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62. CE (US) highlighted that there is a dashboard within the USPTO which shows progress of getting through the current backlog.
 63. CP (US) mentioned that the June statement refers to an agreement made on SPCs within the withdrawal agreement – what was this agreement. NC (UK) clarified that there was an agreement regarding SPC applications which are pending when the UK leaves the EU. The agreement is that EU regulations would still apply to those applications that have already been filed.
 64. CP (US) asked if post EU exit, will EU regulations on SPCs apply. NC (UK) stated that the Withdrawal Act carries over EU legislation for the interim period to provide certainty for business, but that the future system is subject to the negotiations of the FEP.
 65. NC (UK) highlighted that there were UK stakeholder concerns regarding the EU SPC Manufacturing waiver and there is ongoing consultation with stakeholders (innovators and generics). The proposal allows a generic manufacture to produce SPC protected medicines if done exclusively to export to non-EU markets where such a protection has expired or never existed. Innovators do not disagree in principle, however there is concern around stockpiling of non-exported products, for day 1 generic entry. From a legal standpoint we (UK) are concerned about the lack of clarity in the text. There also needs to be clarification around whether this change will be to new SPC applications or if it will apply retrospectively.
 66. CE (US) described a scenario where the UK leaves and cannot agree with the EU on medicines, and implied that this would make the UK an export market. Will this lead to an issue with markets being flooded with competitor products. NC (UK) answered that this will be considered during the FEP negotiations.
 67. CP (US) stated that stakeholders are concerned about stock piling, export exceptions and the proposal the European Commission (EC) has made. The US are concerned how it could expand/morph in parliament and are monitoring closely. NC (UK) highlighted that the UK still has seat at the table to influence the proposal and the EC want an agreement by May 2019.
 68. The US asked if a patentee can get a SPC even if they were not the original party that submitted the data for the approved product. (UK) The SPC right follows the patent, so this could be possible.
 69. Negative SPC - A rare but possible strategy when marketing authorisation was granted within the 5-year period. This would result in a negative term SPC; however, innovators do apply for negative SPCs to which there are additional extensions e.g. an applicant has their application approved in 4 years and 9 months. Under the formula 5 years would then be subtracted leaving them with an SPC of negative 3 months. However, by obtaining this SPC they can then add extensions to it which provide protections e.g. a 6-month paediatric extension (giving the applicant a 3 month right).
 70. CE asked if SPCs can also apply to biologics. NC (UK) confirmed this was the case. CE (US) asked how an active biologic is defined. NC (UK) explained that this has not yet been tested in the courts and only a handful of biologics have got far enough to qualify for SPC protection. As SPCs fall under EU law there is a role for the CJEU which can interpret the legislation with referrals mainly to provide clarity. CJEU is not bound to follow its own precedent and some interpretations have created uncertainty. Our relationship with the CJEU depends on our FEP negotiations.



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