SURANA & SURANA
International Attorneys
Chennai | New Delhi

COCHIN UNIVERSITY OF SCIENCE AND TECHNOLOGY

Moot Proposition

2ND SURANA & SURANA AND CUSAT SCHOOL OF LEGAL STUDIES, DR. A.T MARKOSE MEMORIAL MOOT COURT COMPETITION, 2021

22 – 24 OCTOBER 2021

Minto Biotech Pharmaceuticals Ltd. v. Central Drug Authority

1. The Federal Republic of Samantica is a democratic country situated in the Southern part of the Asian Sub Continent. It is the second-most populous country, the seventh-largest country by land area, and the most populous democracy in the world. It is a pluralistic, multilingual and multi-ethnic society. The country has become a fast-growing major economy and a hub for information technology services. The Constitution of Samantica entrusts the State with the obligation to provide healthcare for its people. Till the end of 20th Century, only public hospitals were allowed in the Republic of Samantica and it was only in the wake of the new millennium, private entities were given licence to establish and run hospitals.

2. Beginning of the 21st Century witnessed a boom in the healthcare sector in Samantica with several super speciality hospitals being established at various cities across the country. Private hospitals in Samantica offered world class quality healthcare at a fraction of the cost for medical procedures in comparison with the hospitals of the developed countries, which made Samantica a popular destination for medical tourists from various parts of the world. By the end of first decade of the 21st Century, the private healthcare industry in Samantica grew into one of the most established healthcare systems of the world.

3. The Government of Samantica formulated a National Health Policy in 2015 (hereinafter referred to as NHP) with an aim to expand the research and development in the healthcare sector. The NHP allowed the foreign investors to invest in the healthcare sector, which resulted in the entry of various international hospital brands in Samantica. The procedure for approval and licensing of the pharmaceutical drugs and medical devices in the Republic of Samantica is governed by the Drugs and

Medical Devices (Approval and Registration) Act, 1957 (hereinafter referred to as the Act). Under the Act, the Central Drug Authority (hereinafter referred to as CDA) is vested with the power to give approval and license for the medical devices. In case of any dispute arising out of the approval and license of any pharmaceutical drugs or medical devices, the appeal from CDA shall lie to the High Court within whose jurisdiction the licensee or the company is located.

4. Minto Biotech Pharmaceuticals Inc., a Multinational Company having presence in almost all major countries, is in all sense, a pharmaceutical giant, established it's Subsidiary Company in Samantica in 2016. The Company was registered under the Companies Act, 2013 with the name, Minto Biotech Pharmaceuticals Ltd. (hereinafter referred to as Minto Biotech) with its head-quarters at the city of Alpaca in the State of Leh. Apart from the development of drugs and medical consumables, Minto Biotech is also a major player in innovations in medical devices for diagnosis, surgical devices and medical interventional solutions for Orthopaedics, Surgery (General & Advanced), Vision and so on. Many break-through medical devices using state of the art technology were conceived, developed, manufactured and marketed across the world by Minto Biotech.

5. Minto Biotech initiated a project in the year 2017 as a joint venture with a few major hospitals around the world for developing Information and Communications Technology (ICT) enabled medical devices and invasive surgical devices. The joint venture was involved in the Research and Development of Artificially Intelligent programmed devices for diagnosis, development of treatment protocol, drug development, personalised medicine, and patient monitoring and care. Minto Biotech was specifically focused on the development of an artificially intelligent prototype to perform complicated diagnostic and medical procedures for certain serious medical conditions. The automated device they developed was named as Dr.AI (hereinafter referred to as "the device"). The device used some proprietary complex algorithms

designed to perform certain automated tasks and were embedded with capability to improve by itself using 'Deep Learning'.

6. Minto Biotech filed an application before the CDA on 21st January, 2020, in the specified format under the Medical Device Rules, 2018 for getting the approval and license for the device to put in use. In the said application, the Minto Biotech specifically disclosed that the procedures encoded in the device were in tune with the standard operating procedures followed by the medical fraternity. However, the application of Minto Biotech also stated that subsequent improvements in the procedures would be self learning by the device through Artificial intelligence embedded in it. The application further stated that the device as a result of such self-leaning will improvise the settled or accepted protocol which is available currently. Such improvised protocols will be developed by the device itself on the basis of the results of procedures done by the device over a period of time.

7. CDA thoroughly analysed the application and suggested that the protocols which are fed to the device should be conveyed clearly to the CDA in a time bound manner and such devised protocols should get the approval by the CDA before it could be put to use in healthcare systems. The CDA followed the procedure prescribed under the Drugs and Medical Devices Act, 1957 with respect to the approval process and held that the process submitted by Minto Biotech could not be approved as they are not confident as to what protocols will be developed by the device on its own in future. CDA also expressed its apprehension over the development of diagnostic and procedural protocols by the device on its own, through Artificial Intelligence without any Human intervention or input. The decision of rejection of application was communicated to Minto Biotech in writing on 24th of February, 2020.

8. Aggrieved by this decision taken by CDA, the Minto Biotech approached the High Court of Leh on 6th of March, 2020. Minto Biotech argued that the device is innovative and can be put to use for the diagnosis and treatment of various serious diseases in a large scale at lower cost which will result in increased Health care access

to mankind. Minto Biotech contended that the development of new diagnostic and treatment protocols can not be given in advance to the CDA as the device will be developing the new protocols on the go using its self-learning technology. According to Minto Biotech, each procedure performed by the device is also a learning process for the device. Thus, various procedures developed for each individual diagnosis will be individualistic in nature and will be of different variations. Minto Biotech further contended that the new protocols that will be created by the device may be totally different from the existing ones or improvement of the existing ones, as the device is capable of evolving and generating future protocols on its own, but will be only inconsonance with the end objective

9. The High Court decided that the condition prescribed under the Act is not suitable to deal with the technological advancements, especially in relation to the application of AI and the condition automatically reduces the scope of utilization of the latest technologies for the betterment of mankind. In its judgment, the High Court noted that the initial procedures carried on by the device were based on the established protocols which were already fed into the device. However, the improvised or developed protocols, which the device may develop in future, were only improvements of these initial protocols. Hence, the High Court of Leh ordered CDA to reconsider giving approval for the prototype after analysing whether there is any error in the procedure followed by the device.

10. The High Court further directed that in order to ascertain the efficacy of the device with respect to different procedures, CDA has to conduct a trial run of the device and based on the same, to compare the errors made by the device *vis a' vis* the chances of human errors for the same procedure. If the errors made by the device are lesser when compared to the human errors in the similar procedures, then CDA can decide to give approval to the device.

11. Following the direction, Minto Biotech put the prototype for the trial run as per the parameters set by the CDA. CDA after careful and close monitoring has concluded that the chances of error of the device were negligible and the efficiency was far

superior than that of the similar procedure performed by even experienced doctors. Thus, based on these findings, and in consonance with the order of High Court of Leh, CDA gave approval for Dr.AI.

12. On the basis of the approval given by the CDA, various hospitals which were part of the joint venture, installed the device in their facilities. Certain hospitals which belonged to other countries also gave approval to the technology in their domestic jurisdiction straightaway, as it was approved by the CDA. Thus, by the end of 2020, the device was installed in various hospitals in various countries across the globe. However, there were other countries that mandated independent approval by their own regulatory authorities. Hospitals in such jurisdictions made arrangements in the hospitals within Samantica whereby they were willing to share their facilities which could be used after transferring the patients to Samantica.

13. All Dr.AI devices around the world were centrally linked to a master system which collated all the procedures done by the devices throughout the world and used the data therein for improving the already fed procedures by using Artificial Intelligence to evolve the new procedures by the device. The learning curve of the system was exponential as a result of analysing the diagnostic procedures and the large number of complicated invasive procedures performed with the assistance of the device and the derivative information gathered from that. The efficiency of the device could be explained in simple language as similar to a team of specialists performing diagnosis procedures and a team of expert surgeons performing multiple surgeries simultaneously. The device was automatically getting upgraded with newer protocols and procedures which it was learning through Artificial Intelligence acquired through the feed of the diagnostic procedures and surgeries performed.

14. However, within a very short span of time, the technical team of Minto Biotech was incapable of identifying the amount of self-learning done by the device even with the help of experts in the medical field and they were unable to predict or even think of what the device would be doing during the next diagnostic and invasive procedures. In short, Minto Biotech has lost its control over the procedures and protocols followed

by the device. This was the position of all the hospitals which implemented the device.

15. The medical fraternity across the globe noticed that though the device was highly efficient, the newly developed protocols were against many of the already laid down protocols. At times, device self-made protocols were also even contradictory to the established protocols which the device was fed with during the application process for approval. The deep learning algorithm of the device was not only improving itself by devising new protocols, but also evolving *de novo* by negating the techniques that were fed to it initially.

16. Irrespective of all the issues, the success rate of the device was so high so that it was impossible to find any errors in the process *vis a' vis* that of the end result. However, Dr. Perfect, Head of the Department of Cardiology, Lifefine Multi Specialty Hospital, city of Alpaca, who was also a part of the team of experts involved in the development of the device, was worried about the total dependence on the device, which was not at all in the control of Minto Biotech nor the doctors involved therein. Dr.Perfect expressed his concerns during the Annual Conclave of Cardiologists which took place from 17th to 20th of January, 2021. A few cardiologists led by Dr. Perfect, under the name Society of Cardiologist of Samantica (hereinafter referred to as SCS), made a representation to CDA to cancel the approval and license given to the device.

17. SCS also requested to CDA to prevent the use of the technology driven automated devices on the ground that the initially fed protocols which were the basis of the approval by CDA is no more followed by the device. SCS expressed its concern that the approval process itself was vitiated and the direction of the court in its spirit was floated as the device is working on the protocols created by itself, and requested CDA to cancel the approval given to the device. SCS also observed that, the purpose for which Dr.AI was created initially has been altered by the product itself and no one has the control over what will be done by the device in the next procedure. They were of the opinion that it would be "shocking to accept the fact that the way in which the

device is unlearning the old information fed to it and developing new algorithms would be disastrous to the healthcare sector".

18. Meanwhile, CDA was alerted about the present dilemma which is faced by the device, by various professional bodies including Samantican Medical Association (hereinafter referred to as SMA). Medical practitioners and surgeons who were also experienced in automated medical devices also expressed their concern regarding the same. Taking note of this, CDA issued an order on 18th February, 2021 to stop using the device immediately in all hospital facilities, until further orders, within the territorial limits of Samantica.

19. Aggrieved by this order, Minto Biotech approached the Supreme Court of Samantica *via* Writ Petition contending that the action taken by the CDA is violative of the provisions of the Act as well as against the principles of natural justice. Minto Biotech also contended that the CDA had already given approval after analysing the efficiency of the device and only after fully convinced that the device is far way more efficient than the diagnostics and medical procedures performed even by the most experienced medical practitioners and surgeons. Minto Biotech further contended that they have invested huge amount in the research and development of the device. On the same day of the CDA's order to stop using Dr.AI at the hospitals, the value of Minto Biotech Pharmaceuticals Inc. and its subsidiaries has gone down drastically in the Stock Markets. License given by various countries to operate Dr.AI in their respective jurisdictions solely on the ground that it was approved in Samantica by CDA, was also at stake because of the new order given by CDA.

20. Since it was a matter which required urgent disposition, the Supreme Court of Samantica decided to hear the matter and issued notice to all the parties concerned. As an independent medical body, Supreme Court also issued notice to SMA to give their professional expert opinion regarding the subject matter. The questions related to the *locus standi* of the parties and maintainability has been decided and the Supreme Court posted to hear the matter on --/10/2021.

21. The issues framed by the Supreme Court to argue before it is as follows:

a. Whether the action of CDA in revoking the approval and license of the device is valid?
b. Whether the "process" followed by the device is to be taken into consideration or the "results" produced by the device is to be considered for the purpose of approval and license by CDA?
c. Whether the self-developed protocols of the device, which are not in conformity with the established medical protocols, could be permitted to be followed in the diagnosis and treatment?
d. Whether a highly beneficial technological improvement, be considered as not acceptable only because of the reason that it is against the established protocols and expertise, and for not fitting into the existing legal framework?

Note:

- The Constitution and laws of the Republic of Samantica are in *pari materia* to the laws of India. However, the Drugs and Medical Devices (Approval and Registration) Act, 1957 does not correspond to any existing legislations in India.
- This moot proposition is a work of fiction. Names, characters, businesses, places, events and incidents are either the product of the author's imagination or used in a fictitious manner. Any resemblance to actual persons, living or dead, or actual events is purely coincidental.
- The decisions of the organizers shall be final and binding.