes” (in short, a “manufacturing waiver”). The rationale behind it is that the introduction of this new exemption to the rights conferred by supplementary protection certificates (“SPCs”) would allegedly boost the European generics and biosimilars industry. It would bring all sorts of benefits to Europe. Thousands of jobs would be created. Europe would become the pharmaceutical industry’s paradise. There are even rumours that Real Madrid would no longer win the Champion’s League (by the way, congratulations to Real Madrid supporters). No such comparable benefits can be traced back in history since the time when Noah devised his famous Ark.
The question is whether the new exemption would pass WTO’s scrutiny and, in particular, whether it would be compatible with TRIPS.

To begin with, the proposal is not easy to reconcile with the conclusions reached by the WTO’s panel report of 17 March 2000 in *Canada – Patent Protection of Pharmaceutical Products* where, ironically, the complaint had been filed by the European Commission and its Member States. Although the exemption found to be contrary to TRIPS in that case was not a “manufacturing waiver” exemption but a “stockpiling” exemption, the legal reasoning of the panel report is equally

applicable to the former. The new exemption would go far beyond the strict limitations enshrined in Article 30 of TRIPS. If, as the Commission seems to assume, a "manufacturing waiver" could be accommodated within the narrow contours of Article 30, one wonders why WTO members devoted so much time and effort to introducing Article 31 bis. Readers will recall that this article was introduced for the purpose of allowing the grant of compulsory licences for the export of medicaments with certain precautions to non-manufacturing countries suffering from pandemics. For example: HIV, tuberculosis and malaria. Clearly, if a "manufacturing waiver" was truly compatible with Article 30 of TRIPS, the introduction of Article 31 bis would have been a futile exercise.

A second argument mastered to try to justify the compatibility betweeen the proposed exemption and TRIPS is that the TRIPS Agreement would allegedly apply to patents but not to SPCs. The argument does not take into account that all "*patent rights*" (regardless of the precise legal title from which they originate) are subject to TRIPS (see, for example, Article 27.1 and Article 30 thereof). And even accepting that patents, on the one hand, and SPCs, on the other, may be justified by slightly different rationales, the fact remains that SPCs confer "patent rights" and, therefore, are subject to TRIPS' empire. It may be added, in passing, that outside the European Union those very same "patent rights" are extended under the form of a "patent term restoration" which is of course subject to TRIPS. As the European Commission itself highlighted in another WTO case arising from a complaint also filed by the European Commission (*Japan Alcohol Beverages II*), an apple does not cease to be an apple by calling it an orange.

Finally, the philosophy that inspires the proposed exemption (aiding European industry), although of course legitimate, appears to be at odds with WTO's longstanding tradition of disliking state aid.

In conclusion, for the reasons hinted here in a nutshell, it is doubtful whether the "manufacturing waiver" proposed by the European Commission would pass the TRIPS test.