Federal Court  Cour fédérale

Date: 20170109

Docket: T-2510-14

Citation: 2016 FC 1361

Ottawa, Ontario, January 9, 2017

PRESENT: The Honourable Mr. Justice O'Reilly

BETWEEN:

JANSSEN INC. AND ALZA CORPORATION

Applicants

and

ACTAVIS PHARMA COMPANY
AND THE MINISTER OF HEALTH

Respondents

PUBLIC JUDGMENT AND REASONS
(Identical to the Confidential Judgment and Reason issued December 9, 2016)

I. Overview

[1] The applicants (Janssen) seek an order prohibiting the Minister of Health from issuing a Notice of Compliance to the respondent Actavis Pharma Company. The NOC would allow Actavis to market its generic version of a drug marketed by Janssen under the brand name Concerta®. Concerta is used in the treatment of Attention Deficit Hyperactivity Disorder (ADHD). ADHD is one of the most prevalent mental disorders affecting children. Symptoms

include inattention, hyperactivity and impulsiveness. The active ingredient in Concerta is methylphenidate (MP).

[2] The patent for Concerta (Canadian Patent No 2,264,852 (the '852 patent)) does not relate to MP itself, a well-known compound that has been used to treat ADHD for decades. Rather, it relates to the use of compositions that release MP in a "sustained-ascending dose over time".

[3] Actavis alleges that the '852 patent is invalid and, in addition, that Actavis's generic version of the drug will not infringe it. Actavis says that the patent should not stand in the way of its receiving an NOC.

[4] In my view, Actavis has not met its burden of showing that its allegations are justified. Therefore, I will grant the order Janssen seeks, prohibiting the Minister from issuing an NOC to Actavis for its generic MP product.

[5] Both parties presented expert evidence to support their positions. A summary of the experts' qualifications is set out in an Annex.

II. The '852 Patent

[6] Most of the history leading up to the '852 patent is uncontested. However, as will be seen below, the parties do dispute the construction of the patent.

A. *Background*

[7] The first product containing MP for the treatment of ADHD was Ritalin® IR, an immediate release tablet. Ritalin IR was developed by Ciba-Geigy in the 1950s. Later, in the 1980s, Ciba-Geigy marketed a sustained release version, Ritalin SR. Both products were problematic.

[8] Ritalin IR was effective for 3-4 hours, so dosing was recommended either twice a day (BID) or three times a day (TID). Accordingly, most school children had to find a way to take it over their lunch break. A number of issues arise from that scenario: Who will possess the tablets and be responsible for administering them? (As MP is a controlled substance, an adult has to be responsible). How will the tablets be controlled to ensure that persons who have not been prescribed the drug do not have access to it? How will the child's privacy be protected?

[9] In addition to these issues, MP's side-effects – insomnia, appetite suppression, and stomach aches – were believed to be associated with the peaks and valleys in plasma concentrations of MP corresponding with the two or three doses of Ritalin IR taken over the course of a day.

[10] Ritalin SR was meant to overcome those issues. The sustained release tablet was supposed to provide efficacy over an 8-hour period, the length of an entire school day. However, it did not live up to expectations. Ritalin SR turned out to be effective only for a few hours.

Many physicians stopped prescribing Ritalin SR and reverted back to Ritalin IR, either BID or TID.

[11] This was the state of the art in the early to mid-1990s, when researchers at the applicant Alza Corporation started exploring ways to provide a more effective treatment for ADHD. Available to them at that point was a 1989 research paper showing the pharmacokinetics of Ritalin IR and SR, including the maximum plasma concentration achieved, and the time taken to reach that maximum (Patrick 1989). Patrick showed that the plasma concentrations of MP for Ritalin SR rose until about two hours after administration; the concentration plateaus for the next four, and then it drops off.

[12] Another paper available to Alza researchers was a 1992 review by Dr Greenhill. He postulated a number of reasons why Ritalin SR was ineffective, including poor compliance, faulty formulation, weight change, new stress, and acute tolerance (tachyphylaxis).

[13] Dr Suneel Gupta, then director of clinical pharmacology at Alza, explained that researchers were puzzled about why Ritalin SR achieved poor results. Ritalin SR's effects appeared to be desirable – achieving a relatively stable plasma concentration over a significant period of time, and avoiding the peaks and troughs thought to be associated with Ritalin IR's side effects. Experts thought the problem might be the absence of the high peaks achieved with the immediate release tablet, or with the wax matrix formulation that was used.

[14] Dr Gupta wished to test an alternate explanation – acute tolerance. Acute tolerance refers to a situation where a patient becomes tolerant to a drug, not over a long term, but, rather, within a single dosing period. His colleagues were doubtful, believing that the real problem was the formulation.

[15] Rather than addressing the issue of tolerance in customary ways by increasing the dose or decreasing the frequency of administration, Dr Gupta wanted to try administering MP at a continuously increasing rate. He says that his colleagues remained skeptical.

[16] Dr Gupta's team developed a study to test his theory of acute tolerance, as well as his colleagues' idea that a flat concentration profile was most desirable. The team developed a "sipping study" which involves administering small amounts of a drug to mimic the dynamics of various formulations. Four scenarios were tested: the first replicated the twice-daily administration of MP, similar to Ritalin IR BID; the second replicated the flat plasma concentration profile of Ritalin SR; the third, Dr Gupta's, created an ascending plasma profile of MP over an 8-hour period; and the fourth was a placebo.

[17] This double-blinded study also included behavioural testing of the children to whom the drugs were administered (so-called SKAMP and CLAM tests), to determine the drug's dosing efficacy. The placebo had no effect. The flat profile showed declining efficacy over the course of the day. The ascending dose regime displayed improved results over the day, comparable to the BID model, even when the plasma concentrations were lower.

[18] For Dr Gupta, this study confirmed his theory of acute tolerance. A second study was devised to provide further data. The second sipping study tested a modification of the ascending profile in which the initial dose and the overall quantity of MP was higher. Again, four groups were tested: the first replicated administration of Ritalin IR TID; the second was Dr Gupta's ascending profile; the third was a variation of the first, in which the timing of the second dose was varied; the fourth, again, was a placebo.

[19] The results of the second study showed that the varied regime (group three) did not show an improvement over the Ritalin IR TID pattern (group one). To Dr Gupta, this provided further evidence of acute tolerance, and showed that the tolerance could not be addressed simply by increasing the dose. The ascending dosage achieved equivalent behavioural improvements to Ritalin IR TID, with no significant elevation of side effects. These results were subsequently confirmed in a study of adults.

B. *Description of the '852 Patent*

[20] The '852 patent was filed on September 16, 1997. It is entitled "Use of methylphenidate or a pharmaceutically acceptable salt thereof". The patent's owner is Alza; Dr Gupta is one of the named inventors.

[21] The '852 patent states that the invention "pertains to both a novel dosage form and to a novel method for administering a drug for producing a therapeutic effect". The patent specifies that the dosage form in question is one in which the drug is administered "over a predetermined period" at a "sustained and continuously ascending rate", and includes a dosage form where an

initial dose of the drug is administered and then is followed by “a sustained and increasing dose” “over an extended time”.

[22] The patent sets out the background leading to the claimed invention. It begins by referring to the class of drugs used for treatment of ADHD, then makes clear that the invention is generic because it relates to drugs administered according to “the dosage forms and the method of the invention”. It gives the example of central nervous system drugs, such as MP, which have been administered in an immediate dose form and a sustained release form. With respect to the immediate dose form, the patent points out some of the problems associated with multiple daily doses. Regarding the sustained release MP drug, the patent states that patients often develop acute tolerance to it, which diminishes the duration and intensity of its effect.

[23] Based on this background information, the patent goes on to conclude that there is a “critical need” for a drug that overcomes the problems in the prior art. In particular, the patent notes the need for a dosage form and method for administering a drug at a “sustained-increasing rate” to address the problem of acute tolerance, particularly in the treatment of ADHD. The patent specifically refers to the need to provide treatment throughout the school day.

[24] Several pages of the ‘852 patent are devoted to a description of the objects of the invention. I need only refer to the most relevant parts. The patent stresses that one of the invention’s immediate objects is to provide a means of overcoming the shortcomings in the prior art. More particularly, the invention is meant to provide a dosage form that increases the dose of the drug over time, especially to address the problem of maintaining a therapeutic effect in

patients who experience acute tolerance to the drug. The patent addresses specifically the need to provide a dosage form in which the drug, including a central nervous system drug, including MP, is delivered at an increasing rate over a prolonged time period such as a school day of 4 to 8.5 hours.

[25] The next main section of the patent provides a "Detailed Disclosure of Specification". This section begins by describing acute tolerance with reference to scholarly papers on the subject. It then sets out how a sustained ascending dosage form could be made. It goes on to discuss central nervous system drugs, including MP, which can be used to treat ADHD and points out the problem of acute tolerance. Again, it describes the invention as addressing the problem with a sustained release drug, including acute tolerance, referring specifically to the issue of acute tolerance to MP, which can occur within hours of administration.

[26] The patent then sets out a number of examples. Example 1 describes the results of the first sipping study set out above. Example 2 provides the results of the second sipping study. The remaining examples teach methods for making various ascending-release formulations.

[27] The patent contains 119 claims. Claims 1, 41, and 78 are the independent claims in issue here:

> 1. Use of a composition comprising 100 ng to 500 mg methylphenidate or a pharmaceutically acceptable salt thereof, together with a pharmaceutically acceptable carrier, the composition releasing methylphenidate or a pharmaceutically acceptable salt thereof in a sustained-ascending dose over time, for regulation of tolerance to methylphenidate or a pharmaceutically acceptable salt thereof.

> 41. Use of a composition [. . . releasing methylphenidate . . .] in a sustained-ascending dose over a period greater than 6 hours and up to 12 hours, for the treatment of [ADHD].
>
> 78. Use of a composition [. . . releasing methylphenidate . . .] in a sustained-ascending dose over time, for treatment of [ADHD] and compensation of acquired tolerance to methylphenidate or a pharmaceutically acceptable salt thereof.

C. *Construing the Claims of the '852 Patent*

[28] The parties agree that the claims should be construed as of September 30, 1996. The parties also agree that the patent should be construed from the perspective of a skilled person in the art, namely, a composite hypothetical person who is a physician with at least two years' experience treating ADHD and a good knowledge of pharmacology, and a drug formulator with a graduate degree and two years' experience in developing extended-release products. The foregoing description of the skilled person was accepted by Justice Russel Zinn in *Janssen-Ortho Inc v Canada (Health)*, 2010 FC 42 at para 93 in respect of the same patent. I see no reason to depart from that conclusion here. While Dr Chris Hollis, Actavis's expert in clinical psychology, suggested that the skilled person should also have experience treating children and adolescents with ADHD, I do not see that his position adds much to the description accepted by Justice Zinn.

[29] Justice Zinn also construed the phrase "sustained-ascending dose over time" in the '852 patent to mean that the MP is released from the tablet at an increasing rate, not that the plasma concentrations in the patient increased at an ascending rate. As a result, he found that Novopharm's product did not infringe the '852 patent. The parties agree that Justice Zinn's interpretation should apply here.

[30] Actavis maintains that the skilled person would read the ‘852 patent as claiming a dosage form and a method of administering a drug that involves providing an increasing rate of release throughout the entire extended dosing period (*eg*, a full day), not just some portion of it.

[31] I do not agree with Actavis’s construction of the patent.

[32] In my view, the phrase “sustained-ascending dose over time” does not mean “over an entire dosing period”. Obviously, “over time” connotes an extended period, not just any duration. For example, the Ritalin IR tablet could be said to provide an ascending dose over time if one considered only the first two hours after administration. The ‘852 patent specifically distinguished the invention from an immediate release tablet. The word “sustained” also implies that the period under consideration is relatively long compared to the profile of immediate release products.

[33] On the other hand, I do not believe the skilled person would interpret the words “over time” and “sustained” to mean an entire dosing period. One of the main objects of the invention was to provide a medication that would be effective over the course of a school day of 4 to 8.5 hours. A tablet would not have to deliver a sustained-ascending release profile over the entire duration of that period to be effective. The experts agree that efficacy is sustained for a period of time beyond the point when MP is last released from the tablet. Therefore, to be effective over an 8-hour period, for example, the sustained-ascending dosage form would have to rise over the course of the first 6 hours or so, not the entire dosing period.

[34] Dr John Markowitz, a clinical pharmacologist testifying for Janssen, (see Annex for a Summary of experts' qualifications), explained that he did not regard the examples in the patent, which show a sustained-ascending dosage form over the entire test period, as being identical to what is claimed. A drug that had a sustained-ascending release profile over a few hours would continue to be effective for a few hours after the drug stopped releasing MP into the plasma. He read the patent as addressing a sustained-ascending dosage form over a period of at least four hours.

[35] While the four-hour sustained-ascending dose might be at the low end for achieving efficacy for a school day, the patent, according to Dr Markowitz, is directed to a treatment period of up to eight hours, or longer.

[36] Dr Hollis agreed that the effects of a drug containing MP will generally continue for 1.5 to 2 hours after MP stops being released into the plasma.

[37] Actavis also submits that the patent should be read as claiming dosage forms containing as little as 100 ng, and up to 500 mg, of MP. It points out that those amounts are specifically mentioned in the claims and that the claims must be interpreted accordingly.

[38] I disagree. I do not believe a skilled person would read claim 1, for example, to claim a dosage form containing a mere 100 ng of active ingredient that would be capable of regulating acute tolerance to MP. Rather, I agree with Dr Markowitz that the likely explanation for including 100 ng in the claim was to address the minimum content of individual components of a

particular dosage form that might be formulated to deliver a sustained-ascending release profile, the sum total of which might be as high as 500 mg. Dr Hollis conceded that Dr Markowitz's interpretation was reasonable.

III. Issue One – Is Actavis's allegation of invalidity justified?

[39] Actavis's principal argument is that the invention identified in the '852 patent was obvious. The parties agree that the test for obviousness is set out in *Apotex Inc v Sanofi-Synthelabo Canada Inc*, 2008 SCC 61.

[40] Actavis alleges that the so-called invention set out in the '852 patent was obvious and that the patent is therefore invalid.

[41] I disagree. In my view, the invention of the '852 patent represented an inventive step over the state of the art at the relevant time.

[42] I have set out above the common general knowledge that the skilled person would have possessed at the relevant time. The skilled person would have aware of the performance and shortcomings of the available drugs for treating ADHD. In particular, he or she would have regarded administration of Ritalin IR BID or TID as the height of the art.

[43] The inventive concept of the '852 patent is the use of a formulation that delivers a sustained-ascending dose of active ingredient over time in order to address acute tolerance. This

represented an advantage over the prior art, given the problems associated both with Ritalin IR and Ritalin SR.

[44] Actavis argues that the only difference between the inventive step in the patent and the state of the art is that the inventors confirmed the postulation in the prior art that the problem was acute tolerance to MP. Researchers at Alza, according to Actavis, merely conducted routine tests to arrive at that conclusion. Moreover, they arrived at a well-known solution to the problem of drug tolerance: increasing the dose.

[45] I disagree with Actavis's submission on this point. As the description of the background to the '852 patent, set out above, makes clear, the inventors invested considerable effort in discovering the underlying problem with Ritalin SR. Dr Gupta and his colleagues devised what Dr Markowitz called an "elegant" and "imaginative" study to test a number of theories, one of which was acute tolerance. The results surprised the Alza researchers.

[46] The problem with acute tolerance to MP was unknown in the prior art. True, Dr Greenhill mentioned it as one of the many potential causes of reduced efficacy with Ritalin SR. However, no one prior to the studies that led to the '852 patent had specifically identified it as the source of Ritalin SR's inefficacy. The inventors of the patent identified this problem, and devised a novel and effective solution to it.

[47] As described above, it was not obvious to try to develop a sustained-ascending dosage form to address acute tolerance. Dr Gupta's colleagues doubted that acute tolerance was even a

problem. Further, using a sustained-ascending dosage form of MP had never before been tried as a means of addressing acute tolerance.

[48] Actavis's experts have not persuaded me that the invention contained in the '852 patent was obvious. Dr Rue assumed that acute tolerance was a known problem and that an ascending release formulation was the solution. He opined that if a skilled formulator had been asked to make a sustained-ascending dosage form he or she could have done so using routine techniques. Similarly, Dr Hollis assumed that acute tolerance was known to be a potential problem based on the Greenhill paper. However, he would only go so far as to assert that the skilled person would not have dismissed acute tolerance as being one of the problems with Ritalin SR. He went on to state that the skilled person would have tried to replicate the peaks (but not the troughs) in the Ritalin IR TID profile as a means of addressing acute tolerance. He concluded that the skilled person would have easily arrived at a sustained-ascending formulation that would have achieved the desired result.

[49] I see nothing in the prior art or common general knowledge that would have allowed the skilled person to operate from the assumption that acute tolerance to MP was a problem to be solved. Dr Hollis's opinion strikes me as impermissible hindsight. Accordingly, even if the solution to that problem would have been obvious to the skilled person, as alleged by Actavis, I cannot conclude that the invention contained in the '852 patent was itself obvious. This allegation is unjustified.

[50] Actavis also alleges that the utility of the invention described in the ‘852 patent was neither demonstrated nor soundly predicted at the relevant time.

[51] I disagree. The stated utility of the ‘852 patent is that the claimed invention will regulate acute tolerance by means of a sustained-ascending dosage form for the treatment of ADHD. In my view, that utility was clearly demonstrated by way of the two sipping studies, described above. The data from those studies was provided in the patent and support the inventors’ conclusions. I find that this allegation is also unjustified.

[52] Actavis further submits that the patent lacks utility because it covers a range of inoperable products, namely, tablets containing as little as 100 ng of MP. I have set out above my construction of the relevant claims. Accordingly, I find that the patent does not claim a tablet containing 100 ng of MP; rather, it claims a dosage form in which as little as 100 ng of MP may be contained in one of its components. Therefore, I find that Actavis’s allegation is also unfounded.

[53] Finally, Actavis suggests that the ‘852 is invalid because its claims are overbroad. This allegation also relates to the inclusion of 100 ng of MP within the patent’s claims. I agree that 100 ng is not an effective dosage of MP. However, as above, I do not believe a skilled reader would interpret the patent as claiming a sustained-ascending dosage of 100 ng of MP.

[54] Actavis also alleged inutility at the upper end of the claimed range. Specifically, Actavis asserts that a 500 mg dose of MP would be fatal. However, I have no evidence before me to

support that assertion, other than a remark made by Dr Hollis in cross-examination. Accordingly, I find that this allegation is unjustified.

[55] Overall, therefore, I find that Actavis's several allegations of invalidity are unjustified.

IV. Issue Two – Is Actavis's allegation of non-infringement justified?

[56] Actavis maintains that its product does not infringe the '852 patent because the MP contained in its tablets is not released at a sustained-ascending rate over an extended period to compensate for acute tolerance. It relies on the analysis carried out by Dr Peter Rue, an expert formulator, who studied the release rate of MP in Actavis tablets in a variety of media.

[57] Dr Peter Rue found that, on average, the Actavis tablets did not release MP at a sustained-ascending release rate over time. Further, he opined that not enough of the active ingredient would be released at a sustained-ascending rate to deal with acute tolerance. Dr Rue concluded from this that the Actavis product would not infringe the '852 patent.

[58] I disagree. The preponderance of evidence shows that the Actavis product does release MP at a sustained-ascending rate over a sufficiently long period to regulate acute tolerance. Therefore, the Actavis tablets infringe the '852 patent.

[59] Janssen identifies a number of problems with Dr Rue's evidence. I need not deal with all of them. I am satisfied that Dr Rue's opinion is questionable in two areas, causing me to doubt his conclusions. First, Dr Rue construed the '852 patent to claim a sustained-ascending release

rate of MP over an entire dosing period. I have already considered and rejected that interpretation. However, Dr Rue erroneously relied on that construction to conclude that since the Actavis tablets did not provide a sustained-ascending dose over an entire dosing period, they would not infringe the ‘852 patent.

[60] Second, Dr Rue relied on mean data, not the results from analyzing individual Actavis tablets. Accordingly, his analysis tells us only whether a batch of tablets might infringe the patent. However, a batch of tablets might not infringe the patent even when a substantial portion of the individual tablets within it might do so. Dr Rue’s approach could permit a large quantity of infringing material to enter the market.

[61] Dr Leah Appel, also an expert formulator and who provided opinion evidence for Janssen, thoroughly analyzed the dissolution data for the Actavis tablets in various media. She measured the release of MP over hourly periods and found that most of the tablets release MP at a sustained-ascending rate for a minimum of 4 hours, and some for longer periods. Her analysis was based on tablet-by-tablet data, not mean figures for batches.

[62] Dr Appel’s analysis of the Actavis tablets showed that they contain an initial dose of MP and thereafter release MP at a sustained-ascending rate over a sufficient period of time, at least 4 hours, to regulate acute tolerance. Dr Appel compared her data against all of the claims of the ‘852 patent and found that many of them were infringed, most particularly the independent claims set out above – claims 1, 41, and 78.

[63] Further, Actavis's product monograph confirms that the tablets will release MP at an ascending rate for 6 to 10 hours. According to Dr Markowitz, the release rate profile of Actavis's tablets largely corresponds to Janssen's. Similarly, Dr Declan Quinn, a specialist in child psychiatry who provided expert evidence for Janssen, confirmed that physicians reading the Actavis product monograph would note that it is virtually identical to the Concerta product monograph, and would prescribe the Actavis product in the same way as they would Concerta. Accordingly, Dr Quinn concludes that the monograph is essentially telling physicians that the Actavis product provides a sustained-ascending dosage form for MP that can overcome acute tolerance.

[64] In my view, this evidence shows that Actavis's allegations of non-infringement are not justified.

V. Conclusion and Disposition

[65] Actavis has not established that its allegations of invalidity and non-infringement are justified; the preponderance of evidence is to the contrary. Accordingly, I will grant the order Janssen seeks prohibiting the Minister of Health from issuing an NOC to Actavis for its generic version of Concerta. Janssen is entitled to its costs.

JUDGMENT in T-2510-14

THIS COURT'S JUDGMENT is that the order sought by Janssen prohibiting the Minister of Health from issuing an NOC to Actavis is granted, with costs.

"James W. O'Reilly"
Judge

Annex

Summary of Experts

Janssen

Dr Leah Appel, B.S. (Chemical Engineering), Ph.D. (Pharmaceutics)

Dr Appel was a research chemist at Green Ridge Consulting, which does formulation and process development consulting, where she is now Managing Partner. She is an expert in the development and application of drug delivery technology, including SR formulations. She has 14 publications and 11 issued patents, and has acted as an advisor for the Journal of Pharmaceutical Sciences.

Dr John Markowitz, B.S. (Biology), Pharm.D.

Dr Markowitz is currently a Professor of Pharmacotherapy at the University of Florida's College of Pharmacy, as well as a Board Certified Psychiatric Pharmacist. He has experience in the field of clinical pharmacology of psychotropic medications, including drugs that are used in the treatment and management of ADHD. His experience also extends to investigations directed at the assessment of drug-drug interactions in psychopharmacology.

Dr Declan Quinn, BAO, B. Surg., B.A., Bc.H.

Dr Quinn is a Professor of Psychiatry at the Royal University Hospital at the University of Saskatchewan, and has a Fellowship in Psychiatry from the College of Physicians and Surgeons. He is a psychiatrist, specializing in children and adolescents, and has been involved in research and clinical practice regarding ADHD for over 25 years. He has also been involved in pharmacokinetic studies with different psychostimulants, including methylphenidate.

Dr David Goodman, B.A. (Honors Psychology), M.D.

Dr Goodman is a Board Certified Psychiatrist whose clinical practice has been the diagnosis and treatment of bipolar and major depression disorders, ADHD and related disorders, and anxiety disorders since 1986. He is an Assistant Professor of Psychiatry and Behavioural Sciences at Johns Hopkins University School of Medicine, as well as the Director of the Adult Attention Deficit Disorder Centre of Maryland. He has been a principle investigator for multi-site Phase II and III drug trails for the treatment of ADHD.

Actavis

Dr Chris Hollis, B.Sc. (Psychology), MBBS, BCH (Paediatrics), MRCPsych, Ph.D. (Psychiatry)

Dr Hollis is a Professor of Child & Adolescent Psychiatry at the University of Nottingham, and was Chair of the Division of Psychiatry at the School of Community Health Services for 12 years. He conducts research in several psychiatric areas, including ADHD. He has been an expert member and psychopharmacology lead for the National Institute for Health and Care Excellence ADHD Guideline Development Group. He maintains a clinical practice in association with the University of Nottingham Medical School, where his specialty is child and adolescent psychiatry and psychopharmacology, particularly in neurodevelopmental disorders like ADHD. He has authored or co-authored 170 peer-reviewed publications, books, and book chapters.

Dr Peter Rue, B.Sc. (Pharmacy), Ph.D. (Pharmacy)

Dr Rue has been a pharmaceutical consultant and Visiting Professional Fellow in the Department of Pharmacy at the University of Aston for the past 15 years. His area of expertise is pharmaceutical formulation, specifically solid dosage forms, a field he has worked in for over 30 years. He has also assisted smaller companies as a pharmaceutical consultant. He has published over 25 articles, almost all of which are regarding pharmaceutical formulations and compositions.

FEDERAL COURT

SOLICITORS OF RECORD

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