D YOUNG & CO PATENT NEWSLETTER no.78

August 2020
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Editorial

In this most unusual of summers, we turn our attention away from the microscopic arena of viral infection to the boundaries of space. For in the world of space study, this summer is proving to be unique. The alignment of Earth and Mars has seen the successful launch of 3 missions to the red planet from the US, UAE and China. The sophistication of the rockets involved and more importantly, the equipment required for a successful Mars landing has involved much skill and intelligence that has been brought together during this challenging time on planet Earth. Concurrently, we have witnessed the first privately designed and built mission to the International Space Station. For those of us remaining earth-bound there has been the opportunity to catch sight of the Perseid meteor shower (best one of the year) while cooling off during a midnight/(very) early morning walk! Overall, the article discussing the protection and enforcement of space assets leading this newsletter is truly well-timed. Enjoy whatever new interests you take up this summer. There is plenty out there to see!

Neil Nachshen, Editor

Webinars

https://dycip.com/web-bio-jul20
European patent biotech case law

Presented by partners Simon O'Brien and Catherine Keetch (first broadcast 08 July 2020).

https://dycip.com/spc-jun-2020
CJEU tightens the net on SPCs

Partner Garreth Duncan discusses case C-650/17 from the CJEU, which will have a significant impact on SPCs in Europe in the future.

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Space technology

The space IP race
Protection & enforcement of your orbiting assets

At 3:22 pm on 30 May 2020, from the same Florida launchpad that once served the Apollo missions and the Space Shuttle, SpaceX lofted two American astronauts out of the atmosphere and into space. Although not the first time in space for the two astronauts, they were the first to be blasted into the cosmos using a space capsule built by a private company.

As the astronauts sat in their space capsule watching the world from on-high, they may have spotted that a lot more technology is orbiting the Earth than when they first went into space many years ago. SpaceX is currently undertaking the Starlink project where several thousand satellites orbiting the Earth will provide high speed, low latency, broadband to anywhere on the planet. SpaceX is not alone, however in trying to achieve this dream. Oneweb (a British based company backed by Softbank amongst others), and Project Kuipier run by Amazon owner Jeff Bezos, also have this ambition.

> So, with all this technology whizzing around the Earth, how can companies protect their investment in R&D associated with the technology? On the other hand, is there anything that can be done to avoid patents owned by other people covering the technology in your orbiting object?

Before launch

Obviously, objects which are to be ultimately launched into space need to be constructed somewhere on Earth, prior to launch, by companies registered and based on Earth. The filing strategy issues for companies associated with this part of the life-cycle of the soon-to-be orbiting technology are the same as with more traditional technology. For example, where will competing products be manufactured, what companies will be making the competing products and where are these companies based?

Moreover, as there are only a few countries that have the infrastructure available to launch objects into space, a patent covering one of those jurisdictions may be useful to prevent the object being imported into that country for launch.

However, after launch, where the competing technology is orbiting the Earth and so is not located in any one country, there are many issues to consider, especially around the issue of patent infringement.

After launch - jurisdiction

The immediate challenge that is faced when considering potential patent infringement concerns which country will have jurisdiction over the orbiting object and so which country's laws will be used to determine patent infringement. As a space technology company investing in R&D, therefore, where should patent applications be filed to protect technology in orbit?

The answer to this question is provided in a treaty from 1967 called the United Nation's Committee on the Peaceful Uses of Outer Space, where it is stated that: "A State Party to the Treaty on whose registry an object launched into outer space is carried shall retain jurisdiction and control over such object…while in outer space".

So, it is fairly easy to establish the country which has jurisdiction; it is dependent upon the registry on which the orbiting object is located.

After launch - infringement

As the object is orbiting the Earth, and so is not located within one particular territory, we have to look to the patent law of the country having jurisdiction to determine whether an infringement has actually occurred.

This is a very complicated issue for space technology companies.

At present, there is only one country that has provided clarity on the question of infringement of a patent by an object in space.

What IP laws protect your investment before and after launch?

In the United States of America, 35 US Code 105 states that: "Any invention made, used or sold in outer space on a space object or component thereof under the jurisdiction or control of the United States shall be considered to be made, used or sold within the United States… Therefore, if the orbiting object that contains potentially infringing technology is on the registry in the US, then the US has jurisdiction and any infringement will be judged (in most cases) as if the orbiting object was located in the US".

This clarity is very useful for space technology companies wishing to protect their innovation as any infringement of an invention on a space object that is under the jurisdiction of the US (is on the register in the US), will be judged as if the orbiting object was based in the US.

This means that claim drafting considerations for such companies such as including independent claims to the orbiting object itself rather than claims to a system including the orbiting object are important.

However, whilst this provides clarity regarding orbiting objects that are on the register of the US, and thus fall under the jurisdiction of US patent law, as noted above, other countries have infrastructure that allows orbiting objects to be launched. Therefore, it is possible that companies may register their orbiting objects on a different country's register.

Typically, the question of infringement in other countries is not so straightforward. Indeed, with orbiting objects being fleetingly above a country, or in some cases never even being above a country, there is a question whether infringement occurs in other countries at all.

With this doubt over infringement in other countries, therefore, has the clarity of the US patent law created a loophole that would allow a company to register the orbiting object on a different country's register (like a "flag of convenience" that occurs in maritime) to specifically avoid the clarity of US patent law in this respect?

Like all good science fiction, we will investigate this further in our next instalment.

Author:
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Covid-19

Coronavirus Changed practice at the EPO

The EPO has postponed oral proceedings before the opposition divisions that are scheduled until 31 December 2020 (previously 14 September 2020) unless already confirmed to take place by videoconference or the parties agree for them to be held by videoconference. The EPO intends to maintain oral proceedings in opposition scheduled to take place on the premises of the EPO in the new year. Oral proceedings before the examination divisions will continue to be held by videoconference as the default. For summons issued from 02 April 2020, oral proceedings before the examination divisions will be by videoconference unless there are serious reasons for holding them in person. For summons issued before 02 April 2020, oral proceedings before the examination divisions will be held by videoconference if this was already confirmed or if the applicant subsequently agrees for them to be held by videoconference.

The Board of Appeal continues to hold oral proceedings. It will no longer contact parties to ask whether they are able to attend oral proceedings. If parties cannot attend oral proceedings for which they have been summoned, they must request a change of date. To assist with distancing some appeal oral proceedings will be held in the Isar building in Munich in addition to the main building in Haar, there may be staggered start times, and attendance is generally restricted to a maximum of two people per party. Parties will not be sent a communication informing them of a change of venue or starting time and changes may take place at short notice. It is up to the parties to consult the EPO online oral proceedings calendar about three days before their oral proceedings to check these details (we will of course monitor any changes of location and time and advise clients accordingly). Parties wishing to attend with more than two people should submit a reasoned request to that effect in advance and the Board of Appeal will decide their request. Board of Appeal hearings can only be held via videoconference with the consent of all parties.

Further detail regarding European IP offices' changed practice is kept updated at: https://dycip.com/covid-19-ip-offices.

Digital Access Service
EUIPO joins WIPO DAS for EU registered design applications

Further information
The EUIPO's announcement concerning WIPO DAS is available at https://dycip.com/euipo-wipo-das

In a welcome announcement, the EUIPO has confirmed that, with effect from 11 July 2020, it is now possible for any submitted EU registered design application to be made available to the Digital Access Service (DAS), which is run by WIPO.

As background, the DAS is a convenient service run by WIPO which allows participating IP offices to effectively electronically share copies of IP applications as applied for. In practice, the service is used in the context of a first IP application (which might be a patent, trade mark, or registered design application) applied for in a first territory which is then used as a priority claim for any second IP application applied for in a different territory. In such situations, and without DAS, it was often necessary to submit a certified copy of the first IP application to the relevant IP office responsible for handling the second IP application, such to support the priority claim back to the first IP application. In contrast, with DAS, the IP offices can access an electronic copy of the first application as applied for between themselves, in a way that obviates the need to submit a certified copy of the first application to the IP office handling the second application.

With the introduction of DAS in respect of EU registered design applications, upon submitting any new EU registered design application, there is now the option to submit any given design(s) from the application to the WIPO's DAS as part of the initial filing process.

On the basis such a request is made as part of the initial filing process for the given design(s) from the EU registered design application, each of these designs will then be issued with a corresponding DAS code as part of the filing. In that respect, it is be noted that not all of the designs from the EU registered design application will necessarily be provided with the same DAS code.

Any such issued DAS code(s) can then be used at the time when any second registered design application is made, which claims priority from the EU registered design application, such to allow the design registry handling the second registered design application to access an electronic version of the EU registered design application as applied for. In this way, the need to submit a certified copy of the EU registered design application to that latter design registry (so long as it, too, is participating in the DAS scheme) can be avoided.

The EUIPO has joined WIPO DAS with effect from 11 July 2020

> The introduction of DAS should be particularly helpful when it comes to pursuing any EU registered designs outside the EU before design registries that are similarly participating in the DAS scheme, such as the USPTO in respect of US design patent applications.

Regrettably, this service offering from the EUIPO is only currently available for making copies of EU registered design applications available to DAS. In that respect it is not currently possible to ask the EUIPO to use the DAS scheme to retrieve a priority document in support of a priority claim to an earlier design filing. In other words, the EUIPO can currently **upload** EU registered design filings to DAS, but it cannot **retrieve** priority documents from DAS to support a priority claim in an EU registered design application. Pleasingly however, the intention is that this latter service offering will be made available by the EUIPO later this year.

On a final note, and separate to DAS, the EUIPO continues to provide electronic certified copies of EU registered design applications as applied for, if required. However, such electronic certified copies cannot be requested in respect of EU registered designs which are currently the subject of deferred publication (which is practically often the case at the time when any EU registered design application is being applied for outside the EU, at the end of the six month priority period). Accordingly, in those instances where the EU registered design is currently the subject of deferred publication, to support a priority claim in a second registered design application claiming priority from the EU registered design, it will still be necessary to either use the DAS scheme to support this priority claim, or request a paper certified copy of the EU registered design application as filed from the EUIPO.

Should you have any questions in respect of the above, please do not hesitate to contact the author or your usual D Young & Co designs advisor.

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WIPO PROOF
A new tool to safeguard IP

WIPO has launched a new digital notarisation tool which allows users to obtain a tamper-proof evidence of the existence of any digital file at a specific point in time. Such digital evidence might not be necessary for all intellectual assets, however, having such proof on hand might for instance become valuable in infringement or litigation cases, for example to prove the existence of a specific copyrighted work prior to the alleged infringing work.

WIPO PROOF can be used for any digital file in any format. The content of the file can be classified into one of nine different categories such as creative design, creative work or data and especially trade secrets and know-how. For example, one might record the status of a musical work or a prototype of a product, which is still at the development stage, where filing for the actual IP right application does not make sense yet.

It is important to note that the service does not require the upload of the digital file itself. Instead, a local browser will create a unique "digital fingerprint" (hash) of the file which will be uploaded together with a digital time print. The tamper-proof token for this specific file will then be created based on this data using a digital encryption technology.

While no WIPO account is necessary to access WIPO PROOF, it is required for payment purposes. The costs per token amount to CHF 20, but discounts are offered in the form of bundles and may be negotiated. Once verified, it is possible to obtain a premium certificate for a token, which can be downloaded and printed if needed. The verification of the token is free of charge. At the time of verification, the digital file is compared to the file connected to the token. In case the file has been modified in the meantime, verification will fail.

WIPO PROOF is accessible at: https://www.wipo.int/wipoproof/en.

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UP & UPC
UK withdraws ratification of UPC Agreement

In a move which appears to run counter to the German Government's intention to bring the Unified Patent Court (UPC) system into effect, the UK Government announced, on Monday 20 July 2020, by way of diplomatic memorandum, that the UK has withdrawn its ratification of the UPC Agreement (UPCA) with immediate effect.

A statement by Amanda Solloway, Under Secretary of State in the UK Parliament, indicated that since the UK has withdrawn from the European Union, the UK no longer wishes to be a party to the Unified Patent Court systems, because participating would mean that the UK would be bound by decisions by the CJEU and a court which applies EU law.

> The reason given for the withdrawal now was that, although not yet in force, the UK's withdrawal from the UPC will ensure clarity regarding the UK's status and to facilitate the orderly entry into force of the UPC for other states, without the UK's participation.

The UK's position contrasts with attempts by the German Government to bring the UPC into effect by the Bundestag voting to ratify the UPC, which may happen later in 2020.

According to its decision in March 2020, the German Federal Constitutional Court indicated that although member states of the UPC have to be member states of the European Union, ratification by Germany would mean that the UPC could come into force because the UK had ratified the UPC.

Ratification by Germany would mean that the conditions required for the UPC to come into effect would be satisfied, regardless of the UK's subsequent actions.

Although the relevant article of the UPC (Article 89 of EU Regulation No 1257/2012) does not explicitly mention the UK, the condition for the UPC coming into effect requires that at least thirteen states ratify the UPC, including three member states in which the highest number of European patents had effect in 2012, which were the UK, Germany and France.

The withdrawal now of the UK appears to cast doubt on whether the current form of the UPC can come into force without amendment of the UPC Agreement.

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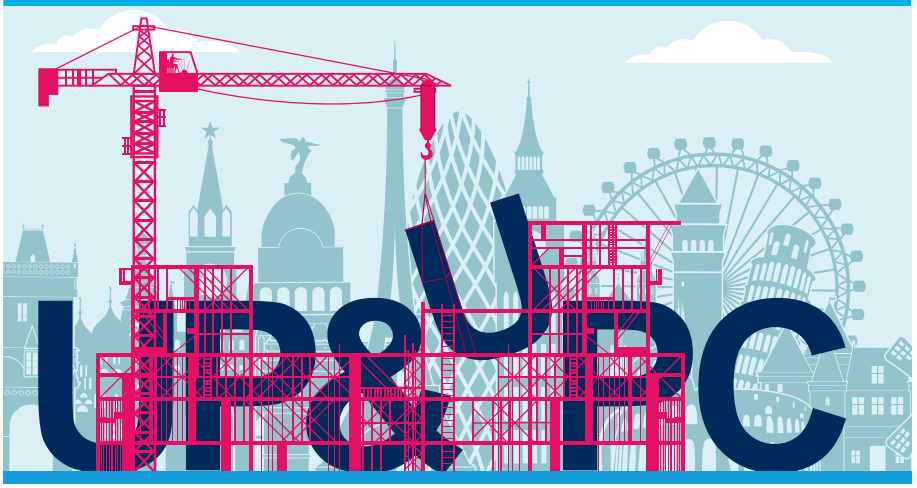

Santen (C-673/18)
CJEU takes a restrictive view on "first authorisation" for new therapeutic applications

In July 2020, the CJEU handed down its eagerly anticipated decision concerning the question of whether applicants can be granted an SPC based on a "second medical use" patent and a marketing authorisation for a new therapeutic application of a medicinal product previously authorised for a different application. This decision clears up a great deal of uncertainty in the interpretation of Article 3(d) of the EU medicines SPC Regulation (469/2009) that has raged since the CJEU's earlier decision in Neurim (C-130/11), although perhaps not in the way some in the pharmaceutical industry may have hoped.

SPCs extend the term of patents for medicinal and plant protection products in Europe which have been granted a marketing authorisation (MA). However, Article 3(d) of the SPC Regulation requires that the MA is the "first authorisation to place the product on the market as a medicinal product". This decision addresses the issue of whether an MA can be considered to be the "first authorisation" if it is directed to a new therapeutic application of an active ingredient that has previously been authorised for a different therapeutic use.

Brief history leading to uncertainty

As noted above, Article 3(d) requires that the MA relied upon must be the first authorisation to place the product on the market. Article 1(b) of the SPC Regulation defines the "product" as the active ingredient or combination of active ingredients of a medicinal product. Therefore, a literal reading of the Regulation would appear to forbid an SPC for a medicinal product based on a new MA for a product previously authorised for another therapeutic use because the product is defined in the Regulation as referring to the active ingredient itself rather than including in its definition the indication. Early CJEU case law appeared to confirm this, with decisions such as Pharmacia Italia (C-31/03) and Yissum (C-202/05) stipulating that the concept of "product" cannot include the therapeutic use of an active ingredient.

However, in its decision in Neurim (C-130/11), the CJEU, perhaps surprisingly, allowed an SPC based on a second medical use patent and an MA which fell within the scope of that patent, despite the existence of an earlier MA for a veterinary use of the same product. The basis for its decision in Neurim was predominantly concerned with ensuring that the fundamental objective of the SPC Regulation – to provide sufficient protection to encourage pharmaceutical research – was achieved. The CJEU therefore did not focus on the literal wording of the Regulation when reaching the decision in Neurim, but rather took a teleological approach to interpreting the provisions to protect the aims and objectives of the Regulation.

Since Neurim, there has been much uncertainty as to whether the principles must be limited to the facts of Neurim (for example, veterinary v human application), or whether they can be applied more widely to allow SPCs for any new therapeutic applications (or even different formulations, dosages and methods of administration) of previously authorised products.

Summary of decision

In this case, Santen had applied for an SPC in France based on a European patent claiming an ophthalmic emulsion in which the active ingredient is cyclosporine. In its application, Santen referred to the MA it had been granted in 2015 for the product "Ikervis" whose active ingredient is cyclosporine. The MA was granted for the use of Ikervis in treating severe keratitis. At first instance, the French Patent Office rejected the SPC application on the basis that the MA for Ikervis was not the "first authorisation" to have been granted for the product, citing an MA that had been granted back in 1983 for a product called "Sandimmun" for preventing rejection of transplants; the active ingredient in Sandimmun was also cyclosporine.

Santen appealed against this decision to the French Court of Appeal, citing Neurim. The Court of Appeal subsequently referred the matter to the CJEU, asking questions that sought to clarify how far-reaching the decision in Neurim is for the interpretation of Article 3(d).

In contrast to Neurim, the CJEU in Santen started with a consideration of the meaning of the term "product". In particular, it first considered whether a new therapeutic application of an active ingredient may be considered as being a product distinct from another already known application of the same active ingredient. Based on the definition in Article 1(b), the CJEU held that the notion of "product" does not depend on the way in which the product is used, thus agreeing with the earlier CJEU decisions in Pharmacia and Yissum.

It then considered whether an MA granted for a new therapeutic application of an active ingredient may be regarded as being the first MA within the meaning of Article 3(d) where that MA is the first MA to fall within the scope of protection of the basic patent invoked. The CJEU noted that Article 3(d) does not refer to the scope of protection of the basic patent: if it were to be taken into consideration, this would also call into question the "strict definition of the notion of "product", within the meaning of Article 1(b)".

The CJEU therefore departed from the Neurim decision and held that the scope of the basic patent was irrelevant in determining whether Article 3(d) was met. In fact, the CJEU went as far as to entirely dismiss the premise a:rising from Neurim that it may be possible to obtain an SPC for a new therapeutic application of a previously authorised active ingredient.

Reasons

At the heart of this decision is the strict interpretation given to the meaning of the term "product" in Article 1(b). The CJEU concluded that this narrower interpretation fulfils the objectives of the SPC Regulation by balancing the encouragement of pharmaceutical research with the interests of public health. The CJEU also factored into its decision that a wider interpretation would compromise the simplicity of the SPC system and lead to divergent decisions from national patent offices. It has long been accepted that a "teleological" interpretation of the SPC Regulation – an interpretation in line with

Related webinar

Our June 2020 SPC webinar is now available on demand from our website webinar library. Partner Garreth Duncan discusses case C-650/17 from the EU Court of Justice, which will have a significant impact on SPCs in Europe in the future.

See: https://dycip.com/spc-jun-2020

At the heart of the Santen decision is the strict interpretation to the meaning of "product"

the aims and objectives of the Regulation – is to be applied. In Santen, the CJEU seemingly reconciled a literal interpretation of the Regulation with a teleological interpretation in this particular instance.

Emphasis was placed in the decision on point 11 of the Explanatory Memorandum for the proposed SPC Regulation (1990) to support the CJEU's view that a wider interpretation would run counter to the Regulation's objectives. This point 11 indicates that the Regulation should not involve granting a certificate for all medicinal products that are authorised to be placed on the market, and that only one certificate may be granted for any one product with a product being understood to mean an active substance "in the strict sense".

Of interest is the CJEU's reference to point 12 of the Memorandum, which states: "the proposal is not confined to new products only. A … new application of the product may also be protected by a certificate. All research, whatever the strategy or final result, must be given sufficient protection".

Whilst this paragraph could be interpreted in a number of different ways, the CJEU commented that the narrow interpretation of "product" was not called into question by this paragraph. Indeed, it noted that it is still possible to obtain an SPC for a new application of a known product if that product has not been authorised in an earlier MA (i.e. a second medical use patent may still also serve as the basic patent for an SPC).

It is also interesting to note the difference in reasoning between the CJEU in Neurim and Santen regarding the interpretation of the Memorandum:

- In Neurim, the CJEU adopted a wider interpretation based on the statement made in point 29 of the Memorandum that "all pharmaceutical research, provided that it leads to a new invention that can be patented, whether it concerns … a new application of a new or known product …, must be encouraged, without any discrimination". In its Neurim decision, the CJEU therefore placed more weight on the encouragement of all pharmaceutical research.

- Conversely, the CJEU in its Santen decision took an interpretation that balances more evenly the encouragement of pharmaceutical research and the interests of public health. In this regard, the CJEU opined that the Memorandum makes it clear that the purpose of SPC Regulation is not to promote protection of **any** pharmaceutical research, but rather to promote that which leads to the **first placement** of a product on the market.

The CJEU's decision in Santen was thus unequivocal in ruling out the possibility of obtaining an SPC for a new therapeutic application of a previously authorised product. If it were the intention of the legislator to allow such SPC protection, then this could perhaps still be achieved through a change in the legislation itself.

Implications & take-home message

The CJEU's decision in Santen has provided some much-needed clarity on the interpretation of Article 3(d). However, it may cause concern amongst some practitioners that the distinction between the term of protection that may be restored by an SPC for an entirely new (unauthorised) product and that for a previously authorised product may disincentivise research into new uses of previously authorised products.

In terms of practical implications, the take-home message should of course be that it will not be possible to have an SPC granted based on an MA that is directed to a new therapeutic application of an active ingredient (or combination of active ingredients) that has already been the subject of an earlier MA directed to a different application. However, that is not to say that a second medical use patent cannot serve as the "basic patent" for an SPC. An MA granted for a new indication or application within the scope of the second medical use patent may be the "first MA" within Article 3(d) if the product has never before been the subject of an MA. Indeed, many instances can be envisaged where products have been disclosed (perhaps in earlier patent filings), but which have never gone on to be authorised for any other use prior to the authorisation being relied upon within the scope of the later-filed second medical use patent.

The key question to consider when devising any SPC filing strategy must therefore be whether the active ingredient (or combination of active ingredients) has ever before been the subject of an MA for any therapeutic application.

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And finally...

D Young & Co news

Wir ziehen um!
Our new Munich office

D Young & Co LLP - London, Munich, Southampton

In response to the year-on-year growth of our flourishing Munich-based IP team, we are delighted to give our regular newsletter readers advanced notice that this team will soon be moving (wir ziehen um) to more spacious and permanent office premises.

In the heart of Munich, our new office is situated on Rosental, between Rindermarkt and Viktualienmarkt. Due to the proximity of Marienplatz and Sendlinger Tor we will enjoy excellent transport connections and will be within easy walking distance of the European Patent Office as well as a variety of banks, hotels and restaurants.

We are currently in the final stages of fitting out the office space and expect to announce our official opening and share details of our new Munich office address, fax and telephone numbers in the early Autumn.

We look forward to welcoming visiting clients and colleagues to our new office space and wish our Munich team every success in their new office.

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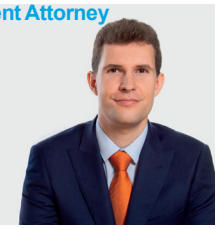

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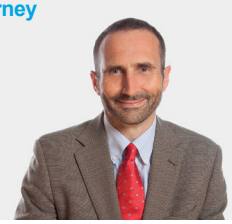

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