

From: Oliver Smith <oliver.smith@simigen.com>
To: Attorney
Re: Proposed lawsuit for infringement of patent

PRIORITY CONFIDENTIAL EMAIL

Dear Attorney,

I write further to our previous correspondence confirming your engagement for legal action in relation to infringement of our patent. The relevant factual background is provided below.

Our company, Simigen Pvt. Ltd. is a reputed pharmaceutical company having its registered office and carrying on business in the Combined States of Asia (*hereinafter 'CSA'*) and is engaged in the development and manufacture of life saving drugs at affordable prices to consumers.

We have been carrying on business through our registered office in New City since 1995 and also have corporate offices in four states of CSA viz. Hypercity, Chexpress, Begalor and Mumpav. Our company records as available on the official website of the Ministry of Corporate Affairs are enclosed as **Annexure – A**.

Simigen is one of the leading innovators in the biotech space and we have an extensive portfolio of biotech drugs based on indigenous innovation and acquisitions. Our main research focus is in the field of diabetes and we have obtained several patents covering our innovations.

Simigen is the owner of the Patent No. CSA777555 (*hereinafter the '555 Patent'*) which has corresponding patents in several countries, including the United States of America, for acidic insulin preparations having improved stability. A copy of the 555 Patent is enclosed as **Annexure – B**.

We have been marketing the aforesaid product under the trademark 'Acilin pH' in Europe since 2004, which is when we received European approval.

We commenced import and sale of Acilin pH in CSA in May 2004, upon receiving approval from the CSA Drug Regulatory Authorities. We also have exclusivity for our product in view of the Biologics Price Competition and Innovation Act, 2009 (*hereinafter the 'BPCI Act'*). The act is enclosed as **Annexure – C**.

Gencon GmbH is a European company, with a pharmaceutical patent portfolio which includes several biopharmaceutical products. Please find enclosed the records and relevant details of this company as **Annexure – D**.

In early 2015, Gencon claimed to have developed insulin glargine which has a similar therapeutic profile to that of Acilin pH as well as heat stability properties which enabled it to be stored without refrigeration. They also claimed to have applied for patents in relation thereto in the European Patent office and several other countries. Gencon claims that its patent application is presently pending in CSA.

Gencon operates through its wholly owned subsidiary in CSA viz. Gencon CSA Pvt. Ltd. (*hereinafter 'GCPL'*), which has its registered office in Hypercity. Details pertaining to GCPL are provided in **Annexure E**.

In May, 2016 GCPL applied for marketing approval in CSA under the BPCI Act in order to employ the expedited pathway for approval of biosimilars provided therein. As per BPCI Act, GCPL and Simigen were to engage in a multi-stage exchange of information which includes the biosimilar application and manufacturing information.

Accordingly, GCPL shared with Simigen's in-house counsel, some of their confidential information for the manufacturing process and composition of insulin glargine. Even this much information confirms that GCPL

will infringe the '555 Patent. We immediately responded to GCPL and stated that on the basis of the information provided by GCPL, their proposed product would infringe the '555 Patent. GCPL, despite agreeing that the '555 Patent is relevant for the present dispute, broke down the ten-day long negotiations, stating that they have been advised by their counsel that such exchange of information is not mandatory. We strongly object to this, as they are refusing to 'dance' as per the provisions of the BPCI Act.

We were taken by surprise when GCPL announced its intention to launch their insulin glargine, Innoglar, across CSA by August 28, 2016. A recent news report pertaining to this is enclosed as **Annexure – F**.

You will note from these reports that GCPL officials repeatedly refer to their proposed product as an Acilin pH biosimilar and propose to launch Innoglar at less than half the cost of Acilin pH. We are naturally very concerned that the launch of Innoglar will have a detrimental impact on the sales of Acilin pH. We have obtained a sample product packaging for Innoglar which is enclosed as **Annexure – G**.

GCPL claims that Innoglar will have a suitable shelf life for the hot CSA weather. We issued a letter to GCPL informing them that Innoglar infringes our '555 Patent. In its reply however GCPL denied the validity of our '555 Patent on the grounds of lack of inventive step and novelty and non-patentability under section 3 of the CSA Patents Act.

GCPL also claims to have filed a patent for a temperature resistant form of insulin glargine. However we do not have a copy of this patent application since it does not seem to have been published. No information related to any such patent was shared with us during the "patent dance" with GCPL.

Since Innoglar has not yet been launched in the market, we have been unable to conduct any tests to confirm whether it infringes any of the claims of the '555 Patent. However we are certain that any product which provides a stable insulin glargine, like Innoglar, will infringe the '555 Patent.

We therefore wish to file a law suit to restrain Gencon and GCPL from infringing the '555 Patent and commercially launching the infringing product Innoglar in the market. However the core issue which is of primary importance to us is that GCPL is obligated to provide us all relevant information during the "patent dance" process and is denying the same. You will appreciate that this information is crucial for us and we strongly want to obtain a court order holding that the exchange of information under the BPCI Act is mandatory and directing Gencon to furnish us with the same.

I will be signing the documents for this suit and have been designated the Constituted Attorney for the suit.

Kindly take urgent action in the matter. Please note that we will require the plaint and supporting applications, if any, **latest by July 21, 2016**.

Best regards

Oliver Smith
Asst. Vice President
Legal Operations
Simigen Pvt. Ltd.