Gobinathan Devathasan *v* Singapore Medical Council
[2010] SGHC 51

Case Number	: Originating Summons No 1027 of 2009
Decision Date	: 10 February 2010
Tribunal/Court	: High Court
Coram	: Chan Sek Keong CJ; Andrew Phang Boon Leong JA; V K Rajah JA
Counsel Name(s)	: Myint Soe and Xu Daniel Atticus (Myintsoe & Selvaraj) for the appellant; Alvin Yeo SC, Melanie Ho, Sean La'Brooy, and Kylee Kwek (Wong Partnership LLP) for the respondent.
Parties	: Gobinathan Devathasan — Singapore Medical Council

Professions – Medical Profession and Practice – Professional Conduct

Evidence – Proof of Evidence – onus of proof – standard of proof

10 February 2010 Judgment reserved.

V K Rajah JA (delivering the judgment of the court):

Introduction

1 This is an appeal by Dr Gobinathan Devathasan ("Dr Devathasan") against the decision of a Disciplinary Committee ("the DC") of the Singapore Medical Council ("the SMC") as constituted under the Medical Registration Act (Cap 174, 2004 Rev Ed) ("the Act"). After a hearing that took place in two tranches between 19 January 2009 and 22 January 2009 and 3 August 2009 and 8 August 2009 ("the DC hearing"), the DC found Dr Devathasan guilty of one charge of professional misconduct under s 45(1)(*d*) of the Act, and ordered that he be, *inter alia*, fined $5,000. Section 45(1) of the Act states:

> 45. —(1) Where a registered medical practitioner is found or judged by a Disciplinary Committee —
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> (a) to have been convicted in Singapore or elsewhere of any offence involving fraud or dishonesty;
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> (b) to have been convicted in Singapore or elsewhere of any offence implying a defect in character which makes him unfit for his profession;
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> (c) to have been guilty of such improper act or conduct which, in the opinion of the Disciplinary Committee, brings disrepute to his profession;
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> (d) to have been guilty of professional misconduct; or
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> (e) to have contravened section 64, 65 or 67,
>
> the Disciplinary Committee may exercise one or more of the powers referred to in subsection (2).

[emphasis added]

2 The charge in question related to Dr Devathasan's inappropriate administration of Ultrasound Sonolysis or Therapeutic Ultrasound (referred to hereafter as "Therapeutic Ultrasound" for convenience) on Madam Thio Tjoei Ing ("the Patient"). The detailed reasons for the decision of the DC can be found in its grounds of decision dated 8 August 2009 ("the GD").

Background facts

3 Dr Devathasan is a specialist (in the area of neurology) of 32 years' standing. He has had, in the words of the DC, a "brilliant professional career as a doctor". [note: 1] Since 1991, he has been in private practice at Mount Elizabeth Medical Centre. Prior to entering private practice, Dr Devathasan had, at various points in his career, appointments as a visiting associate professor of neurology at John Hopkins University, the head of the neurology division at the National University Hospital, and an associate professor of medicine at the National University of Singapore. Over the years, he has written close to 100 papers and articles, both locally and internationally, in various journals, books, conference papers, and has also been invited to speak at various seminars. In addition, Dr Devathasan has held several appointments in public organisations.

4 The Patient is an elderly woman with a chronic and complicated neurological syndrome (see, further, [16]–[17] below). The term "the Patient's condition" hereafter should be taken as a general reference to the Patient's medical condition. The Patient was first brought to Dr Devathasan's clinic on 15 August 2006 for a second opinion in the hope that her health could be improved. She was 77 years of age at the material time. Prior to her consulting Dr Devathasan, the Patient was under the care of Dr Tang Kok Foo ("Dr Tang"), whom Dr Devathasan alleged had instigated the complaint ("the Complaint") against him. The Patient returned to Dr Tang for consultation in October 2006 and was last seen by Dr Tang in April 2007.

5 The DC proceedings arose from the Complaint, which was dated 27 November 2006, and lodged by the Patient's husband and daughter-in-law ("the Complainants") together with a supporting Statutory Declaration affirmed by the husband on 21 December 2006. In essence, the Complaint related to Dr Devathasan's use of two treatments; specifically, Repetitive Transcranial Magnetic Stimulation ("rTMS") and Therapeutic Ultrasound. As provided for under the Act, a Complaints Committee ("the CC") first investigated the Complaint and Dr Devathasan provided a written explanation for his actions. The CC subsequently referred the Complaint to the DC for a formal inquiry, in accordance with s 41(1)(*b*) of the Act. Before the DC, Dr Devathasan was charged under s 45(1)(*d*) of the Act for professional misconduct.

6 In all, Dr Devathasan faced two charges of professional misconduct. The first charge ("the First Charge") related to his use of rTMS on the Patient between 15 August 2006 and 18 August 2006. It read as follows: [note: 2]

> That you, [Dr Devathasan], a registered medical practitioner under [the Act], whilst practising at Devathasan Neurology Practice Pte Ltd located at 3 Mt Elizabeth #11-16 Mount Elizabeth Medical Centre Singapore 228510, did during the period from 15 August 2006 to 18 August 2006, recommend and administer the treatment of [rTMS] to [the Patient] … which you knew or ought to have known, was not the appropriate treatment,
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> Particulars
>
> (1) The Patient was at the material time, a 77 year old lady who had senile dementia of the

Alzheimer's type, a history of psychotic disorder and a transient ischemic attack in 2005 with the internal development of small asymptomatic infracts in the basal ganglia …;

(2) You administered [rTMS] on the Patient on 15 August 2006, 16 August 2006, 17 August 2006, and 18 August 2006 …;

(3) [rTMS] was not indicated for [the Patient's condition];

(4) [rTMS] was not generally accepted by the medical profession as a form of clinical treatment or therapy for [the Patient's condition]; [and]

(5) The appropriate treatment for [the Patient's condition] is medical therapy.

and that in relation to the facts alleged you are guilty of professional misconduct under section 45(1)[(d)] of [the Act].

[underlining added in original]

The second charge ("the Second Charge") related to his use of Therapeutic Ultrasound on the Patient between 16 August 2006 and 18 August 2006. It read as follows: [note: 3]

That you, [Dr Devathasan], a registered medical practitioner under [the Act], whilst practising at Devathasan Neurology Practice Pte Ltd located at 3 Mt Elizabeth #11-16 Mount Elizabeth Medical Centre Singapore 228510, did during the period from 16 August 2006 to around 18 August 2006, recommend and administer [Therapeutic Ultrasound] to [the Patient] … which you knew or ought to have known, was not the appropriate treatment,

Particulars

(1) The Patient was at the material time, a 77 year old lady who had senile dementia of the Alzheimer's type, a history of psychotic disorder and a transient ischemic attack (TIA) in 2005 with the internal development of small asymptomatic infracts in the basal ganglia …;

(2) You administered [Therapeutic Ultrasound] on the Patient on 16 August 2006, 17 August 2006, and 18 August 2006 …;

(3) [Therapeutic Ultrasound] was not indicated for [the Patient's condition];

(4) [Therapeutic Ultrasound] was not generally accepted by the medical profession as a form of clinical treatment or therapy for [the Patient's condition]; [and]

(5) The appropriate treatment for [the Patient's condition] is medical therapy.

and that in relation to the facts alleged you are guilty of professional misconduct under section 45(1)[(d)] of [the Act].

[underlining added in original]

7 Both the First Charge and the Second Charge are largely similar – the main difference being the treatment in question. That said, it should be noted, at this juncture, that the charges which Dr Devathasan faced at the DC hearing were quite different in scope from that which the SMC

originally preferred against him ("the original charges"). The original charges alleged that Dr Devathasan had recommended and administered rTMS or Therapeutic Ultrasound to the Patient "for the purpose of treating and improving her memory and behaviour". [note: 4] However, both charges were eventually amended at a very late stage. About six days before the first tranche of the DC hearing, the SMC informed Dr Devathasan that it would formally apply to the DC at the commencement of the DC hearing to amend the two charges by deleting the references to memory and behaviour. This application to amend the charges was successful and resulted in allegations of misconduct against Dr Devathasan which were considerably wider than those which he initially faced. It is worth noting that all of the expert evidence was prepared on the basis that Dr Devathasan would face the original charges.

8 Dr Devathasan contested the First Charge and the Second Charge. At the DC hearing, the Patient and her family did not testify. The SMC, which was the prosecuting party, called four experts to give evidence; these were:

(a) Assoc Prof Benjamin Ong ("Assoc Prof Ong"), who gave evidence on both rTMS and Therapeutic Ultrasound;

(b) Prof Lee Wei Ling ("Prof Lee"), who also gave evidence on both rTMS and Therapeutic Ultrasound;

(c) Assoc Prof Lo Yew Long ("Assoc Prof Lo"), who gave evidence on rTMS only; and

(d) Dr Vijay Kumar Sharma ("Dr Sharma"), who gave evidence on Therapeutic Ultrasound only.

Dr Devathasan called two experts:

(a) Dr Allan Keith Lethlean ("Dr Lethlean"), who gave evidence on both rTMS and Therapeutic Ultrasound; and

(b) Dr T Thirumoorthy ("Dr Thirumoorthy"), who gave evidence on medical ethics.

9 At the conclusion of the DC hearing, the DC acquitted Dr Devathasan of the First Charge (which related to rTMS), but "[r]eluctantly" convicted him on the Second Charge (which related to Therapeutic Ultrasound). [note: 5] In convicting him, the DC commented that Dr Devathasan "must have known that he had overstepped the line, or in his enthusiasm, at the least he turned a blind eye". [note: 6] . It was ordered that Dr Devathasan:

(a) be fined $5,000;

(b) be censured;

(c) provide a written undertaking to the SMC that he would not continue with Therapeutic Ultrasound other than for indications as generally accepted by the community of neurologists; and

(d) pay the full costs of the legal assessor as well as 60 per cent of the SMC's costs.

The DC hearing

The SMC's case

10 In essence, the SMC's case was that neither rTMS nor Therapeutic Ultrasound was appropriate for the Patient's condition, whether that condition was as stated in the charges or as described by Dr Devathasan. Its position was that:

(a) both treatments were not indicated for the Patient's condition;

(b) both treatments were not generally accepted by the medical profession as a form of clinical treatment or therapy for the Patient's condition; and

(c) the appropriate treatment for the Patient's condition was medical therapy.

11 The starting premise of the SMC's case was para 4.1.4 of the SMC Ethical Code and Ethical Guidelines ("the ECEG"), which provides:

> A doctor shall treat patients according to *generally accepted methods* and use only licensed drugs for appropriate indications. A doctor shall not offer to patients, management plans or remedies that are not *generally accepted* by the profession, except in the context of a formal and approved clinical trial.
>
> …
>
> It is not acceptable to experiment or authorise experiments or research which are not part of a formal clinical trial and which are not primarily part of treatment or in the best interest of the patient, or which could cause undue suffering or threat to the life of a patient.
>
> [emphasis added]

12 The SMC's position was that a doctor should not offer a patient a form of medical treatment which was not generally accepted by the medical profession, unless the administration of that treatment took place in the context of a formal clinical trial, which the present instance was clearly not. It relied heavily on the evidence of three of its experts, *viz*, Assoc Prof Ong, Prof Lee, and Dr Sharma, that the available medical literature did not support ultrasound as having a therapeutic role in chronic stroke (as opposed to acute stroke) or any other neurological illness such as dementia or Parkinsonism. Assoc Prof Ong opined in his expert report: [note: 7]

> As such, even if there were any intention to "treat" [the Patient] using ultrasound, in view of the brief time in which ultrasound was applied (15 to 20 minutes), it would appear that such treatment did not serve any useful purpose. However, it remains my view that ultrasound is not clinically indicated nor approved for use as a tool for therapy for a patient with this medical condition.

Prof Lee on her part concluded in her report: [note: 8]

> At best, the use of Sono Thrombolysis [*ie*, Therapeutic Ultrasound] as therapy is experimental and is not medically proven to have any therapeutic effects nor is it clinically approved for such a use. The articles referred to by Dr Devathasan in his written explanation were tentative in their conclusion and studies only involved acute ischemic strokes which again, was not the state of [the Patient] when she [was] presented to [Dr Devathasan].

In light of the evidence, the SMC submitted that Therapeutic Ultrasound was not generally accepted by the medical profession, and was hence inappropriate for the Patient's condition. The SMC also

relied on evidence by Prof Lee and Dr Sharma that Therapeutic Ultrasound could even harm the Patient. Prof Lee, for one, referred in her report to a clinical trial which indicated that "ultrasound may actually lead to increased risk of haemorrhage for stroke patients". [note: 9]

Dr Devathasan's case

13 In response, Dr Devathasan's case was that the complaint against him was the work of a professional rival who had sought to undermine his standing. His case was also that whilst both rTMS and Therapeutic Ultrasound might be novel to some doctors, there was sufficient medical literature to support their use, and that safety was not an issue for either treatment. With regard to Therapeutic Ultrasound, he adduced literature which dealt with the effects of both high and low frequency ultrasound in different tissues. He relied on safety parameters for the use of ultrasound in obstetric practice, coupled with the principle that what was safe for the foetus was *a fortiori* safe for the adult, as well as the "ALARA" (*ie*, "as low as reasonably achievable") principle, which effect in the present instance was that the patient ought to be exposed to the lowest level of ultrasound possible. He also produced literature on the use of ultrasound, with and without Tissue Plasminogen Activator ("TPA") (*ie*, a protein involved in the breakdown of blood clots), to manage acute stroke.

14 Additionally, Dr Devathasan said that both rTMS and Therapeutic Ultrasound were used as adjuncts to the accepted mode of treatment for the Patient's condition, which was medical therapy. He said that the Patient's husband informed him that the Patient had failed to respond to standard therapy even though nine previous specialists (including four neurologists) had been consulted, and that the Patient had approached him specifically for alternative forms of treatment(s). Dr Devathasan also said that his sole purpose of applying both treatments was to benefit the Patient, and he only applied the treatments to the Patient because she had failed to improve, despite having consulted several other neurologists and specialists. He claimed that the treatment benefited the Patient in that she became "very vocal", [note: 10] "significantly mobile", [note: 11] and could walk without assistance, unlike before.

The DC's findings

15 The full reasons for the acquittal of Dr Devathasan on the First Charge and conviction on the Second Charge can be found in the GD. For present purposes, the following key findings in the GD are significant:

(a) Dr Devathasan's diagnosis of the Patient's condition was acceptable;

(b) the Patient had derived some benefit from rTMS and Therapeutic Ultrasound;

(c) Dr Devathasan had acted in good faith and had wanted to improve the Patient's condition;

(d) Dr Devathasan was not guilty of the First Charge even though rTMS was not generally accepted;

(e) there was a lack of evidence that the Patient suffered any harm from Therapeutic Ultrasound; and

(f) Therapeutic Ultrasound was inappropriate due to Dr Devathasan's failure to prove that it was safe for patients.

The acceptance of Dr Devathasan's diagnosis

16 The Patient suffered from a chronic and complicated neurological syndrome, which diagnosis Dr Devathasan and experts for the SMC could not agree on. Dr Devathasan diagnosed that she had "Parkinsonism of the atherosclerotic type, … cerebral atrophy, ischemia, small vessel disease[,] and [possibly] associated Gait Apraxia, all these [contributing] to her severe immobility". [note: 12] He stated that she was in "Stage 4 Parkinsonism, meaning that she was no longer able to walk on her own" and "had Parkinsonism with some degree of cognitive impairment and possibly psychosis". [note: 13] The SMC took the view that she suffered from "senile dementia of the Alzeheimer's type, a history of psychotic disorder and a transient ischemic attack … in 2005 with the internal development of small asymptomatic infarcts in the basal ganglia" (see the charges at [6] above). Assoc Prof Ong broadly agreed with Dr Devathasan's diagnosis. He labelled the disease as "vascular dementia" [note: 14] and agreed with Dr Devathasan that the Patient's condition could be labelled as "chronic stroke" [note: 15] and that Atherosclerotic Parkinson's Disease was a sub-type of chronic stroke. [note: 16]

17 That there were differences between the opinions on the Patient's condition was recognised by the DC in the GD. [note: 17] The DC proceeded to accept Dr Devathasan's diagnosis, stating that it would "take the physician's word under the present circumstances", and noted the SMC's position that it was not fatal to their case should Dr Devathasan's diagnosis be accepted. [note: 18] We should also point out here that none of the SMC's experts had ever examined the Patient.

Benefits to the Patient from rTMS and Therapeutic Ultrasound

18 The DC was prepared to accept that the Patient derived some benefit from rTMS and Therapeutic Ultrasound, notwithstanding the concerns of Prof Lee (see [12] above) and Dr Sharma (see [23] below). This was made clear in the GD, where the following was stated: [note: 19]

> The Complainants alleged the Patient's condition deteriorated but he claimed otherwise. None of the [SMC] experts examined the Patient to determine her condition. Mindful that it is a quasi-criminal hearing and that neither the Complainants nor the Patient testified, *we are prepared to accept [Dr Devathasan's] assessment that the Patient derived some benefit from the treatments he gave* …. [emphasis added]

Dr Devathasan having acted in good faith

19 The DC accepted that Dr Devathasan had acted in good faith and had wanted to improve the Patient's condition. In the GD, the DC listed five mitigating factors, two of which contained important findings in this connection. The two factors in question, in the words of the DC, are as follows: [note: 20]

> a) Dr Devathasan was *motivated to provide some relief to [the Patient's] condition, as he did with his other patients in similar situations*. He thought that the use of Ultrasound Therapy coupled with the rTMS could prolong the beneficial effects produced by the rTMS;
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> b) He had *practised his novel treatment openly*, and had published a paper on those treatments in a Congress in Vancouver and written to the Government about it;
>
> ….
>
> [emphasis added]

20 That Dr Devathasan acted in good faith was also acknowledged by counsel for the SMC, Mr Alvin Yeo SC ("Mr Yeo"). When we asked Mr Yeo whether the SMC was prepared to accept that Dr Devathasan had acted in good faith, he replied that the DC did find that Dr Devathasan acted as such and that the SMC was not appealing against that finding, although he stressed that the DC also found that Dr Devathasan knew or ought to have known that Therapeutic Ultrasound was inappropriate.

The acquittal on the First Charge

21 The DC acquitted Dr Devathasan on the First Charge even though it was of the opinion that rTMS was not generally accepted by his peers in Singapore. As mentioned at [6] above, Dr Devathasan faced two charges of professional misconduct, the first (*ie*, the First Charge) relating to his use of rTMS on the Patient and the second (*ie*, the Second Charge) relating to his use of Therapeutic Ultrasound on the same Patient. At the conclusion of the DC hearing, the DC acquitted Dr Devathasan on the First Charge. In so doing, the DC said: [note: 21]

> 30. Whilst the use of rTMS is not generally accepted in our local practice, Dr Devathasan's work may represent novel treatment and may aid the progress and innovation in medicine.
>
> 31. In our view, these above stated studies and other studies do support the basis of the application of rTMS as an extended indication or auxiliary treatment for a patient with PD [ie, Parkinson's Disease], especially one who has failed other treatment options.
>
> [emphasis added]

22 Even though the DC had stated in the GD that rTMS had not found general acceptance in the local medical practice, [note: 22] it did not immediately conclude that rTMS was inappropriate for the Patient. Instead, it went on to consider the possibility that treatment with rTMS "may represent novel treatment and may aid the progress and innovation in medicine". It then concluded that there were sufficient studies to support the use of rTMS as an auxiliary treatment for a patient with Parkinson's Disease, especially since the Patient had failed to respond to other treatment methods. Accordingly, it could not say, beyond all reasonable doubt, that the treatment with rTMS was inappropriate for the Patient's condition. The upshot of the DC's approach with respect to the First Charge was that even though a particular treatment was neither indicated for the Patient nor generally accepted by the medical profession, it was nevertheless possible for that treatment to still be regarded as appropriate for the Patient.

The lack of evidence that the Patient suffered harm

23 The DC found that there was "[n]o evidence that any harm has come to the Patient from the use of ultrasound". [note: 23] In so finding, the DC rejected Dr Sharma's evidence that the use of Therapeutic Ultrasound was dangerous, stating that "Dr Sharma's evidence that it was very dangerous to use Therapeutic Ultrasound on the brain, we think, is an overstatement". [note: 24] During the DC hearing, Dr Sharma emphasised on several occasions that Dr Devathasan's use of ultrasound, which was not at the established frequency of 2MHz, was not in conjunction with TPA, and after the conventional three-hour window of symptom-onset had lapsed, would compromise the safety of his (*ie*, Dr Devathasan's) patients. This was even though there was no obvious untoward effect to the Patient and Dr Sharma could not produce any literature or study to support his rather absolute position.

The failure to prove that Therapeutic Ultrasound was safe

24 The DC found Therapeutic Ultrasound to be not indicated and not generally accepted, and hence inappropriate, because Dr Devathasan had failed to prove that applying Therapeutic Ultrasound on the brain was safe for patients. In this regard, the following passages from the GD are revealing: [note: 25]

> 37. … [T]here is no experimental evidence or physical proof of the safety of [Therapeutic Ultrasound] on the human brain. Dr Sharma's evidence that it was very dangerous to use Therapeutic Ultrasound on the brain, we think, is an overstatement. But as the safety of patients or "do no harm" is a cardinal principle for doctors, it behooves the applicant to satisfy us that the application of Therapeutic Ultrasound on the brain is safe on patients. …
>
> 38. Thus, we find that the use of Therapeutic Ultrasound as a modality is not an appropriate extension of use into clinical neurology practice, particularly with regard to insonation of the brain.
>
> 39. Accordingly, we find that the treatment with Therapeutic Ultrasound was not indicated and clearly, not generally accepted by his peers and as such, not an appropriate treatment for the [Patient's condition].
>
> [emphasis added]

25 By holding that it "behooves the applicant to satisfy us that the application of Therapeutic Ultrasound on the brain is safe on patients", the DC *shifted the burden of proof* on to Dr Devathasan to prove that Therapeutic Ultrasound was safe for patients when used to treat neurological brain diseases. The DC was not satisfied that there was any experimental evidence or physical proof that Therapeutic Ultrasound was safe for patients when used to treat such diseases. It was also not convinced by Dr Devathasan's extrapolation of Therapeutic Ultrasound's potential beneficial effects from existing studies. The DC took the view that Dr Devathasan had, at no time during the DC hearing, "indicated that he had verified his assumptions or conclusions through expert consultation, in-vitro or in-vivo experimentation or tests in any form". [note: 26] Accordingly, he had not proved that Therapeutic Ultrasound was safe for patients. Thus, using Therapeutic Ultrasound to treat neurological brain diseases (of which the Patient's condition was a type) was not an appropriate extension of its usual use.

The present appeal

26 The present appeal is limited to Dr Devathasan's conviction on the Second Charge (as he was acquitted of the First Charge). Numerous grounds for the appeal were set out in his originating summons filed for the appeal; but, to summarise, the grounds related, in the main, to the DC having gone beyond the ambit of the Second Charge and having dealt erroneously with certain aspects of the evidence. In the event that this court confirms his conviction, Dr Devathasan seeks, in the alternative, to limit the scope of the undertaking he has been required to give.

The role of this court

27 Before turning to the merits of this appeal, it is perhaps appropriate to first outline the role of this court in hearing appeals emanating from decisions of the SMC's Disciplinary Committees. A medical practitioner who is "aggrieved" by any decision of a Disciplinary Committee may appeal to the High

Court against that decision, pursuant to s 46(7) of the Act, which states:

> Any person who is aggrieved by any order referred to in subsection (6) [*ie*, an order of a Disciplinary Committee] may, within 30 days after the service on him of the notice of the order, appeal to the High Court against the order; and any such appeal shall be heard by 3 Judges of the High Court and from the decision of that Court there shall be no appeal.

Section 46(8) then provides:

> In any appeal to the High Court against an order referred to in subsection (6), the High Court shall accept as final and conclusive any finding of the Disciplinary Committee relating to any issue of medical ethics or standards of professional conduct unless such finding is in the opinion of the High Court *unsafe, unreasonable or contrary to the evidence*. [emphasis added]

28 In the recent decision of this court in *Low Cze Hong v Singapore Medical Council* [2008] 3 SLR(R) 612 ("*Low Cze Hong*"), we endorsed the English position that the High Court's jurisdiction in such appeals is appellate in nature and that the court is fully entitled to substitute its own decision for that of the Disciplinary Committee. However, we also noted that there are limits to the court's powers. At [39] of *Low Cze Hong*, we held that in considering an appeal, "a court will be slow to interfere with the findings of the disciplinary committee unless the grounds in s 46(8) of the Act are satisfied". As such, it will ordinarily not be easy to displace a finding or an order of a Disciplinary Committee. The court will only interfere if the Disciplinary Committee's finding is "unsafe, unreasonable or contrary to the evidence" (*per* s 46(8) of the Act).

29 We are mindful that the Disciplinary Committee has the benefit, which we do not have, of hearing oral evidence on both sides; and it is a specialist tribunal with its own professional expertise and understands what the medical profession expects of its members. Nevertheless, decisions of Disciplinary Committees must be reasonably reached in accordance with the evidence presented. In other words, while we would accord an appropriate degree of respect to a Disciplinary Committee's decision, we will not defer to that decision if it is not in accordance with law and/or the established facts. With these considerations in mind, we now turn to the merits of this appeal.

Analysis of the DC's decision

30 Having analysed and considered the GD and the submissions of both parties, we conclude that the DC has erred in convicting Dr Devathasan of the Second Charge for reasons that can be listed as follows:

(a) The DC went beyond the scope of the Second Charge in convicting Dr Devathasan.

(b) The DC's conclusion that Therapeutic Ultrasound was neither indicated nor generally accepted by Dr Devathasan's peers did not necessarily follow from its analysis on the issue of safety.

(c) The DC applied the standard of proof erroneously.

(d) The DC's opinion that Dr Devathasan had "overstepped the line" or "turned a blind eye" (mentioned earlier at [9] above) was contrary to evidence.

The scope of the Second Charge

31 In our view, the DC's conviction should be set aside on the basis that it had exceeded the ambit of the Second Charge. The crucial parts of the Second Charge are now set out:

> That you, [Dr Devathasan], … did … recommend and administer the treatment of [Therapeutic Ultrasound] to [the Patient] which you knew or ought to have known, was not the appropriate treatment,
>
> Particulars
>
> …
>
> (2) You administered [Therapeutic Ultrasound] on the Patient on 16 August 2006, 17 August 2006, and 18 August 2006 …;
>
> (3) [Therapeutic Ultrasound] was not indicated for [the Patient's condition];
>
> (4) [Therapeutic Ultrasound] was not generally accepted by the medical profession as a form of clinical treatment or therapy for [the Patient's condition]; [and]
>
> (5) The appropriate treatment for [the Patient's condition] is medical therapy.
>
> [underlining added in original]

32 Three observations can be made on the form of the Second Charge. First, Dr Devathasan's alleged misconduct was in respect of his use of Therapeutic Ultrasound on the Patient, not rTMS (which was the subject of the First Charge), or the combined use of rTMS and Therapeutic Ultrasound. However, considerable evidence was led during the DC hearing which suggested that it was the *combined* use of Therapeutic Ultrasound with rTMS that was inappropriate, not the use of Therapeutic Ultrasound itself. One example would be a paper that Dr Devathasan had co-authored and presented at the 15th International Congress of Biomagnetism held in 2006 ("the Paper"), which he sought to rely on to justify his administration of Therapeutic Ultrasound and rTMS on the Patient. This Paper addressed the combined use of Therapeutic Ultrasound and rTMS, rather than Therapeutic Ultrasound in isolation. It concerned the use of rTMS and Therapeutic Ultrasound on patients with Gait Apraxia.

33 Further, during Dr Lethlean's cross-examination, Mr Yeo also appeared to have focused Dr Lethlean's attention, almost exclusively, on the combined use of Therapeutic Ultrasound and rTMS. Since the focus was on the combined treatment and that combination was a novel treatment for chronic stroke, naturally there would not have been any literature on it. A novel treatment, by its very definition, cannot be said to be generally accepted. As Dr Lethlean's aptly put it, "you can't look for a map where no one has gone before". [note: 27] In this regard, it cannot be certain if the DC, in holding that "the use of Therapeutic Ultrasound as a modality [was] not an appropriate extension of use into clinical neurology practice", [note: 28] was influenced by this evidence in coming to its decision, and if so, the extent to which this evidence was influential. Clearly, however, there is the possibility that this evidence on the novel nature of the *combined* treatment could have influenced the DC's finding that Therapeutic Ultrasound *itself* was an inappropriate extension of its current accepted use.

34 It could be further added that Dr Devathasan also produced other medical literature to justify the novel manner in which he had used ultrasound on the Patient. This evidence appears to have

been glossed over by the DC. Here, we note the difference between Diagnostic Ultrasound and Therapeutic Ultrasound. The former is used for identifying causes of illnesses or disorders whilst the latter is used for treatment purposes. Dr Devathasan's administration of Therapeutic Ultrasound was a deviation from the current accepted manner of the application of ultrasound in at least three ways:

(a) he administered ultrasound at a lower frequency of 1MHz whereas the conventional frequency used was 2MHz;

(b) he administered this lower frequency ultrasound to stroke patients after the conventional three-hour window of stroke symptom-onset had lapsed; and

(c) he did not administer ultrasound with TPA.

The implications of the deviations will now be elaborated on.

35 First, in respect to Dr Devathasan's administration of ultrasound at a frequency lower than 2MHz, Dr Sharma's oral testimony was that only ultrasound applied at a frequency of 2MHz had been shown to be safe for therapeutic purposes and that ultrasound applied at frequencies lower than 2MHz was dangerous. In response to Dr Sharma's views, Dr Devathasan said that he had always kept to the safety parameters for Diagnostic Ultrasound in his application of Therapeutic Ultrasound, and that the use of 1MHz ultrasound was considered to be safe diagnostically. He cited an article which showed that 1MHz ultrasound was already established for diagnostic purposes and could possibly be used for therapeutic purposes. To establish the safety profile of Therapeutic Ultrasound, he also relied on a principle, used by the World Ultrasound Organisations, that what was safe for foetuses and neonates was also safe for adults, and submitted that what he had done was within the safety parameters for foetuses and neonates.

36 Second, in respect to Dr Devathasan's administration of ultrasound after the first three hours of the onset of stroke symptoms, both Prof Lee and Dr Sharma were of the opinion that it was pointless to apply ultrasound after the initial time period had lapsed (Dr Sharma was willing to accept that this time period could stretch up to nine hours from symptom-onset). To Prof Lee, administering ultrasound would be ineffective as there was no clot to lyse and hence nothing to clear in the brain. Dr Sharma's evidence was that the purpose of exposing a patient's brain to ultrasound was to save parts of the brain from dying. Where the brain tissue was already dead, applying ultrasound was in fact more likely to cause harm than any benefit to the patient. He repeated time and time again that it was pointless to use ultrasound for any therapeutic purpose beyond the initial hours of symptom-onset, and that he had never heard of any therapeutic use beyond this time period. In response to Prof Lee's and Dr Sharma's criticisms, Dr Devathasan explained that he applied ultrasound after the initial three-hour period not to disintegrate any blood clot but to improve cerebral blood flow so that the beneficial effects of rTMS may be sustained (according to Dr Devathasan, the effects of rTMS would subside within a month or so where ultrasound was not administered), and produced studies which demonstrated that ultrasound did have vasodilatory effects on blood vessels.

37 Third, in respect to Dr Devathasan's administration of ultrasound without TPA, Dr Sharma repeated on several occasions during his oral testimony that TPA was an essential part of the ultrasound treatment and that the combination of 2MHz ultrasound with TPA, used within the first three hours of symptom-onset, was the only known treatment which would improve a patient's chance of recovery. In response, Dr Devathasan said that he was not intending to lyse any blood clot (*ie*, the aim of administering Therapeutic Ultrasound was not to treat the Patient for acute stroke (see, also, [36] above)), implying that he was in fact applying Therapeutic Ultrasound for a different purpose than ordinarily used and as such, there was no need to follow the accepted treatment

protocol which Dr Sharma listed. He also said that his decision not to use TPA was based on the increased risk of brain haemorrhages, the mortality rate when TPA was used with ultrasound, and the fact that only a small percentage of patients qualified for such use. He implied that what he did was in fact safer than the established practice. Crucially, he sought to justify his extended use of rTMS and Therapeutic Ultrasound, beyond Gait Apraxia patients, by reference to the Paper. The Paper concerned the use of rTMS and Therapeutic Ultrasound on patients with Gait Apraxia and was subsequently published (though it was disputed whether publication was in peer-reviewed journals or their equivalent). Dr Devathasan explained that because Gait Apraxia and the Patient's condition were both sub-types of chronic stroke, and that his Paper showed that rTMS and Therapeutic Ultrasound could be used to treat Gait Apraxia, accordingly, there was a basis for administering the combined treatments on patients with the Patient's condition.

38 At this juncture, we pause to stress that in spite of the numerous publications and medical literature produced by both sides, no amount of theoretical extrapolations can contradict the fact that aside from the Complaint, no other patient has, as far as the Record of Proceedings before us is concerned, complained against Dr Devathasan or produced *prima facie* evidence that he or she has suffered any harm because of Therapeutic Ultrasound.

39 This brings us to our second observation on the wording of the Second Charge, *viz*, that it was specifically tied to Dr Devathasan's treatment of *the Patient*. Numerous references to the Patient and the Patient's condition in the Second Charge make it clear that Dr Devathasan was not being charged for using Therapeutic Ultrasound on patients in general. However, upon scrutiny of the Record of Proceedings, we note that the DC hearing drifted continuously beyond a consideration of the use of Therapeutic Ultrasound on the Patient specifically to Therapeutic Ultrasound as a modality *per se* without any reference to the Patient. This deviation was crystallised in the GD, where the DC held that it was for Dr Devathasan to prove that "that the application of Therapeutic Ultrasound on the brain [was] safe *on patients*" [emphasis added]. [note: 29] Had the DC kept to the parameters of the Second Charge, it would not have been improbable for the DC to have concluded that Therapeutic Ultrasound was in fact safe for the Patient, given that it was prepared to accept that the Patient did derive some benefit from Therapeutic Ultrasound (see [18] above) and it had not found any evidence that she had suffered any harm from Therapeutic Ultrasound (see [23] above). It could be added that requiring Dr Devathasan to prove that all patients generally would be better off would be to impose an impossible burden of proof for him to discharge. We note that as far as his patients were concerned, he was prepared to submit their medical records for examination by the DC (see, also, [64] below).

40 Our third observation concerns the phrase "appropriate treatment". It is clear that the Second Charge concerned the "appropriateness" of Therapeutic Ultrasound for the Patient and that there was no reference either in the charge or its particulars to any allegation that Therapeutic Ultrasound was "unsafe" or might cause harm (whether to the Patient herself or to all patients in general). If the SMC had intended to rely on safety considerations to justify the allegation of misconduct, such a serious allegation ought to have *expressly* formed part of the charge and have been *fully particularised*. However, Mr Yeo, in summing up the thrust of the SMC's case before the DC, emphasised that safety was not part of the charges: [note: 30]

> … I will focus on the key issues in my cross-examination, which is essentially he should not be engaging in experiential treatment in the name of therapy outside clinical trials, and all the articles he has referred to only go to show the experimental stage at which a lot of these treatments are at. *We have already said we have not put in the charges that it's harmful*. [emphasis added]

For this very reason, it was not open to the DC to convict Dr Devathasan on the ground of safety

(whether in respect of the Patient herself or all patients in general). The Second Charge as framed was not satisfactorily established factually to justify such a conviction.

41 Additionally, we might add that if the Second Charge had included the element of safety to the Patient as the basis of an allegation of inappropriate treatment, it would not have been made out on the evidence. Pertinently, two expert witnesses for the SMC, Assoc Prof Ong and Prof Lee, both concluded that Therapeutic Ultrasound would have had *no* effect on the Patient, beneficial or otherwise. In his expert report (see [12] above), Assoc Prof Ong said:

> [E]ven if there were any intention to "treat" this patient using ultrasound, in view of the brief time in which ultrasound was applied (15 to 20 minutes), it would appear that such treatment did not serve any useful purpose.

He later corroborated this position in his oral testimony. Prof Lee also said in her oral testimony that "neither ultrasound nor [rTMS] has been evidenced … to show that it has an effect". [note: 31] Accordingly, the DC's conviction of Dr Devathasan on the Second Charge on safety considerations was not justified by the form of the charge.

Therapeutic Ultrasound being neither indicated nor generally accepted

42 In our view, the DC's conclusion that Therapeutic Ultrasound was not indicated and generally accepted because there was no evidence to show that it was safe is problematic.

43 It is clear from the Record of Proceedings and the GD that considerable time and effort was spent on the issue of whether Therapeutic Ultrasound was or was not "generally accepted" by the medical profession. The phrase "generally accepted" is embodied in the particulars given in the Second Charge (see [6] above), and this was in turn based on para 4.1.4 of the ECEG. At this juncture, para 4.1.4 bears repetition:

> A doctor shall treat patients according to *generally accepted methods* and use only licensed drugs for appropriate indications. A doctor shall not offer to patients, management plans or remedies that are not *generally accepted* by the profession, except in the context of a formal and approved clinical trial.
>
> …
>
> It is not acceptable to experiment or authorise experiments or research which are not part of a formal clinical trial and which are not primarily part of treatment or in the best interest of the patient, or which could cause undue suffering or threat to the life of a patient
>
> [emphasis added]

44 The importance of the ECEG was emphasised in *Low Cze Hong* at [37], where we said that they serve "a crucial role in providing an ethical "compass" to guide doctors on what the acceptable standards are from which a departure may constitute professional misconduct". The introduction to the ECEG is also clear on this point:

> *This Ethical Code represents the fundamental tenets of conduct and behaviour expected of doctors practising in Singapore. The Ethical Guidelines elaborate on the application of the Code and are intended as a guide to all practitioners as to what [the] SMC regards as the minimum standards required of all practitioners in the discharge of their professional duties and*

responsibilities in the context of practice in Singapore. It is the view of the SMC that serious disregard or persistent failure to meet these standards can potentially lead to harm to patients or bring disrepute to the profession and consequently may lead to disciplinary proceedings. [emphasis added]

45 Turning to para 4.1.4 which sets a standard of good medical practice, the position appears to be that whenever appropriate, patients should be treated with time tested methods where the benefits and risks have been well researched and documented. The purpose of requiring doctors to conform to generally accepted practices is to ensure that "patients suffer no harm".

46 During the DC hearing, expert witnesses for both sides broadly agreed on the test for when a particular therapy treatment would become generally accepted. In essence, the following factors would be crucial:

(a) there had to be at least "one good study"; [note: 32]

(b) the results of the study can be replicated and reproduced under the same sort of like treatment parameters and conditions; [note: 33]

(c) the study had been written up in publications and presented at meetings; [note: 34]

(d) the study had received peer review; [note: 35]

(e) the study had to have "clear-cut results" and the sample had to be "statistically significant"; [note: 36] and

(f) the study had to have some form of controls, such as randomised double-blind trials. [note: 37]

47 That there was such an agreement on the test to be applied was recognised by the DC in the GD: [note: 38]

Except for Dr Devathasan's personal views, the experts, including Dr Lethlean, have broadly agreed as to what evidence is necessary to constitute a generally accepted method of treatment. *There should be at least one good study involving a statistically significant sample size, followed by publication, discussions and peer review, and which can then be replicated*. [emphasis added]

48 There was nothing to indicate that patient safety would be a crucial factor in determining general acceptance. Yet, in finding that Therapeutic Ultrasound was not generally accepted by the Dr Devathasan's peers, the DC appeared to have applied a test of patient safety and then concluded that because Dr Devathasan had not proved that Therapeutic Ultrasound was safe to patients in general, this treatment was accordingly not generally accepted. Issues of patient safety, however, appear to be more relevant to the test for establishing the situations in which "off-label" uses of treatments are allowed. In other words, the DC appeared to have conflated two different tests in reaching its conclusion of non-general acceptance.

49 From the evidence, "off-label" use of a particular treatment refers to the use of that treatment to treat a condition for which it has not received approval by a regulatory agency. During the DC

hearing, Dr Sharma said: [note: 39]

> [M]y general impression is, off-label means you are using a therapeutic modality. It's a drug, it's a device, it's a combination, whatever it is. *You are using it for an indication which is not mentioned in the literature, or which is not approved by FDA* [*ie*, American Food and Drug Administration], *or it is not approved by any of the approval agencies …*. This is my understanding about off-label use. [emphasis added]

50 The medical profession, both locally and internationally, accepts the practice of using treatments for unapproved indications, provided this is done within certain limits. Expert witnesses for both Dr Devathasan and the SMC agreed that off-label use of treatments was allowed in Singapore. Once again, Dr Sharma's testimony would be revealing: [note: 40]

> This is off-label use. We do off-label use -- In Singapore, if -- you must be knowing [*sic*] it, TPA is not licensed in Singapore to be used in [*sic*] acute stroke. It's not licensed here. We in NUH [*ie*, National University Hospital] use it extensively. In 2008, we gave TPA to 70 patients. Now, this is – this is off-label use.

51 This position was echoed by Dr Devathasan's expert witness, Dr Thirumoorthy, who said: [note: 41]

> I think basically with all due respect to the panel who are practising physicians and clinicians, *I think we do this everyday*, in other words *cases are always complex and difficult and therefore we realise that there are a lot of uncertainties and inadequate information, and it is therefore appropriate that in these sort of situations where we do not have evidence or certain knowledge that extrapolation from modalities, experiences of previous patients that we have treated [*sic*] and sometimes we use a logical appearance [*sic*] balancing of course the risk benefit ratio, the lowest of treatment and the patient's preferences and this is something that happens all the time*, continuously everyday in all the hospitals and the clinics in Singapore. [emphasis added]

52 Earlier, in his expert report, Dr Thirumoorthy wrote: [note: 42]

> In the management of patients of complicated and complex medical illness, *the best available evidence can ethically include the extrapolation from modalities and experience of the clinician from treating other illnesses and the best exercise of logic while balancing the benefits, risk and the likelihood of achieving the set goals of therapy*. The classical example of such exercise of clinical judgment is in the use of medications or drugs in the *"Off-label use" of approved drugs or devices*. [emphasis added]

53 The ECEG unfortunately does not touch on when the use of treatments off-label is allowed. However, some guidance may be derived from both the British General Medical Council ("the GMC") and the American Food and Drug Administration ("the FDA"). In its Supplementary Guidance entitled "Good Practice in Prescribing Medicines (September 2008)" (available at <http://www.gmc-uk.org/guidance/ethical_guidance/prescriptions_faqs.asp> (accessed 8 February 2010)), the GMC dealt with the topic of "Prescribing medicines for use outside the terms of their licence (off-label)", stating: [note: 43]

> 19 You may prescribe medicines for purposes for which they are not licensed. Although there are a number of circumstances in which this may arise, it is likely to occur most frequently in prescribing for children. Currently, pharmaceutical companies do not usually test their medicines

on children and, as a consequence, cannot apply to license their medicines for use in the treatment of children. The use of medicines that have been licensed for adults, but not for children, is often necessary in paediatric practice.

20 When prescribing a medicine for use outside the terms of its licence you must:

(a) *be satisfied that it would better serve the patient's needs than an appropriately licensed alternative*[;]

(b) *be satisfied that there is a sufficient evidence base or experience of using the medicine to demonstrate its safety and efficacy;* the manufacturer's information may be of limited help, in which case the necessary information must be sought from other sources[;]

(c) take responsibility for prescribing the medicine and for overseeing the patient's care, monitoring and any follow up treatment, or arrange for another doctor to do so (see also paragraphs 25-27 on prescribing for hospital outpatients)[; and]

(d) make a clear, accurate and legible record of all medicines prescribed and, where you are not following common practice, your reasons for prescribing the medicine in the patient's notes.

[emphasis added]

54 Similarly, the FDA, in its Information Sheet Guidance entitled ""Off-Label" and Investigational Use of Marketed Drugs, Biologics and Medical Devices" (available at <http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm116355.htm> (accessed 8 February 2010)), sets out similar criteria for off-label use in the US:

Good medical practice and the best interests of the patient require that physicians use legally available drugs, biologics and devices according to their best knowledge and judgement. *If physicians use a product for an indication not in the approved labelling, they have the responsibility to be well informed about the product, to base its use on firm scientific rationale and on sound medical evidence, and to maintain records of the product's use and effects*. Use of a marketed product in this manner when the intent is the "practice of medicine" does not require the submission of an Investigational New Drug Application (IND), Investigational Device Exemption (IDE) or review by an Institutional Review Board (IRB). However, the institution at which the product will be used may, under its own authority, require IRB review or other institutional oversight. [underlining in original; emphasis in italics added]

55 Dr Thirumoorthy's position in both his expert report and his testimony during the DC hearing reflected the British and American position. In the course of his cross-examination, he agreed that there had to be, *inter alia*, "a *[f]irm scientific rationale* and fundamentally sound to use in the chosen clinical situation" [emphasis added], [note: 44] as well as "[e]vidence of *benefit* from anecdotal reports, accepted and used by clinical colleagues" [emphasis added]. [note: 45] Dr Thirumoorthy's evidence was largely corroborated by Dr Sharma, who said that there were "definite rules to say what is off-label, [and] what is not off-label": [note: 46]

… *I will not take something as off-label use if there has been no scientific basis for that particular thing*, right? I am having headache [*sic*]. If I drink this water, and I say my headache goes away, this is not off-label use, Right [*sic*]? Water is not known to remove headache [*sic*].

> One, this water is not scientifically proven to relieve headache [*sic*]. So I cannot tell this was my off-label use [*sic*]. *So off-label has to be that the drug or the device has a scientific basis, or some kind of scientific background is there that you can believe that this is the mechanism, how it can work in that particular situation. This [*sic*] is not proven to be harmful in that condition*. That particular condition is not supposed to be a contraindication for this thing. [emphasis added]

56 Dr Sharma then used TPA as an example and explained why its use was justified as off-label use for acute stroke: [note: 47]

> TPA is known to do the similar kind of thing in heart. It dissolve[s] the blood clot in the heart. So this is how it was developed for brain [*sic*]. If it could dissolve the blood clots in the heart arteries, it can also dissolve the blood clot in the brain arteries. This was the scientific basis of [*sic*] using it in the brain.

57 From Dr Sharma's explanation, it is clear that the use of TPA in acute stroke was based on an extension and/or extrapolation of its existing use in heart arteries to brain arteries. In the same vein, the DC's concerns as reflected in its GD arose from the alleged lack of scientific evidence upon which Dr Devathasan based his extrapolations and conclusions. As regards the absence of a "firm scientific rationale" for Dr Devathasan's use of Therapeutic Ultrasound, it was stated: [note: 48]

> Our concerns arise out of this reasoning being directly applied in a clinical setting without any intermediary experimental or other evidence that the conclusions he sought to draw are valid. At no time in the proceedings has Dr Devathasan indicated that he had verified his assumptions or conclusions through expert consultation, in-vitro or in-vivo experimentation or tests in any form.

58 Immediately thereafter, the DC considered the issue of safety of Therapeutic Ultrasound, stating: [note: 49]

> As a consequence, *there is no experimental evidence or physical proof of the safety of this modality on the human brain*. Dr Sharma's evidence that it was very dangerous to use Therapeutic Ultrasound on the brain, we think, is an overstatement. But as the safety of patients or "do no harm" is a cardinal principle for doctors, it behooves the applicant to satisfy us that the application of Therapeutic Ultrasound on the brain is safe on patients. The extrapolation of potential *beneficial effects* of ultrasound based on studies on extra-cranial tissues to the ischemic brain is also, in our view, weak. [emphasis added]

Here, we pause to mention that the reference above to evidence of "potential benefits" being "weak" does not sit easily with the finding that the Patient benefitted from all the treatments administered to her (see [18] above). If this was indeed the case the DC ought not to have been prepared to make such a finding, at least in respect of the Patient.

59 Based on the twin factors of "firm scientific rationale" and "safety for patients in general", the DC proceeded to find that the use of Therapeutic Ultrasound was "not an appropriate extension of use into clinical neurology practice, particularly with regard to insonation of the brain". [note: 50] What then followed was a failure by the DC to distinguish between the practice of off-label use of drugs or modalities of treatment and the general acceptance of treatment modality. The DC linked its conclusion back to the issue of whether Therapeutic Ultrasound was indicated and generally accepted: [note: 51]

> 38. *Thus*, we find that the use of Therapeutic Ultrasound as a modality is not an *appropriate*

extension of use into clinical neurology practice, particularly with regard to insonation of the brain.

39. *Accordingly*, we find that the treatment with Therapeutic Ultrasound was not indicated and clearly, not generally accepted by his peers and as such, *not an appropriate treatment* for [the Patient's condition].

[emphasis added]

60 What the DC essentially did in the just-mentioned passages was to reason that because the extension of Therapeutic Ultrasound to the human brain was not appropriate (with the consequence that this off-label use of Therapeutic Ultrasound was not acceptable), therefore Therapeutic Ultrasound was not indicated and not generally accepted. However, the off-label use of any treatment, by definition, is the use of that treatment for an indication which has not been approved, as mentioned at [49] above. Thus, the DC erred in using the test for when off-label use of Therapeutic Ultrasound is allowed to establish that Therapeutic Ultrasound was not indicated and not generally accepted. The test for general acceptance was that which was outlined at [46] above. The evidence was clear that issues of safety and presence of scientific rationales for extrapolations had a closer nexus to the determination of when off-label use of a particular treatment is allowed, and not whether Therapeutic Ultrasound was indicated and generally accepted by Dr Devathasan's peers to begin with. It appears, therefore, that the DC relied on the test concerning off-label use to establish that the use of Therapeutic Ultrasound was not indicated and not generally accepted. However, there are different tests for general acceptance and off-label use that can be allowed, and the issue of safety appears to specifically pertain to the latter and not the former.

The standard of proof

61 In the GD, the DC first said that the SMC bore the burden of proving the charges beyond a reasonable doubt. [note: 52] Puzzlingly, it later said that the burden was on Dr Devathasan to prove that Therapeutic Ultrasound was safe for patients (stating that "it behooves the applicant to satisfy us that the application of Therapeutic Ultrasound on the brain is safe on patients"). [note: 53] In our view, the safety of a treatment is not a necessary facet of the inappropriateness of a treatment (see, also, [40] above). Indeed, the SMC's case before the DC was that Therapeutic Ultrasound was inappropriate without any allegations that it was unsafe (see [40] above).

62 In any event, where safety of the patient is an element of the charge, the *legal* burden should still be on the SMC to prove, beyond a reasonable doubt, that the treatment is unsafe for the patient. In such a case, all that the respondent (*ie* the defending doctor) has to show is that there is a reasonable doubt that the treatment is unsafe for that patient. However, where the safety of the patient is not an element of the charge, as here, and where the charge is for inappropriate treatment because that treatment is not indicated for that condition and not generally accepted by the profession, then the *evidential* burden is on the defending doctor to prove that safety of the patient is a reason to negative an assumption of inappropriate treatment on the analogy of "off-label" treatment. We are of the opinion that where a doctor embarks on a treatment that is not indicated or generally accepted in the profession, but the doctor is of the view that his novel treatment may do some good, but will do no harm to the patient, placing such a burden on him to establish that no harm will come to that patient strikes a correct balance between two important considerations in medicine, *viz*, promoting innovation and progress, provided that the patient's well-being is not compromised. On this issue the DC insightfully observed in the GD: [note: 54]

25. … *The practice of medicine is increasingly complex* and the judgment of an experienced clinician is important. *Innovation to help a patient should not be discouraged but neither should the application of novel treatment endanger the patient*.

…

27. … Many a time, *doctors are required and encouraged to innovate for the benefit of the patient* who is in need of help, *provided it is safe and reasonable in the circumstances*.

[emphasis added]

63 The problem with the present case is that the DC could not make up its mind what the gist of the grievance against Dr Devathasan was since neither the Patient nor the Complainants gave evidence. This would explain why it meandered into the area of safety without having first having been satisfied that Therapeutic Ultrasound was inappropriate.

64 In our view, there is yet another unsatisfactory feature in the way the DC conducted the proceedings. This would be its failure to consider Dr Devathasan's evidence on the safety of Therapeutic Ultrasound for patients. Dr Devathasan had produced the names of some patients who had allegedly received and benefitted from the same treatment. He also claimed that he had used the same treatment on approximately 200 patients before the Patient received treatment from him and about 700 patients in total at the time of the DC hearing. In his opinion, Therapeutic Ultrasound could be used not only on Gait Apraxia patients (for which he adduced the Paper to support his use of Therapeutic Ultrasound in conjunction with rTMS), but also those suffering from acute stroke, chronic stroke and other chronic stroke sub-types such as Atherosclerotic Parkinsonism, Cerebral Ischemia and small vessel disease. Lists were provided at the DC hearing, and evidence was also led on specific patients before the DC. Dr Devathasan was put in the invidious position of having to prove that Therapeutic Ultrasound was safe for not only the Patient but also for patients generally. Despite this he had relevant evidence for this purpose. However, the DC declined to consider his evidence.

65 It is not clear why the DC declined to consider Dr Devathasan's evidence. If it was due to the SMC's stance that such evidence was irrelevant to the determination of the appropriateness of Therapeutic Ultrasound (without the element of safety, whether in respect of the Patient or other patients in general), then the DC should not have brought up the issue of safety at all. If the charge was confined to inappropriate treatment arising from treatment which was not indicated or not generally accepted by the profession, then the SMC's case rested only on the absence of one good study and the other requirements laid out at [46] above. If, however, the safety of patients in general was an issue, then in refusing to consider any of the other cases that Dr Devathasan had produced at the DC hearing, the DC had erred in failing to consider material evidence.

66 Dr Devathasan had also produced medical literature and mathematical calculations to establish the safety parameters which he said he complied with. To justify his use of ultrasound at a frequency lower than the accepted level of 2MHz, he calculated the resulting mechanical and temperature changes with reference to two indexes, namely the Mechanical Index ("MI") (which is an estimate of risk from the nonthermal effects of diagnostic ultrasound) and the Thermal Index ("TI") (which is an estimate of risk from heat), and said that the MI and TI levels which resulted from his use of ultrasound were both within the limits accepted by the FDA to be diagnostically safe. He also demonstrated that the amount of ultrasound energy which he used was within the international limit of 500 Joules/sq cm of brain tissue per day.

67 Despite the numerous medical literature and calculations Dr Devathasan produced, the DC found

that "there [was] no experimental evidence or physical proof of the safety of this modality on the human brain", and that "the extrapolation of potential beneficial effects of ultrasound based on studies on extra-cranial tissues to the ischemic brain [was] also … weak". [note: 55] This is puzzling when contrasted with the DC's approach in respect of Dr Devathasan's treatment with rTMS. For that treatment the DC did not require similar proof of safety. The DC's consideration of medical literature adduced in support of rTMS was limited to whether there was a "basis [for applying] rTMS as an extended indication or auxiliary treatment for a patient with [Parkinson's Disease], especially one who has failed other treatment options". [note: 56] As it found that Dr Devathasan's treatment using rTMS "may represent novel treatment and may aid the progress and innovation in medicine", [note: 57] the DC was unable to conclude that his treatment with rTMS was inappropriate for the Patient's condition.

68 Additionally, it was also unclear how the DC factored into its finding of guilt two crucial findings, *viz*, the finding that the Patient benefitted from all the treatments administered to her (see [18] above) and the finding that there was no evidence that any harm had come to the Patient (see [23] above). *Ex facie*, this would call into question its conclusion that Dr Devathasan had failed to establish that he had not compromised the Patient's well-being. It was plain from both findings that the issue of safety was not against Dr Devathasan insofar as the Patient was concerned. She had not come to any harm.

Overstepping the line or turning a blind eye

69 Before convicting Dr Devathasan on the Second Charge, the DC said: [note: 58]

> On this charge, we are of the view that he *must have known that he had overstepped the line, or in his enthusiasm, at the least he turned a blind eye*. After all, Dr [Stephen] Meairs after the 2006 Congress advised him to begin his clinical trials, and the medical literature he produced clearly provided no support. [emphasis added]

70 In our view, the DC's conclusion that Dr Devathasan "must have known that he had overstepped the line, or in his enthusiasm, at the least he turned a blind eye" is contrary to evidence.

71 The DC suggested that Dr Meairs' advice to commence clinical trials ought to have put Dr Devathasan on notice that "he had overstepped the line". [note: 59] However, we note that on the evidence, this advice to Dr Devathasan took place in *2008* (not 2006), *ie*, two years *after* Dr Devathasan had administered rTMS and Therapeutic Ultrasound to the Patient. Dr Devathasan wrote to Dr Meairs, seeking his comments on the Therapeutic Ultrasound aspect of the Paper, after the 6th World Stroke Congress held in 2008. Dr Meairs later replied via e-mail with some advice and encouraged him to prove his concept that ultrasound might have a therapeutic effect by studying a homogenous group of patients and carefully designing the parameters to measure the outcome. The DC was thus mistaken in holding that the exchange between Dr Devathasan and Dr Meairs took place after the 15th International Congress of Biomagnetism held in 2006. As such, it was not open to the DC to deduce from Dr Meairs' e-mail reply that Dr Devathasan "must have known that he had overstepped the line, or in his enthusiasm, at the least he turned a blind eye".

72 Further, we cannot see how Dr Devathasan could be said to have "overstepped the line" or "turned a blind eye" to either the appropriateness or safety considerations of Therapeutic Ultrasound in the light of his *uncontradicted* evidence that before treating the Patient, he had evaluated the suitability of Therapeutic Ultrasound for the Patient, and had administered rTMS and Therapeutic Ultrasound only after adjusting her medication in accordance with standard procedure for such

treatment. Throughout the application of the combined treatments, he also took clinical notes and continued to prescribe the altered medication. Significantly, Dr Devathasan also said that he would not have used both treatments on the Patient had she been a "new case". In this regard, the Patient was not a "new case" in that she had consulted several other neurologists and specialists but had not improved. In our view, the DC's finding was also inconsistent with its acceptance that Dr Devathasan was motivated to help the Patient (see [19]–[20] above), that the Patient benefitted from Therapeutic Ultrasound (see [18] above) and that no harm had come to the patient (see [23] above).

73 Furthermore, the evidence shows that Dr Devathasan not only believed that Therapeutic Ultrasound could help this particular patient, he was confident that when used in combination with rTMS, it would benefit patients afflicted with conditions similar to the Patient's condition *in general*. Dr Devathasan's honest belief in the efficacy of Therapeutic Ultrasound was reflected in a proposal he submitted to the Agency for Science, Technology and Research and the Ministry of Health detailing his novel combination of rTMS and Therapeutic Ultrasound. In his proposal, he explicitly stated his belief that this combination of therapies would place Singapore in the forefront of medicine and that he was not seeking funding. Crucially, he said in his proposal that further clinical trials to verify his findings might be desired, even though his personal view was that they were not necessary: "[i]f needed (although I feel there is no need) you could initiate an institutional clinical study double blind". [note: 60] This was not the conduct of a doctor who must have "known that he had overstepped the line".

Conclusion

7 4 *The present appeal was not a case where the SMC had taken issue with the doctor's motivation for administering a particular treatment, his competence in that field of medicine or his firm belief that the treatment he administered would be efficacious*. The SMC had not suggested that Dr Devathasan was motivated by improper pecuniary or other reasons in prescribing unnecessary procedures to the Patient. In fact, it even acknowledged during the proceedings before us that Dr Devathasan had acted in good faith in treating the Patient. This echoed the opinion of the DC that Dr Devathasan honestly believed that the treatment was in the interests of the Patient.

75 For the reasons given above, we find that the DC's decision in convicting Dr Devathasan was wrong in law. The Second Charge was not proved beyond reasonable doubt. In coming to our decision, we make no finding as to whether Therapeutic Ultrasound was efficacious or safe or scientifically established. Our role as an appellate court is to ensure that the DC's finding is not "unsafe, unreasonable or contrary to the evidence". Unfortunately, given the way in which the charge was framed, the manner in which the proceedings were conducted (including the fact that neither the Patient nor the Complainants testified during the DC hearing and showed no further interest in pursuing the matter against Dr Devathasan beyond the lodgement of the Complaint) and the diffused reasoning of the DC, we find that Dr Devathasan's conviction on the Second Charge was unsafe, unreasonable and contrary to the evidence and therefore set it aside.

76 With regard to the costs for the proceedings before the DC and this court, we have decided that in all the circumstances, we will not order the SMC to pay the costs of the proceedings as we are prepared to give it the benefit of the doubt that it had acted in good faith and in the public interest in trying to stop what it believed to be an inappropriate treatment for a particular medical condition. The parties are to bear their own costs. The usual consequential orders are to apply.

77 In closing, we find it necessary to express our concern that the DC's failure to understand the nature of the charge against Dr Devathasan and the evidence required to prove the same left much to be desired. The proceedings against Dr Devathasan, beginning with the framing of the original

charges, to the amendment of the same very late in the day, to the relevancy of the evidence that was adduced to prove the charge, and finally the legal reasoning leading to the finding of guilt against Dr Devathasan on the Second Charge, could have been better handled. In this connection, it is just as well that the Act has been recently amended to allow the appointment of a legally trained person (be it an ex-Judge or ex-Judicial Commissioner of the Supreme Court, an advocate or solicitor of at least 15 years' standing, or a legal officer from the Singapore Legal Service with at least 15 years' experience) to sit as one of the members in the SMC's Disciplinary Committees. Unlike the external legal assessor who only advises on issues referred to him or her, we believe that having a legally trained member as part of a Disciplinary Committee would ensure due process and a fuller appreciation of the nature of the proceedings against alleged errant doctors. In the present case, the DC tied itself up in a confusing pattern of intricate legal knots which we have found impossible to unravel without having to set aside the conviction.

[note: 1] GD at para 1

[note: 2] Dr Devathasan's affidavit filed on 7 September 2009 at pp 94–95

[note: 3] Dr Devathasan's affidavit filed on 7 September 2009 at pp 95–96

[note: 4] Dr Devathasan's first affidavit filed on 7 September 2009 at pp 69–71

[note: 5] GD at para 41

[note: 6] GD at para 40

[note: 7] Inquiry Bundle vol 1, p 9

[note: 8] Inquiry Bundle vol 1, pp 60–61

[note: 9] Inquiry Bundle vol 1, p 61

[note: 10] Record of Proceedings vol 3, p 748

[note: 11] Record of Proceedings vol 3, p 747

[note: 12] Dr Devathasan's first affidavit filed on 7 September 2009 at para 22

[note: 13] Dr Devathasan's first affidavit filed on 7 September 2009 at para 22.

[note: 14] Inquiry Bundle vol 1, p 8

[note: 15] Record of Proceedings vol 1, p 254

[note: 16] Record of Proceedings vol 1, p 254

[note: 17] GD at para 6

[note: 18] GD at para 6

[note: 19] GD at para 13

[note: 20] GD at para 46

[note: 21] GD at paras 30–31

[note: 22] GD at paras 26 and 30

[note: 23] GD at para 46

[note: 24] GD at para 37

[note: 25] GD at paras 37–39

[note: 26] GD at para 36

[note: 27] Record of Proceedings vol 2, p 385

[note: 28] GD at para 38

[note: 29] GD at para 37

[note: 30] Record of Proceedings vol 3, p 680

[note: 31] Record of Proceedings vol 2, p 518

[note: 32] Record of Proceedings vol 2, p 354

[note: 33] Record of Proceedings vol 2, p 355

[note: 34] Record of Proceedings vol 2, p 356

[note: 35] Record of Proceedings vol 2, p 357

[note: 36] Record of Proceedings vol 2, pp 357–358

[note: 37] Record of Proceedings vol 2, p 359

[note: 38] GD at para 17

[note: 39] Record of Proceedings vol 1, p 163

[note: 40] Record of Proceedings vol 1, p 164

[note: 41] Record of Proceedings vol 4, p 848

[note: 42] Inquiry Bundle vol 1, p 315

[note: 43] Good Practice in Prescribing Medicines (September 2008) at paras 19 and 20

[note: 44] Record of Proceedings vol 4, pp 856–857

[note: 45] Record of Proceedings vol 4, p 858

[note: 46] Record of Proceedings vol 1, pp 163–164

[note: 47] Record of Proceedings vol 1, p 165

[note: 48] GD at para 36

[note: 49] GD at para 37

[note: 50] GD at para 38

[note: 51] GD at paras at 38–39

[note: 52] GD at para 21

[note: 53] GD at para 37

[note: 54] GD at paras 25 and 27

[note: 55] GD at para 37

[note: 56] GD at para 31

[note: 57] GD at para 30

[note: 58] GD at para 40

[note: 59] GD at para 40

[note: 60] Dr Devathasan's first affidavit filed on 7 September 2009 at pp 182–183