

Remarking Amendment to VCI submission to the Commissions public consultation on supplementary protection certificates (SPCs) and patent research exemptions

The German Chemical Industry Association (Verband der Chemischen Industrie e. V., VCI) represents the economic-political interests of 1,600 German chemical companies and subsidiaries of foreign groups in Germany, speaking for over 90 percent of the German chemical industry.

Among the members of VCI are both pharmaceutical and crop protection companies. In 2016 the German pharmaceutical industry generated sales of roughly € 48 billion and employed some 115,000 persons while the German crop protection companies were at the same period of time accountable for sales of roughly € 2,1 billion¹.

Both for the pharmaceutical and crop protection companies innovation is crucial. In 2016 alone the German pharmaceutical industry spend about € 6,5 billion² in research and development (R&D) of new medicines while the crop protection industry spend around US-\$ 6,2 billion³ for agrochemical R&D. The extensive range of new medicines and innovative crop protection products that are available today for patients and farmers and the product pipeline for tomorrow would not be there without support for innovations in both sectors concerned. A robust system of Intellectual property protection in the EU is essential to encourage continued investment in research and development, and to ensure the pharmaceutical and crop protection industry maintain their strong innovative base with positive outcome for patients and farmers and the whole society. It applies for both sectors: no innovation without investments and no investments without adequate IP-protection!

Pharmaceutical development is an increasingly high-risk and long-term process, with no guarantee of success. The average research and development time for a new medicine is, according to the latest figures available, about 12 -13 years.⁴ Of 100 candidates considered in the discovery phase, 3 medicines will make it to regulatory approval. The total costs of R&D, including the costs of failure, are now estimated to range from US-\$ 1,0 billion – US-\$ 1,9 billion per successful candidate.⁵

In the crop protection sector there is a very similar picture. The average number of new molecules that are synthesised and subjected to biological research in order to lead to the registration of one new crop protection product has increased from 52.500 in 1995

¹ Chemiewirtschaft in Zahlen 2017, VCI

² Chemiewirtschaft in Zahlen 2017, VCI

³ Calculated on the basis of responses of eleven crop protection companies: Phillips McDougall, The Cost of New Agrochemical Product Discovery, Development and Registration in 1995, 2000, 2005-8 and 2010 to 2014. R&D expenditure in 2014 and expectations for 2019. March 2016.

⁴ EFPIA, The pharmaceutical industry in figures. (2017).

⁵ Mestre-Ferrandiz et al., The R&D cost of a new medicine, OHE, 2012

to 159.574 in the period between 2010 and 2014. The average time from the start of the research process to the entry of the market is, according to the latest figures available, about 11,3 years. The total costs for the development of a new active crop protection ingredient is US-\$ 286 Mio.⁶

Both new medicines and crop protection products have to pass through lengthy authorization procedures before they can be put on the market. IP therefore must incentivize and protect the huge investments on the one hand side while giving a compensation to the IP owners for the period of protection lost during the authorization procedures on the other hand side.

In 1992, to restore the period of protection lost during the lengthy testing and clinical trials period, the EC introduced SPCs in the pharmaceutical area. The EC recognized that the period that elapses between the filing of an application for a patent for a new medicinal product and authorization to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research.

In 1996 the EC further recognized that the competitiveness of the plant protection sector, by the very nature of the industry, requires a level of protection for innovation which is equivalent to that granted to medicinal products and made the SPC-System available also for the crop protection industry.

The EC also recognized at the time of the introduction of SPCs the importance of maintaining parity with IP provision in the US, in order to ensure that Europe could compete effectively for R&D investment. This continues to be of critical importance as markets like China strengthen their own IP provision to be able to compete for R&D investment and create a supportive environment to encourage indigenous world-class innovation. Any dilution of IP protection in Europe would be detrimental to Europe's ability to compete effectively for global R&D investment, affecting jobs and trade balance, competition in the market and, critically, patient access to innovative medicines.

Ever since this time SPCs are the cornerstone of the IP incentive framework for development in pharmaceutical and crop protection industry.

Today SPCs remain more essential than ever. In the crop protection sector for example, the total cost per active ingredient nearly doubled in the last 20 years. The cost for registration and authorization even nearly tripled, and reached about US-\$ 33 million per active crop protection ingredient in the period between the years 2010 and 2014.⁷ Especially the continuous efforts to increase the product safety are causing a

⁶ Phillips McDougall, The Cost of New Agrochemical Product Discovery, Development and Registration in 1995, 2000, 2005-8 and 2010 to 2014. R&D expenditure in 2014 and expectations for 2019. March 2016.

⁷ Phillips McDougall, The Cost of New Agrochemical Product Discovery, Development and Registration in 1995, 2000, 2005-8 and 2010 to 2014. R&D expenditure in 2014 and expectations for 2019. March 2016.

permanent increase in development times and costs. This applies also to new medicines.

Furthermore it has to be taken into account that investment decisions in the concerned industries are long term. Decisions being made now – whether to develop new products, or, where to invest in new R&D or production facilities – are done so with a 20 year plus horizon. Any legal uncertainty around SPCs has the potential to deter investment, postpone costly development decisions and undermine Europe's reputation as a safe cradle for research and development.

Therefore, when reviewing the system of SPCs in pharmaceutical and crop protection area, VCI strongly recommends the Commission to carefully assess whether and to which degree an intervention in the well balanced system of the existing legislative framework, especially the Regulation (EC) No 1610/96 and the Regulation (EC) 469/2009, is necessary.

The VCI is of the opinion that the issues raised by the Commission in its Inception Impact Assessment of February 2017 require a consideration in whole and that it does not seem adequate to discuss individual aspects such as the introduction of a "SPC manufacturing exemption or a revision of the "Bolar exemption" isolated from the whole evaluation. This would bear the risk that an unbalanced system could be established to the disadvantage of EU based innovative pharmaceutical industry.

Regarding the existing SPC regulations VCI states its concern about any proposal to change the SPC system through legislative amendments. As well as being unnecessary, such a re-opening of the regulations would risk to undermine the legal certainty in which pharmaceutical and crop protection development decisions must be made.

However, the VCI now calls on the Commission to move ahead with preparations for the introduction of a unitary-SPC to ensure that such a unitary-SPC is made available until the starting date of the unitary patent system. The introduction of a unitary-SPC is crucial to maintain the future innovation and competitiveness of the pharmaceutical and crop protection industries. It is also a key factor for the success of the unitary patent system. Only if unitary-SPC becomes available the benefits of the unitary patent system will be utilized by the concerned industry. This because the current legal uncertainty with regard to the relation between existing national SPC and the European Patent with unitary effect might hinder companies from choosing the European Patent with unitary effect by the start of the system.

For details:

■ Modernisation of the existing SPC regulations

Firstly, while concerns have been expressed about the number of referrals to the Court of Justice of the European Union (CJEU), VCI believes that this number can not cause any doubt on the overall good functioning of the SPC Regulation. Given the critical

value of SPCs for innovative companies in the concerned industries and the dynamics of the pharmaceutical and crop protection markets, the number of referrals does not seem unreasonable. On the contrary, it is indicative of the fact that overall policy objectives set out by SPC Regulation have been met.

Secondly, questions have arisen regarding the correct scope of SPC availability for more complex product situations stemming from the evolutions of both biological and biopharmaceutical sciences. It is normal for national courts to seek clarification and interpretation of EU laws with regard to these, but these questions have been addressed gradually by the CJEU. VCI believes that, although there will be new referrals from time to time where issues remain unclear, these are likely to concern only a very limited number of cases and will have minor effects on the SPC regime.

In addition, due to the nature of constant and rapid changes in innovation, future potential circumstances may require clarification. However, VCI does not believe that this justifies amending the Regulation. To the contrary, soft law instruments can be swiftly issued and amended, and are thus far better suited to address industry changes. Conversely, because of the rapidity of change, new legislation is highly unlikely to cover all eventualities. Moreover, any fresh provision or wording would inevitably raise new and different questions for interpretation by the CJEU. This would lose the benefit of existing case law as applied to particular product categories and simply introduce new uncertainties.

VCI would therefore favour the Commission's working on guidelines to consolidate the Court case law and provide practical and illustrated support to national examiners reviewing SPC applications.

■ Unitary-SPC

VCI strongly calls for the introduction of a unitary-SPC title. This would remove legal uncertainty, reduce administrative burden, costs and the resources needed for the SPC filings in each Member State. VCI further believes that the creation of a unitary-SPC is crucial for the success of the European Patent with unitary effect. A unitary-SPC would further ensure a consistent interpretation of substantive provisions of the SPC Regulation, especially if relying on examination guidelines, which should build on the most recent case law and would ensure consistent and predictable decision-making.

Concretely, VCI is recommending the creation of a "virtual body" composed of SPC experts from national patent offices for the granting procedure. Such a body should be organisational allocated to an existing EU-Agency and rely on existing expertise at national level and would require limited additional resources intended for the creation of a virtual work-sharing platform. The decisions made by this granting authority should be challengeable within the EU court system, such as the Unified Patent Court.

The unitary SPC title and granting authority should be created jointly for the pharmaceutical and crop protection sector and could be introduced by a stand-alone EU-regulation without requiring any changes to the existing regulatory SPC-framework.

■ SPC manufacturing exception

The SPC system in total is a key factor for investments in further R&D activities of the innovative pharmaceutical industry in Europe. To fulfil this purpose, SPCs should provide the same scope of protection as the basics patents confer. Introducing a SPC manufacturing exemption could fundamentally undermine this right. Further the introduction of a manufacturing exemption would undermine the EU's reputation for the highest standards of IP protection and seriousness about building a knowledge-based economy. Additionally, it would be inconsistent with EU's trade policy where the EU has consistently argued against localisation policies and more particularly about using IP tools to favour domestic production. Finally, such a policy might encourage the introduction of similar exemptions by other countries, which are mostly more competitive than Europe is from a manufacturing perspective.

VCI also doubts that the effects which are expected by the advocates of an SPC manufacturing exemption will even occur. In contrast, the VCI sees significant risks for innovative pharmaceutical companies in Europe.

VCI therefore refuses the introduction of an SPC manufacturing exemption.

■ Bolar exemption

Over all the EU Bolar exemption has provided a much needed clarity on how patent rights can be enforced during clinical trials. This applies even though there are differences in national laws as to the scope of the "Bolar exemption" (for example, whether it extends to activities in support of regulatory applications by innovators as well as those of generic companies)

An increased harmonization of the application of the Bolar exemption in the EU would bring further clarity. VCI supports proposals to recalibrate the scope of the "Bolar exemption" in the pharmaceutical area, which covers innovators activities in support of product registration, Active Pharmaceutical Ingredients (APIs) supply for exempted purposes, testing for foreign approval and additional trials for HTA (health technology assessment) bodies. The provision in the German patent law (Patentgesetz) could serve as a good example in this regard. Furthermore recalibrated Bolar provisions throughout the EU could include acts and preparations for any medicinal product necessary for a timely introduction into the EU market at day 1 after SPC.

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