O-482-16

PUBLIC VERSION OF DECISION

TRADE MARKS ACT 1994

CONSOLIDATED PROCEEDINGS IN THE MATTER OF:

(1) TRADE MARK APPLICATION 3087417
BY ACRE PHARMA LIMITED
TO REGISTER THE FOLLOWING SERIES OF TRADE MARKS IN CLASS 5:

DECADRON

&

Decadron

AND OPPOSITION THERETO (NO. 404042) BY CHEMIDEX PHARMA LIMITED

AND

(2) TRADE MARK REGISTRATION 777861
IN THE NAME OF CHEMIDEX PHARMA LIMITED
IN RESPECT OF THE FOLLOWING MARK IN CLASS 5:

DECADRON

AND AN APPLICATION TO REVOKE ON THE GROUNDS OF NON-USE
(NO.500722) BY ACRE PHARMA LIMITED

Background and pleadings

1. Acre Pharma Limited ("Acre") applied to register the series of marks **DECADRON** and **Decadron** on 24 December 2014. They were published for opposition purposes on 23 January 2015 for the following goods:

Class 5: Pharmaceutical preparations and substances.

2. The mark is opposed by Chemidex Pharma Limited ("Chemidex"). It is the owner of UK registration 777861 which was filed on 20 May 1958 and which consists of the word **DECADRON.** It is registered for the following goods:

Class 5: Pharmaceutical preparations containing hormones.

3. Chemidex rely on its earlier mark to found grounds of opposition under sections 5(1) and 5(2)(a) of the Trade Marks Act 1994 ("the Act").

4. Acre filed a counterstatement. It accepts that sections 5(1)/5(2)(a) "would seem to be applicable", but it highlights the provisions of section 6A of the Act which stipulate that earlier marks which have been registered for five years or more (measured at the time the opposed mark was published) can only be relied upon if they have been genuinely used, or to the extent that they have been genuinely used. Acre put Chemidex to proof that genuine use has been made. It also made an application to revoke Chemidex's registration on the grounds of non-use.

5. Chemidex filed a counterstatement in relation to the revocation, claiming that its mark has been genuinely used. It was accompanied by evidence to which I will return.

6. Both sides are professionally represented, Chemidex by Withers & Rogers, Acre by Mewburn Ellis. Both sides filed evidence. A hearing took place before me on 21 September 2016 at which Chemidex were represented by Ms Amanda Michaels, of Counsel, instructed by Withers & Rogers and Acre by Mr Stephen Hodsdon of Mewburn Ellis.

7. Both sides accepted at the hearing that it was the genuine use issue that was paramount in these consolidated proceedings. If the mark survives the proof of use/revocation assessment then the opposition to the registration of Acre's application will succeed. This is a sensible basis on which to approach the matter.

Genuine use

Legislation and leading case-law

8. In revocation proceedings, section 46(1) of the Act is relevant:

> "The registration of a trade mark may be revoked on any of the following grounds-
>
> > (a) that within the period of five years following the date of completion of the registration procedure it has not been put to genuine use in the United Kingdom, by the proprietor or with his consent, in relation to the goods or services for which it is registered, and there are no proper reasons for non-use;
> >
> > (b) that such use has been suspended for an uninterrupted period of five years, and there are no proper reasons for non-use;
> >
> > (c).....
> >
> > (d).....
>
> (2) For the purpose of subsection (1) use of a trade mark includes use in a form differing in elements which do not alter the distinctive character of the mark in the form in which it was registered, and use in the United Kingdom includes affixing the trade mark to goods or to the packaging of goods in the United Kingdom solely for export purposes.

(3) The registration of a trade mark shall not be revoked on the ground mentioned in subsection (1)(a) or (b) if such use as is referred to in that paragraph is commenced or resumed after the expiry of the five year period and before the application for revocation is made: Provided that, any such commencement or resumption of use after the expiry of the five year period but within the period of three months before the making of the application shall be disregarded unless preparations for the commencement or resumption began before the proprietor became aware that the application might be made.

(4) ……..

(5) Where grounds for revocation exist in respect of only some of the goods or services for which the trade mark is registered, revocation shall relate to those goods or services only.

6) Where the registration of a trade mark is revoked to any extent, the rights of the proprietor shall be deemed to have ceased to that extent as from –

(a) the date of the application for revocation, or

(b) if the registrar or court is satisfied that the grounds for revocation existed at an earlier date, that date."

9. For the opposition proof of use, section 6A is relevant:

"(3) The use conditions are met if –

(a) within the period of five years ending with the date of publication of the application the earlier trade mark has been put to genuine use in the United Kingdom by the proprietor or with his consent in relation to the goods or services for which it is registered [.....]"

(4) For these purposes -

(a) use of a trade mark includes use in a form differing in elements which do not alter the distinctive character of the mark in the form in which it was registered [.....]

(5) ….."

10. Section 100 is relevant to both matters; it reads:

"If in any civil proceedings under this Act a question arises as to the use to which a registered trade mark has been put, it is for the proprietor to show what use has been made of it."

11. In *The London Taxi Corporation Limited v Frazer-Nash Research Limited & Anor,* [2016] EWHC 52, Arnold J. summarised the case-law on genuine use of trade marks:

"217. In *Stichting BDO v BDO Unibank Inc* [2013] EWHC 418 (Ch), [2013] FSR 35 I set out at [51] a helpful summary by Anna Carboni sitting as the Appointed Person in *SANT AMBROEUS Trade Mark* [2010] RPC 28 at [42] of the jurisprudence of the CJEU in Case C-40/01 *Ansul BV v Ajax Brandbeveiliging BV* [2003] ECR I-2439, Case C-259/02 *La Mer Technology Inc v Laboratories Goemar SA* [2004] ECR I-1159 and Case C-495/07 *Silberquelle GmbH v Maselli-Strickmode GmbH* [2009] ECR I-2759 (to which I added references to Case C-416/04 P *Sunrider Corp* v *Office for Harmonisation in the Internal Market (Trade Marks and Designs)* [2006] ECR I-4237). I also referred at [52] to the judgment of the CJEU in Case C-149/11 *Leno Merken BV v Hagelkruis Beheer BV* [EU:C:2012:816], [2013] ETMR 16 on the question of the territorial extent of the use. Since then the CJEU has issued a reasoned Order in Case C-141/13 *P Reber Holding & Co KG v Office for Harmonisation in the Internal Market (Trade Marks and Designs)* [EU:C:2014:2089] and that Order has been persuasively analysed by Professor Ruth Annand sitting as the Appointed Person in *SdS InvestCorp AG v Memory Opticians Ltd* (O/528/15).

[218] …

219. I would now summarise the principles for the assessment of whether there has been genuine use of a trade mark established by the case law of the Court of Justice, which also includes Case C-442/07 *Verein Radetsky-Order v Bundervsvereinigung Kamaradschaft 'Feldmarschall Radetsky'* [2008] ECR I-9223 and Case C-609/11 *Centrotherm Systemtechnik GmbH v Centrotherm Clean Solutions GmbH & Co KG* [EU:C:2013:592], [2014] ETMR 7, as follows:

(1) Genuine use means actual use of the trade mark by the proprietor or by a third party with authority to use the mark: *Ansul* at [35] and [37].

(2) The use must be more than merely token, that is to say, serving solely to preserve the rights conferred by the registration of the mark: *Ansul* at [36]; *Sunrider* at [70]; *Verein* at [13]; *Centrotherm* at [71]; *Leno* at [29].

(3) The use must be consistent with the essential function of a trade mark, which is to guarantee the identity of the origin of the goods or services to the consumer or end user by enabling him to distinguish the goods or services from others which have another origin: *Ansul* at [36]; *Sunrider* at [70]; *Verein* at [13]; *Silberquelle* at [17]; *Centrotherm* at [71]; *Leno* at [29].

(4) Use of the mark must relate to goods or services which are already marketed or which are about to be marketed and for which preparations to secure customers are under way, particularly in the form of advertising campaigns: *Ansul* at [37]. Internal use by the proprietor does not suffice: *Ansul* at [37]; *Verein* at [14]. Nor does the distribution of promotional items as a reward for the purchase of other goods and to encourage the sale of the latter: *Silberquelle* at [20]-[21]. But use by a non-profit making association can constitute genuine use: *Verein* at [16]-[23].

(5) The use must be by way of real commercial exploitation of the mark on the market for the relevant goods or services, that is to say, use in accordance with the commercial *raison d'être* of the mark, which is to create or preserve an outlet for the goods or services that bear the mark: *Ansul* at [37]-[38]; *Verein* at [14]; *Silberquelle* at [18]; *Centrotherm* at [71].

(6) All the relevant facts and circumstances must be taken into account in determining whether there is real commercial exploitation of the mark, including: (a) whether such use is viewed as warranted in the economic sector concerned to maintain or create a share in the market for the goods and services in question; (b) the nature of the goods or services; (c) the characteristics of the market concerned; (d) the scale and frequency of use of the mark; (e) whether the mark is used for the purpose of marketing all the goods and services covered by the mark or just some of them; (f) the evidence that the proprietor is able to provide; and (g) the territorial extent of the use: *Ansul* at [38] and [39]; *La Mer* at [22]-[23]; *Sunrider* at [70]-[71], [76]; *Centrotherm* at [72]-[76]; *Reber* at [29], [32]-[34]; *Leno* at [29]-[30], [56].

(7) Use of the mark need not always be quantitatively significant for it to be deemed genuine. Even minimal use may qualify as genuine use if it is deemed to be justified in the economic sector concerned for the purpose of creating or preserving market share for the relevant goods or services. For example, use of the mark by a single client which imports the relevant goods can be sufficient to demonstrate that such use is genuine, if it appears that the import operation has a genuine commercial justification for the proprietor. Thus there is no *de minimis* rule: *Ansul* at [39]; *La Mer* at [21], [24] and [25]; *Sunrider* at [72]; *Leno* at [55].

(8) It is not the case that every proven commercial use of the mark may automatically be deemed to constitute genuine use: *Reber* at [32].”

12. In *Reber Holding GmbH & Co. KG v Office for Harmonisation in the Internal Market (Trade Marks and Designs)* (OHIM), Case T-355/09, the General Court found that the sale of 40-60Kg per annum of specialist chocolate under a mark was insufficient to constitute genuine use of a national trade mark, which was registered in Germany. On further appeal in Case C-141/13 P, the CJEU stated, at paragraph 32 of its judgment, that:

“not every proven commercial use may automatically be deemed to constitute genuine use of the trade mark in question”. (paragraph of the judgment).

13. The CJEU found that:

> "the General Court conducted an overall assessment of that trade mark, taking into account the volume of sales of the goods protected by the trade mark, the nature and characteristics of those goods, the geographical coverage of the use of the trade mark, the advertising on the website of Paul Reber GmbH & Co. KG and the continuity of the trade mark's use. It thus established a certain degree of interdependence between the factors capable of proving genuine use. The General Court therefore correctly applied the concept of 'genuine use' and did not err in law in its assessment of that use" (paragraph 34 of the judgment CJEU).

14. Proven use of a mark which fails to establish that "*the commercial exploitation of the mark is real"* because the use would not be *"viewed as warranted in the economic sector concerned to maintain or create a share in the market for the goods or services protected by the mark"* is, therefore, not genuine use.

The relevant periods

15. The relevant period for the opposition proof of use is: 24 January 2010 to 23 January 2015.

16. The relevant period for the revocation proceedings, which are based on section 46(1)(b) only, is: 23 December 2009 to 22 December 2014.

The evidence

Chemidex's primary evidence

Dr Engineer's first witness statement – filed with Chemidex's counterstatement

17. Dr Engineer is a director at Chemidex. He explains that Chemidex specialise in the licensing and marketing of prescription pharmaceuticals, DECADRON being one such product. He provides Exhibit DE1 which contains a document issued by the NHS

entitled “Prescription Cost Analysis England 2010”. The title of the document is self-explanatory. In a table within this document, prescription data for Decadron is provided. In a column marked “Prescription Items Dispensed [PXS] (thousands)” the relevant entry is “0.1” and in a column marked “Quantity [QTY] (thousands)” the relevant entry is “4.0”. Dr Engineer states that 133 individual prescriptions were issued for a quantity of 4042 Decadron tablets in England in 2010. The table itself does not show those exact figures, but it was accepted by both sides that the table provided had been rounded down and that other evidence confirms the exact numbers given by Dr Engineer. When referring to the prescriptions, Dr Engineer states that they “are in respect of goods bearing the registration”.

18. Dr Engineer also provides Exhibit DE2, which contains data originating from an organisation called IMS Health who, according to Dr Engineer, are the world’s largest pharmaceutical data house. The document appears to be a filterable/searchable spreadsheet headed IMS DataView. It has two entries for Decadron headed UN/MAT/12/11 and UN/MAT/12/12 containing the numbers 103 and 56 respectively. Dr Engineer states that this relates to 2011 and 2012 pharmaceutical goods bearing the registration being bought and sold in the UK.

Ms Clark’s witness statement - filed with Chemidex’s counterstatement

19. Ms Clark is a trade mark attorney at Withers & Rogers. She explains that DECADRON is a type of dexamethasone tablet. Exhibit TC1 contains an assessment report on dexamethasone issued by The Medicines and Healthcare Products Regulatory Agency (“MHRA”). The document was last updated in January 2015. The drug is authorised for use in the UK and can treat, amongst other conditions, rheumatoid arthritis, allergic reactions, intestinal disorders, asthma and blood disorders. It is a steroid product. The report states that:

> “Dexamethasone 500 microgram Tablets are a “generic” medicine. This means that Dexamethasone 500 microgram Tablets are similar to a reference medicine already authorised in the UK called Dexamethasone 500 microgram Tablets, previously known as Decadron 500 mcg Tablets (PL 17736/0119; Chemidex Pharma Limited trading as Essential Generics, UK), which was

> authorised in the UK following a change of ownership procedure of Decadron 500 mcg Tablets (PL 00025/5046R; Merck, Sharp and Dohme Limited, UK) on 2 March 2009. Decadron 500 mcg Tablets (PL 00025/5046R; Merck, Sharp and Dohme Limited, UK) was granted a Product License in the UK on 11 February 1987. This product was the subject of a Product License of Right (PLR); because Decadron 500 mcg Tablets were on the market before the Medicines Act 1968 came into force in 1971"

20. The report about the generic medicine detailed above appears to relate to a marketing authorisation holder called Trotwood Pharma Limited. Thus, the chronology appears to be that the drug was on the market prior to 1971 as DECADRON. From 1987 it (DECADRON) was marketed (or at least a marketing authorisation was in place) by Merck, Sharp and Dohme Limited ("Merck") under a PLR. The DECADRON brand then changed hands on 2 March 2009 with the new owner being Chemidex who obtained its own marketing authorisation. At some unspecified point, the name of the DECADRON medicine was changed to Dexamethasone, presumably by Chemidex. This is based on the reference in the report to a "…reference medicine already authorised in the UK called Dexamethasone 500 microgram Tablets, previously known as Decadron 500 mcg Tablets" (my emphasis). Subsequently, a generic version of Dexamethasone was also marketed (or at least a marketing authorisation was in force) by Trotwood.

21. Ms Clark gives information about IMS Health. She also claims that it is the world's largest pharmaceutical data house. She states that the document provided by Dr Engineer is a report generated from IMS's DataView software platform which is available by subscription and which provides information relating to the prescription of pharmaceuticals. There is little else by way of fact in Ms Clark's witness statement.

Dr Engineer's second witness statement – filed during the evidence rounds

22. Dr Engineer explains that Chemidex specialise in what he describes as "legacy" pharmaceuticals, which relates to the sale of patent expired pharmaceuticals. He explains that whilst it is normal for the sale of branded pharmaceuticals to fall away

once its patent expires (due to the availability of generic equivalents of the particular drug), there is still a demand for the sale of…

> "..legacy branded products as some doctors will continue to prescribe the product by reference to its branded name and some patients will wish to have and ask for the branded product".

23. Dr Engineer states that Chemidex specialise in such legacy products because it sees a benefit in being able to sell products under the legacy brand name in addition to selling the generically named pharmaceutical, as this maximises market share. Chemidex has purchased a number of pharmaceutical brand names from their original owners after patent protection has expired. Decadron is an example of this and Dr Engineer states that Chemidex has at all times sought to maintain and build upon the legacy of the Decadron brand.

24. Information about the pharmaceutical itself is given, with Dr Engineer explaining that it is synthetic steroid hormone in the corticosteroid group and is used for a range of illnesses. Reference is made to Ms Clark's Exhibit TC1.

25. Dr Engineer explains that although the drug is a corticosteroid, it is not necessarily interchangeable with other corticosteroids. It appears that the drug has a specific application for high-dose therapy where fluid retention would be a disadvantage e.g. where a patient has swelling or raised pressure inside the brain due to a tumour, and it is also useful in treating inherited genetic conditions which cause swelling of the adrenal glands. He considers its core clinical application to be restricted to a very small number of specific conditions where other corticosteroids are not suitable; Dr Engineer considers the market for the drug to be very small.

26. Dr Engineer states that sales of Decadron (as a brand) have probably averaged 1% or less of the market for the drug, but he still considers this to constitute genuine use and that such use will act as a base for future exploitation. In terms of reaching the market, Chemidex use what he describes as a "pre-wholesaler" called Movianto who distribute the goods (essentially on demand) to other healthcare wholesalers. Customers are mainly community and hospital pharmacies. The sales mentioned in

his first witness statement would, Dr Engineer explains, have been released to the wholesaler by Movianto on Chemidex's behalf. The shelf life of the product increased from 6 months in 2009 to one year in February 2010 to two years in September 2010. Dr Engineer states that in consequence of this, supplies to patients after July 2010 must have been manufactured from January 2010 onwards, supplies after February 2011 could not have been manufactured before September 2010 and, therefore, the product was not just sold during the relevant period but was also manufactured.

27. Exhibit DNE3 contains a "to whom it may concern" letter from Movianto dated 19 August 2015 in which it is confirmed that "….it has taken delivery of Decadron (Dexamethasone) tablets 500mcg during the 2010 to 2012 period".

Acre's evidence

Dr Dally's witness statement

28. Dr Dally is a director (of business intelligence and clinical affairs) at Acre. Part of his evidence has been granted confidentiality consisting, as it does, of further data provided by IMS Health which was provided to him upon condition of non-disclosure. Such confidential material will be redacted from the public version of this decision. The relevance of this evidence is that the IMS Health data he obtained appears to conflict with the IMS Health data provided by Dr Engineer. Both sets of data cover the 2011/2012 period. He also provides evidence with a view to countering Chemidex's claimed use in 2010. I will start there.

The 2010 use

29. Exhibit JD1 contains a document from the MHRA entitled "Best Practice Guidance on the Labelling and Packaging of Medicines". Dr Dally highlights section 4.2.1 which is headed "Name of the medicine". It is stated in this document that:

> "The name that is registered in the summary of the product characteristics (SPC) must be used on all packaging components."

30. Dr Dally states that a Freedom of Information ("FOI") request was submitted to the MHRA relating to all of the approved and published versions of SPCs for Dexamethasone 500 microgram tablets between March 2009 and December 2014 (product license PL17736/0019). The results of the FOI are provided in Exhibit JD2, which contains a number of SPCs, all of which identify Chemidex as the authorisation marketing holder. The product license number on all of them is PL17736/0019, a number which matches the product license number of what was described as the reference medicine dexamethasone ("previously known as Decadron") referred to in the information about the generic dexamethasone which I summarised at paragraph 19 above. The SPCs are as follows:

- The first is for the medicine "DECADRON® Tablets" with the SPC stating (in relation to this and all the subsequent SPCs) that the medicine was first authorised in 1977 with a renewal in 2007. The document carries a revision date of 28 February 2009.

- The second is also for DECADRON® Tablets. The document carries a date of revision of "March 2009" [no day is listed]. Dr Dally states that his understanding is that if a day is not specified then the document is a draft not a final SPC. On the cover sheet for this SPC it is stated (presumably by the witness) that this SPC was confirmed by the MHRA as having been superseded by the next two SPCs mentioned.

- The third is for the medicine Dexamethasone 500 microgram tablets. It carries a revision date of 2 March 2009.

- The fourth is also for the medicine Dexamethasone 500 microgram tablets. It also carries a revision date of 2 March 2009. Neither counsel identified any difference between this SPC and the preceding one.

- The fifth is also for the medicine Dexamethasone 500 microgram tablets. It carries a revision date of 21 May 2012.

- The sixth is also for Dexamethasone 500 microgram tablets. It also carries a revision date of 21 May 2012.

- The seventh is also for Dexamethasone 500 microgram tablets. It also carries a revision date of 21 May 2012.

- The eighth is for Dexamethasone 500 microgram Tablets [note the capitalisation of the letter T in tablets]. It carries a revision date of 22 March 2013. On the cover sheet to this SPC it is stated (presumably by the witness) that this is the current SPC.

31. Dr Dally's point is that whilst there was an SPC for Decadron as of 28 February 2009, those dated on or after 2 March 2009 (excluding the second SPC which he says is a draft) are for Dexamethasone.

32. Exhibit JD3 contains data from the relevant English, Scottish, Welsh and Northern Irish authorities showing that Decadron is not listed in the respective Prescription Cost Analysis between 2009 and 2015 other than the 2010 analysis for England provided by Dr Engineer. Dr Dally states that of the 133 prescriptions out of around 29,700 prescriptions for dexamethasone, some or possibly all may not be of UK origin. This assumption is based on the fact that from March 2009 there was no UK SPC for Decadron (only dexamethasone) and that to meet Articles 54 and 55 of EC Council Directive 2001/83/EEC the product licence holder is obliged to identify the name of the product shown in the SPC.

33. Dr Dally goes on to state that in 2009 there was a shortage of dexamethasone and that because Chemidex was the only UK approved marketing authorisation holder, the NHS needed to source non-UK licensed versions from the EU and other international markets. An extract from the website of the Society for Endocrinology supports that there was some form of delay in the availability of dexamethasone from Chemidex at the end of 2009. The document also notes the initial availability of dexamethasone (no mention is made of Decadron) from Chemidex as of March 2009, presumably after it had taken on its product license. Documents from August 2009 issued by the MHRA are also provided which refer to recalls of dexamethasone by Chemidex.

34. Exhibit JD7 is described as an extract of a list of products which the MHRA granted permission to import as an unlicensed (in the UK) product in 2009 – 3 dexamethasone products are identified under the brand name Decadron. Dr Dally states that this was almost certainly in response to the shortage of Chemidex's dexamethasone. It was accepted at the hearing by Mr Hodsdon that this does not show that the medicines were actually imported, only that they could have been.

35. Dr Dally accepts in his witness statement that the above import list does not identify the source of the Decadron. However, he states that Decadron is still sold under national licenses in Italy and Portugal by two different companies that as far as he knows have no links to Chemidex. He provides details of those two companies, highlighting, also, that on the list of import permissions, one of the Decadron products is sold in packs of 10, matching the pack size produced by the Italian company. MD8 and MD8A contain the packaging used by these companies and their respective overseas trade mark registrations.

36. Dr Dally states that information from the MHRA has also confirmed that no import permissions were given for 2010 or 2011. The relevant portions of the import database (showing no entries) is provided in Exhibit JD9.

The 2011/2012 use

37. Exhibit JD10 contains extracts from the trade publication Chemist & Druggist ("C&D") from November 2011, September 2012, March 2013 and November 2014. This trade publication lists goods sold through pharmacies including pharmaceuticals. The extracts show an absence of Decadron where is would have been listed. Dexamethasone is, however, listed. The entry for the supplier Chemidex does not list Decadron.

38. Exhibit JD11 contains various extracts from another trade publication called the British National Formulary ("BNF") from March and September 2009, March 2010, September 2011 and seven further extracts. The common theme is that Decadron is not listed, although dexamethasone is.

39. Exhibit JD12 contains a further extract from the BNF, this time from March 2004. This shows an entry for dexamethasone showing its availability under the name Decadron from Merck who were the owners at this point. Dr Dally states that if Decadron had been used in 2009 (or later) this is how the respective entries would have looked, albeit with reference to Chemidex rather than Merck. Exhibit JD13 contains an extract from the Pharmaceutical Society website dating from 2004 explaining that Decadron had been discontinued by its then owner.

40. Dr Dally then deals with the "to whom it may concern" letter from Movianto, Inc. (my emphasis). The letter is signed by Thaddeus O MacKrell, "Vice President of Movianto (an Owens and Minor Company)". Dr Dally states that there is no mention in this person's LinkedIn profile (Exhibit JD14) of him having any position at Movianto (although it does mention Owens & Minor). He acknowledges, though, that Owens & Minor acquired the Movianto group in September 2012. Exhibits JD15-19 are various documents relating to the acquisition of Movianto, showing that it is a European business. The evidence culminates with an extract from the annual report of Owens & Minor in which it appears that Movianto subsidiary companies are European based as none have Inc. in their names. The point of all this, I think, is to cast doubt on the validly of the letter because it is signed by someone who works for a US corporation which does not have any apparent link with the European business which took over the Movianto Group.

41. The final aspect of Dr Dally's evidence comes in the form of witness statement and accompanying Exhibit MD20 which has been granted confidentiality. The evidence constitutes data Dr Dally obtained after asking IMS Health for information concerning Decadron and generic dexamethasone. [redacted].

Chemidex's evidence in reply

Third witness statement of Dr Engineer

42. Dr Engineer comments upon the various SPCs in Dr Dally's evidence. He explains that SPCs provide information to healthcare professionals on how to use the medicine. Updates must be approved by the MHRA. He highlights that the MHRA Guidelines in Dr Dally's evidence did not came into force until July 2012 and, so, were not in force during the first half of the relevant periods which is when the use was made. He states that no explanation has been provided to explain why multiple SPCs have been provided with the same revision dates. He questions Dr Dally's understanding regarding the absence of a day within a revision date (Dr Dally considered this to indicate that it was a draft). Dr Engineer provides copies of emails between a representative of Chemidex and a representative of the MHRA where it is asked whether the absence of a day on a SPC revision date is indicative of it being a draft. In summary, the answer is that it is not and may just have been how the date was transcribed by the relevant person at the MHRA. More recently, the system has been automated to require a day to be entered, but this was not in place when the SPC in question was revised. Dr Engineer states that if the MHRA's suggestion that the second SPC was superseded by the third and fourth then, clearly, the second SPC must have been more than a draft. Dr Engineer contends that the contents of the various SPCs do not assist at least until the time when the SPCs from May 2012 were introduced.

43. Dr Engineer refers again to the shelf life of the products. He explains that this led to some problems with the supply of the medicine due to stability issues. He disagrees with Dr Dally's suggestion that this ultimately led to the importation of non[UK]-licenced Decadron from overseas. Whilst he accepts that problems arose, he explains that part batches with a reduced shelf life could still be provided. Various emails from the relevant time between Chemidex and its manufacturer (Dales Pharma) and, also, with MHRA, support this. However, it is noteworthy that there is not a single mention of Decadron in any of the exchanges – only Dexamethasone is referred to.

44. Dr Engineer refutes the allegation that the sales in the data he provided could have been imported Decadron. He confirms that the Portuguese and Italian companies referred to by Dr Dally have no relationship with Chemidex. However, he states that whilst there were supply problems, as explained already, some batches of Chemidex's Decadron was released. In the document provided by Dr Dally concerning the supply issues, reference is made to seeking generic dexamethasone from Canada, but Dr Engineer states that this is not relevant and that if anything came from Canada it would have its own entry in the import list [presumably for dexamethasone].

45. Dr Engineer goes onto explain that for any generic or branded product to be imported, the importer would still have to obtain a license from the MHRA. The list provided by Mr Dally reflects what he says are applications to import under what he describes as a "special licence", not that any importation actually took place. He further explains that importation of medicines can be done in one of two ways, as a "special" or as a parallel import. To import as the former, a specials license must be obtained and this is only permitted in the strictest of circumstances. He says that to parallel import a product that is already on the market, the process is totally different from the MHRA notification procedure. He states that Mr Dally's document does not show that a licence was granted or any goods imported. In any event, Dr Engineer highlights the conflict that would have occurred with Chemidex's trade mark rights. He details various notification policies the MHRA would have undertaken to inform Chemidex of any specials importation – he confirms that no notification was received.

46. Dr Engineer accepts that Decadron is not listed in C&D but that this does not take away from the use that has been made. In relation to the BNF, he says the absence of Decadron is not telling as this is an independent publication. In relation to Movianto, a further letter is provided confirming the previous evidence and confirming that Thaddeus O MacKrell is the vice president of Movianto UK.

47. In relation to the conflicting data from IMS Health, Dr Engineer gives evidence about this (which has also been granted confidentiality) explaining that [redacted]

[redacted]

[redacted]

[redacted]

Analysis and findings

55. Mr Hodsdon was highly critical of the evidence that had been filed to show genuine use. It was submitted that the evidence was characterised by an absence of what would ordinarily be expected in genuine use cases, such as invoices, delivery notes, purchase orders and internal records such as turnover figures. He also argued, as I will say in more detail below, that what has been filed does not show any actual use in the UK by Chemidex. He submitted that Chemidex had failed to dot its Is and cross its Ts. Finally, he submitted that even if I accepted that some use had been made then it was not genuine use on account of its extremely small scale.

56. Ms Michaels submitted that whilst there is an absence of the type of evidence referred to by Mr Hodsdon, the evidence that had been provided was sufficient to show genuine use, particularly bearing in mind that the data from the prescription costs analysis and from IMS Health came from independent sources. She submitted that the use put forward did show use in the UK and that such use should be considered genuine in accordance with the case-law.

57. I accept that the evidence could (and should) have been better. There was a discussion at the hearing as to whether pharmaceutical companies employed a particular person to take care of various regulatory affairs and records. Ms Michaels rightly pointed out that if there was such a person then this is something that should have been proven in evidence. However, I nevertheless agree with Mr Hodsdon's general point that in an industry such as this, which is heavily regulated, one would expect records of drug authorisations and sales to be easily locatable. Mr Hodsdon's reference to failing to dot ones Is and cross ones Ts is taken from *De La Mer* (2002) FSR 51 where Jacob J stated:

> "9. In the present cases, use was not proved well. Those concerned with proof of use should read their proposed evidence with a critical eye - to ensure that

use is actually proved - and for the goods or services of the mark in question. All the t's should be crossed and all the I's dotted"

58. The solidity and specificity of evidence was also commented upon by Mr Daniel Alexander QC (sitting as the Appointed Person) in *PLYMOUTH LIFE CENTRE* (BL O-236-13), when in paragraph 22 he stated:

> ".....it is not strictly necessary to exhibit any particular kind of documentation but if it is likely that such material would exist and little or none is provided, a tribunal will be justified in rejecting the evidence as insufficiently solid. That is all the more, so since the nature and extent of use is likely to be particularly well known to the proprietor itself. A tribunal is entitled to be sceptical of a case of use if, notwithstanding the ease with which it could have been convincingly demonstrated, the material actually provided is inconclusive. By the time the tribunal (which in many cases will be the Hearing Officer in the first instance) comes to take its final decision, the evidence must be sufficiently solid and specific to enable the evaluation of the scope of protection to which the proprietor is legitimately entitled to be properly and fairly undertaken, having regard to the interests of the proprietor, the opponent and, it should be said, the public."

59. I also note the decision in *Catwalk* BL O/404/13 where Mr Hobbs QC (also sitting as the Appointed Person) stated at paragraph 22:

> "When it comes to proof of use for the purpose of determining the extent (if any) to which the protection conferred by registration of a trade mark can legitimately be maintained, the decision taker must form a view as to what the evidence does and just as importantly what it does not *'show'* (per Section 100 of the Act) with regard to the actuality of use in relation to goods or services covered by the registration. The evidence in question can properly be assessed for sufficiency (or the lack of it) by reference to the specificity (or lack of it) with which it addresses the actuality of use. As to which see paragraphs [17] to [19] and [24] to [30] of the Decision of Mr. Page"

60. It is pertinent in a case such as this to bear the above guidance in mind. Nevertheless, I cannot reject Chemidex's case purely on the absence of certain types of evidence. I must still consider what has been filed and decide what can be taken from it and then decide, based on those facts, whether genuine use has been established.

61. There was much discussion at the hearing as to the status of the SPCs. Ms Michaels questioned their relevance given a number of factors including: that the MHRA guidelines that stipulate that the medicine named in the SPC is the name that should be used is from after the period relevant to the SPCs; further, that there was nothing, on the face of it, preventing the use of additional names (Decadron in addition to dexamethasone) and; that there was no evidence to suggest that multiple SPCs could not be in force.

62. Ms Michaels is clearly correct in terms of the guidelines. However, and at the very least, the SPCs introduce some doubt into the reliability of the prescription costs analysis data from 2010. SPCs carry revision dates which, it is fair to assume, are only revised when a revision of some form is made to the document. The chronology here is that Chemidex's first (relevant) SPC was for Decadron which would appear to be in force on 28 February 2009. However, this was very quickly changed to Dexamethasone (on 2 March 2009). It is not clear whether SPC 2, the SPC without a named day, is a draft or an approved SPC. If it is an approved SPC, it is not clear whether this SPC preceded the change to Dexamethasone, or followed it. If it is a draft then it is simply not pertinent. If it is an approved SPC then in scenario one (preceding the change to Dexamethasone) there must have been some form of minor change (in the SPC itself) between 28 February and 2 March 2009, with the SPC changing again on 2 March 2009 with the renaming of the medicine to Dexamethasone (which is also the name on all subsequent SPCs). If it is scenario two, Decadron changed its name to Dexamethasone on 2 March 2009, but it was then changed back to Decadron at some point between 2 March 2009 and 21 May 2012, when it was changed back to Dexamethasone again.

63. On the face of it, it seems odd to change the name from Decadron to Dexamethasone, back to Decadron and back again to Dexamethasone. Although I

accept that it is not impossible for this to have occurred, I consider it improbable, particularly bearing in mind some other aspects of the evidence. One aspect is the fact that in late 2009, when there was an accepted shortage of product, it is noteworthy that in all the correspondence between Chemidex, MHRA and Dales Pharma, there is not a single mention of Decadron, only Dexamethasone is mentioned. Another aspect of the evidence that is telling is not what it contains, but what it does not. Despite the clear problems that exist in the interpretation of the SPCs, Chemidex does not explain the position. Acre obtained the SPCs it filed as a result of an FOI request to the MHRA. It was thus in a difficult position to accurately evidence the position, including difficulty in explaining why there were multiple SPCs for the same date. On the other hand, what we are discussing here are the SPCs of Chemidex. The changes of name and any other revisions were made by it. One would have thought that it would be an extremely easy task for Chemidex to provide and explain what SPCs were in force for Decadron/Dexamethasone at any point in time. Not only has it failed to do so, but it has not even explained why it has not done so. Ms Michaels submitted that Chemidex was focusing on the date issue of SPC 2. Whilst I accept that its evidence does, as Ms Michaels submitted, deal with this point, this still does not deal with what I regard to be an omission. In relation to the possibility that two SPCs could be in force, I agree with Mr Hodsdon that the use of revision dates on a single numbered SPC makes this unlikely. In my view, the evidence suggest that regardless of whether SPC 2 was a draft or not, the name Decadron was changed to Dexamethasone on 2 March 2009.

64. Of course, the fact remains that Decadron was dispensed in 2010 in England. This is not really disputed by Acre. It could be said that this lends support to the name not having been changed, as why else would the name Decadron appear in the data? However, one then needs to consider the import list. I accept Ms Michaels' submission that the import permissions list does not show that imports did actually occur. Nevertheless, the fact that there were some supply problems in respect of the medicine (even if this was alleviated, to a certain degree, by Chemidex releasing partial batches (of Dexamethasone) to the market), shows a logical reason for the medicine to appear on the import permissions list. This, in turn, provides a more than plausible explanation as to why the dispensed Decadron may not have been Chemidex's Decadron, an explanation which is even more plausible given that Chemidex, based on the SPCs, may have already elected to change the name of its

medicine from Decadron to Dexamethasone. What is also odd is that the cost of the Decadron that was dispensed is significantly less than UK licensed dexamethasone (which Chemidex must have produced). This may give further credence that the Decadron was imported (cheaper) Decadron, however, I do not place much weight on this as this issue was not highlighted before the hearing meaning that Chemidex did not have a chance to explain why there would be such a price differential. It remains possible that the Decadron could be old stock of Chemidex's Decadron. However, on the basis of what has been provided in evidence by Chemidex, this interpretation represents a leap too far. Again, all of these doubts could have been addressed by Chemidex. As Mr Hodsdon highlighted, there are no invoices or records etc. to show the paper trail. There are no examples of packaging (which is also reason to dismiss Ms Michaels' submission that Decadron could have appeared simultaneously with Dexamethasone).

65. I should also deal with Dr Engineer's point that if a rival Decadron were to be imported into the UK, the MHRA would have notified Chemidex. However, the problem with this point is that if Chemidex had moved away from Decadron in its SPCs, with the name of the medicine being changed to Dexamethasone, it is not logical to assume that a notification would be issued. Similarly, there are suggestions made that if the dispensed Decadron was an import then the prescription data would be marked in such a way (indicating that it is a "special"); however whilst noting Dr Engineer's comments, the evidence he gives on this is not sufficient for me to fully understand the full regulatory regime that would be in place and whether, for example, a specials import of the drug from Italy or Portugal (within the EU) would necessitate appropriate marking in the data or whether specials in the data is indicating something else such as unlicensed drugs which have been manufactured in the UK for a specific reason.

66. That then leads to the data from IMS Health showing, according to Dr Engineer's evidence, sales of Decadron in 2011 and 2012. Based on what I have already discussed, it would seem odd for sales of Chemidex's Decadron to have been made in these years bearing in mind what appears to be a change of the medicine's name. However, I must nevertheless deal with the tension that exists between the data (from the same years) that Dr Dally and Dr Engineer obtained from IMS Health. [redacted]

[redacted]

68. The absence of information on Decadron in C&D and the BNF publications also lends support to the proposition that Decadron was not being used due, presumably, to the name change, although, I accept that I should not place significant weight on this aspect of the evidence.

69. Two parts of the evidence I have not touched on yet are Dr Engineer's comments that Decadron was used and, also, the "to whom it may concern" letter(s) from Movianto. Whilst I have taken these sources into account in the overall assessment required of the evidence, I do not consider that they have significant weight. Dr Engineer's commentary lacks detail with regard to the exact circumstances of use and

strikes me as quite generalistic, with fairly broad assertions. His supporting evidence, as already observed, attracts significant doubt, doubt which Dr Engineer has done little to set aside. Whilst he refers to the intention to keep the legacy brand going, this takes matters no further forward. The weight to be attached to Movianto's letter is limited and is little more than bare assertion. One does not know what the letter writer was asked to write. He may not even have known of the relevant issue and may not have been seized as to the significance of the potential difference between use of Decadron/Dexamethasone. The letter writer refers to "Decadron (Dexamethasone)".

70. The answers to the factual questions are to be based upon the balance of probabilities. Overall, I come to the view that the 2010 prescriptions were not in respect of Chemidex's Decadron. It is more probable that the drugs that were prescribed and dispensed were Decadron imports from unrelated third parties. Chemidex cannot rely on such use as it is not use by it or with its consent. I also take the view that the 2011/2012 IMS data does not show any sales of Chemidex's Decadron. There is simply nothing to rely on. No use having been made means that the genuine use test cannot be met. I should add that even if the question was more evenly balanced (for the record I do not consider it is and the evidence as a whole points towards Acre's interpretation), I take the view that the counter-evidence is sufficiently strong to call Dr Engineer's evidence into significant doubt, doubt which Chemidex have not even come close to overcoming. As such, it would have failed to have discharged the onus placed upon it to establish use.

71. One final point to note is that even if I am wrong on the 2010 Decadron sales and that Chemidex's Decadron was dispensed, perhaps due to old stocks of the previously named medicine being used up, I do not consider that such use would constitute genuine use. I say this for a number of reasons. Such use, despite the market being relatively small, is proportionately tiny and took place for a very short period of time. Further, the using up of old stock (if that is what is is) is not in my view a serious attempt to create or maintain a market share. The nature of such use is simply an incidental use of a name which had been changed. The only use Chemidex has made in order to create or maintain a market share in the product was in respect of Dexamethasone.

Conclusion

72. Chemidex's earlier mark cannot be relied upon in the opposition. Consequently, the opposition to the registration of Acre's mark fails.

73. Chemidex's registration is hereby revoked with effect from 23 December 2014.

Costs

74. Acre has been successful, so it is entitled to a contribution towards its costs. My assessment is set out below:

Official fee (for revocation) - £200

Preparing a statement of case (in the revocation) and counterstatement (in the opposition), and considering those of Chemidex - £600

Filing evidence - £1200

Preparation for and attending the hearing - £600

***Total* - £2600**

75. I order Chemidex Pharma Ltd to pay Acre Pharma Ltd the sum of £2600 within fourteen days of the expiry of the appeal period or within fourteen days of the final determination of this case if any appeal against this decision is unsuccessful.

Dated this 13th day of October 2016

Oliver Morris
For the Registrar,
The Comptroller-General