Intellectual Property Office of Singapore Case Summary: Lonza Biologics Tuas Pte Ltd v Genpharm International Inc [2015] SGIPOS 13

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The applicants applied to invalidate the proprietor's patent (SG 905) in part. In its counter-statement, the proprietor offered to amend some of the disputed claims. It was held that the amendments ought to be allowed since these were made in *bona fide* attempts to narrow the issues in dispute and expedite the proceedings.

The proprietors withdrew from the hearing after filing its counter-statements and evidence. An evidential objection was raised as to whether the proprietor's expert evidence should be considered since it did not participate in the hearing and its expert was not presented for cross-examination. It was held that the proprietor's acquiescence and course of conduct was sufficient to amount to an acceptance of the applicant's proposal to apply the Evidence Act to the hearing. Further, it was held that ***Martek Biosciences Corp v Cargill International Trading Pte Ltd*** **[2011] 4 SLR 429; [2011] SGHC 71** established the principle that the written testamentary evidence a witness who does not appear before a tribunal and allow himself to be cross-examined ought to be excluded, unless a hearsay exception was applicable, as to keep it on record would be prejudicial to the opposing party. Rule 80(10) of the Patent Rules permitted the inclusion of this principle for IPOS hearings. However, expert evidence filed together with the proprietor's counter-statement ought to remain on record as these formed a necessary part of the counter-statement.

The patent was challenged on two main grounds at the hearing: insufficient disclosure and lack of inventiveness. The SG 905 patent claimed a certain affinity binding strength for antibodies produced following the patented process. The applicant's challenge on insufficient disclosure was based on two prongs. First, there is nothing in the patent specifications that showed affinity binding strength in the order of magnitude claimed. Second, assuming that the affinity binding strength in the order of magnitude could be obtained, the patent specifications did not disclose all the steps necessary in order for the reasonably skilled technician to obtain the results. A consideration of the patent specifications bore these challenges out. The example that pertained to affinity binding did not yield binding constants in the range that was claimed. Other examples in the patent specifications disclosed methods of testing for avidity binding.

The applicant relied heavily on the proprietor's prior patent (D8) and the patent re-examination report on its ground of challenge for lack of inventiveness. The inventors of the D8 and the SG 905 were substantially the same persons. Applying the approach set out in ***Windsurfing International Inc. v Tabur Marine (Great Britain) Ltd.*** **[1985] RPC 59**, it was held that the inventive concept of SG 905 was that it produced fully human antibodies with high affinity constants through the introduction of human transgenes into a mouse. Further, the D8 patent in the prior art already taught the introduction of human genetic material into a mouse in order to produce transgenic antibodies, which were known to bind with human CD4 globular antigens. Scientific journals that formed part of the prior art had also taught that the introduction of genetic materials created diversity which in turn improves the therapeutic effect of the resulting antibody. Additionally, the patent specifications for D8 and SG 905 were identical for significant parts thereby leading the applicant's expert and the patent examiner who prepared the re-examination report to conclude that SG 905 was no more than routine analysis of the end product derived from the process taught in the D8 patent. The ground of challenge for lack of inventive step was found to have been successfully established as the affinity values that SG 905 (after its correction) reported were already claimed in the D8 patent. SG 905 appeared to only have expanded the scope of tests conducted to include both naturally occurring and recombinant CD4 human globular antigen. Finally, SG 905 taught the crossing of the KCo5 mouse (disclosed in the D8 patent) with a HC2 mouse in order to increase diversity. In view of the established prior art, this was an obvious step for a reasonably skilled technician to take.

The partial revocation was therefore successful.

Disclaimer: The above is provided to assist in the understanding of the Registrar's grounds of decision. It is not intended to be a substitute for the reasons of the Registrar. The full grounds of decision can be found at https://www.ipos.gov.sg/resources/hearing-mediation.