Federal Court Cour fédérale

Date: 20221027

Docket: T-607-21

Citation: 2022 FC 1476

Ottawa, Ontario, October 27, 2022

PRESENT: The Honourable Mr. Justice Southcott

BETWEEN:

APOTEX INC.

Plaintiff

and

JANSSEN INC., JANSSEN ONCOLOGY INC. and BTG INTERNATIONAL LTD.

Defendants

PUBLIC ORDER AND REASONS

I. Overview

[1] This decision relates to a motion by Janssen Inc., Janssen Oncology Inc., and BTG International Ltd., [together, Janssen], the Defendants in the within action brought under section 8 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-113 [the Regulations].

In the underlying action, the Plaintiff, Apotex Inc. [Apotex], claims against Janssen damages for lost sales of abiraterone acetate.

[2] In this motion, Janssen moves under Rule 51 of the *Federal Courts Rules*, SOR/98-106 [the Rules] to appeal the order dated June 14, 2022 [the Order] of Prothonotary Milczynski (now Associate Judge Milczynski), who is case managing this action [the Case Management Judge]. In the Order, the Case Management Judge declined, on the basis of relevance, to compel Apotex to answer certain discovery questions related to Apotex's United States [US] activities with respect to its abiraterone acetate product.

[3] Some of the evidence adduced in this motion is subject to a Confidentiality Order, in order to protect commercially sensitive confidential information of the parties. A draft confidential decision was therefore sent to the parties on October 7, 2022, to allow them to propose any redactions required for the issuance of the public version of the decision. The parties have jointly proposed redactions. As these redactions will not affect the intelligibility of the decision, I am satisfied that they appropriately balance the interests of protecting confidential information and the public interest in open and accessible court proceedings. As such, two versions of this decision, one public and the other confidential, will be issued simultaneously.

[4] As explained in greater detail below, Janssen's motion is granted, because I find that the Case Management Judge erred in concluding that these discovery questions were not relevant to the issues in this action as defined by the parties' pleadings.

II. **Background**

[5] Janssen markets the prostate cancer drug abiraterone acetate in Canada as ZYTIGA and listed Canadian Patent No. 2,661,422 [the 422 Patent] on the Patent Register in respect of ZYTIGA.

[6] Apotex sought to market a generic abiraterone acetate product and challenged the validity of the 422 Patent. In turn, Janssen commenced an action under section 6 of the Regulations against Apotex in respect of its products. On January 6, 2021, Justice Phelan dismissed Janssen's claim and declared the 422 Patent to be invalid (see *Janssen Inc v Apotex Inc*, 2021 FC 7).

[7] Justice Phelan's dismissal of the section 6 action crystallized a cause of action for Apotex under section 8 of the Regulations. On April 12, 2021, Apotex commenced the within action claiming damages against Janssen for lost sales of Apotex's abiraterone acetate product. This action is scheduled for trial beginning on June 19, 2023.

[8] Apotex's Statement of Claim alleges that, but for Janssen's conduct, it would have received its Notice of Compliance [NOC] from Health Canada and sold its abiraterone acetate product in Canada on August 8, 2019. As a result, Apotex alleges that its sales were delayed from August 8, 2019 until January 11, 2021, when it ultimately received its NOC in the real world.

[9] In response, Janssen pleaded in its Statement of Defence that Apotex did not have the ability and/or capacity to manufacture and supply sufficient quantities of Apotex's abiraterone

acetate product to satisfy the Canadian generic market for this drug. Apotex denied this allegation in its Reply.

[10] Shortly prior to its discovery of Apotex's representative, Janssen produced documentation [that the parties refer to as the US Data Document] purporting to contain data in relation to sales of abiraterone acetate products in the US. As will be explained in more detail later in these Reasons, Janssen alleges this data shows that Apotex suffered a supply disruption beginning in and around March 2019, as a result of which it could not manufacture sufficient quantities of its abiraterone acetate product to satisfy the US market.

[11] During its examination for discovery of Apotex's representative, Janssen's counsel asked a number of questions that Janssen considers to be relevant to whether Apotex could have supplied the Canadian market starting in August 2019 in the but-for world. Apotex refused to answer several questions of this sort, related to its manufacturing for and sales in the US market, following which Janssen brought a motion to compel answers to these questions and others. Relevant to this motion are Items 86, 87, 88, 94, 95, 98, and 241 of Janssen's motion to compel answers from Apotex dated May 20, 2022 [the Disputed Questions], which are reproduced below:

Item	Page No.	Question No.	Question
86	217	617	To advise whether Apotex was ever unable to fulfill orders to customers in the U.S.
87	217-218	618	To advise why Apotex had a decline in abiraterone market share from March 2019 (32%) to June 2019 (2.7%) (see Janssen production 103, Row 15).
88	218	619	To advise whether Apotex had a decline in market share from March 2019 (32%) to June 2019 (2.7%) because it couldn't supply its customers with Apo-abiraterone product (see

			Janssen production 103, Row 15)
94	222-223	632-633	To advise whether the Apo-abiraterone tablets sold in the US is the same product as what is sold in Canada
95	225	637	To advise whether the Etobicoke or the Signet facilities are the plants were (sic) Apo-abiraterone that is sold in the US is made (see Apotex production 15)
98	226-227	643	To advise whether Apo-abiraterone sold in the US has gone on back order and that is why there was a steep decline in Apotex's sales in the US
241	387-388	1053	To advise whether the abiraterone API for the Canadian market was different than for the US market

[12] In the Order under appeal, the Case Management Judge ordered Apotex to answer several questions but dismissed Janssen's motion with respect to the Disputed Questions. Although the Order does not provide reasons for this portion of the Case Management Judge's decision, both parties' written representations characterize the decision as based on the relevance of the questions. I understand it to be common ground between the parties, based on their arguments and the Case Management Judge's comments at the hearing of the motion, that she dismissed this portion of the motion because she found the Disputed Questions to be irrelevant.

III. **Issues**

[13] In this motion, Janssen seeks an order setting aside the part of the Order that relates to the Disputed Questions and requiring that Apotex answer the Disputed Questions and related follow-up interrogatories. Janssen articulates the issues for the Court's consideration on this motion as follows:

A. Whether the Case Management Judge erred in determining that the Disputed Questions were not relevant; and

B. Whether, in any event, the Disputed Questions are relevant and proportional and Apotex ought to be compelled to answer the questions.

[14] I accept that these issues represent an appropriate framework for addressing the parties' arguments, subject to first addressing a disagreement between them as to the applicable standard of review.

IV. **Standard of Review**

[15] The standard of review applicable to decisions of prothonotaries (now associate judges) is that explained by the Supreme Court of Canada in *Housen v Nikolaisen*, 2002 SCC 33 [*Housen*] (*Hospira Healthcare Corporation v Kennedy Institute of Rheumatology*, 2016 FCA 215 at para 79). That is, pure questions of law are reviewable on the standard of correctness. On questions of fact or mixed fact and law, a reviewing court should interfere only if it identifies a palpable and overriding error in the decision under appeal. Consistent with these principles, if the decision involves an extricable question of law, the standard of correctness applies to that question.

[16] Janssen asserts that the first issue articulated above, whether the Disputed Questions are relevant to the pleaded issues in dispute, is a question of law, to be reviewed on a standard of correctness. It submits that the second issue, which includes a proportionality analysis, is subject to the palpable and overriding error standard.

[17] Apotex takes the position that the standard of review is palpable and overriding error for both issues. It asserts that determinations of whether a question posed in an examination for

discovery is relevant is a fact-based inquiry, informed by an appreciation of the applicable legal principles. As these determinations involve questions of mixed fact and law, Apotex argues that they are subject to the palpable and overriding error standard.

[18] To consider the parties' arguments on standard of review, it is useful first to canvas some general principles that apply to motions to compel answers to discovery questions.

[19] Pursuant to Rule 240(a), a person being examined for discovery must answer any question that is relevant to an unadmitted allegation of fact in the pleadings. In determining relevance, the Court will consider whether the question might advance the questioning party's case or damage the responding party's case, or whether the question may fairly lead to a train of inquiry that could lead to either of these results. Whether this test is met will depend on the allegations the questioning party seeks to establish or refute (*Apotex Inc v Bristol-Myers Squibb Co*, 2007 FCA 379 at paras 30-31; *Canada v Lehigh Cement Limited*, 2011 FCA 120 [*Lehigh*] at para 34).

[20] Despite a finding of relevance, however, the Court retains a residual discretion not to compel an answer to a question if a party is abusing the discovery process, where responding to it would place undue hardship on the answering party, where there are other means of obtaining the information sought, or where the question represents part of a fishing expedition of vague and far-reaching scope (*Lehigh* at para 35). Expressed differently, the answer to a discovery question must be not only relevant but also proportionate. Proportionality takes into account considerations such as the fact that evidence has degrees of significance and connection to a

case, the burden required to obtain the information, the scope of the request, and the availability of the information from other sources (*Hospira Healthcare Corporation v Kennedy Institute of Rheumatology*, 2020 FCA 177 at paras 8-9).

[21] Against that backdrop, Janssen submits that, while the proportionality analysis engages considerations of fact that warrant review on a standard of palpable and overriding error, the relevance analysis is a pure question of law. Janssen relies on *Reading & Bates Construction Co v Baker Energy Resources Corp*, [1988] FCJ No 1025 (FCTD) at paragraph 10, which states that the test as to what documents are required to be produced is relevance, which is a matter of law, not a matter for the exercise of discretion.

[22] I accept that the analysis of relevance is not a discretionary matter and that the test for relevance is itself a matter of law. However, I do not agree with Janssen that this translates into a conclusion that the relevance analysis is entirely a matter of law, reviewable on the correctness standard. As the Federal Court of Appeal explained in *694761 BC Ltd v Canada*, 2015 FCA 123 at paragraph 3, the determination whether a particular question is relevant is typically a question of mixed fact and law. Unless an extricable error of law is established, such as using the wrong test in respect of relevance, a reviewing court will intervene only in the case of a palpable and overriding error.

[23] While Janssen submits that the present matter involves an extricable error of law, I find no support in the record before the Court for such a conclusion. Neither the Order nor any other portion of the record suggests that the Case Management Judge misunderstood the test for

relevance or applied an incorrect test. Rather, Janssen's arguments take issue with whether the Disputed Questions are relevant to the pleaded issues in dispute. As this analysis involves consideration of the facts pleaded by the parties, it represents a question of mixed fact and law, reviewable on the palpable and overriding error standard.

[24] As Apotex submits, this standard requires that an error be obvious and apparent (*i.e.*, palpable) and one that goes to the core of the case's outcome and will change the result (*i.e.*, overriding) (*Canada v South Yukon Forest Corporation*, 2012 FCA 165 at para 46; *Hutton v Sayat*, 2020 FC 1183 [*Hutton*] at para 27). Apotex also notes this Court's recognition that a heightened deference should be afforded to case managing prothonotaries (now associate judges) on a Rule 51 appeal, because of the case manager's familiarity with the particular circumstances and issues in the matter (*Hutton* at para 28).

V. **Analysis**

[25] On the basis of these principles governing the standard of review, I now turn to consideration of the substantive issues in this motion.

A. *Whether the Case Management Judge erred in determining that the Disputed Questions were not relevant*

(1) Janssen's position

[26] Janssen submits that one of the central issues in dispute in this action is whether Apotex could supply the market with its abiraterone acetate product as of August 8, 2019. Janssen relies

on the pleading in its Statement of Defence that Apotex did not have the ability and/or capacity to manufacture or obtain sufficient quantities of abiraterone acetate to satisfy the Canadian generic market for that drug.

[27] Janssen further relies on jurisprudence explaining that, in assessing the hypothetical world under consideration in an action under section 8 of the Regulations, the claimant must demonstrate both that it "could have" been in the position to make the sales, the loss of which are the foundation for its damages claim, and that it "would have" made those sales (*Pfizer Canada Inc v Teva Canada Ltd*, 2016 FCA 161 [*Venlafaxine*] at paras 47-52). Janssen notes that *Venlafaxine* identified evidence surrounding the capacity of a manufacturing plant as relevant to the "would have" and "could have" analyses (at para 52). It submits that it is the "could have" portion of the analysis in particular upon which the present motion turns. Janssen has pleaded in support of an argument that Apotex did not have the manufacturing capacity to have made the sales it claims, and it submits that the Disputed Questions are relevant to the issue raised by that pleading.

[28] The Disputed Questions relate to Apotex's ability to supply the US market for abiraterone acetate, including its manufacturing capacity in support of that supply. However, Janssen submits that these questions are relevant to Apotex's ability to supply the Canadian market, because the available evidence [redacted]. Janssen further submits that, in opposing the Disputed Questions on discovery, it was pursuing a theory that Apotex suffered a supply disruption beginning in around March 2019 and could not manufacture sufficient quantities of abiraterone acetate at Signet to satisfy the US market. It argues that, if the answers to the

Disputed Questions support that theory, then they may also support its defence position surrounding lack of capacity to supply the Canadian market.

[29] As noted earlier in these Reasons, Janssen's pursuit of the Disputed Questions at discovery was premised upon its production of the US Data Document, purporting to contain data in relation to sales of abiraterone acetate products in the US. Janssen alleges this data shows that:

A. Apotex began selling its abiraterone acetate products in the US in November 2018;

B. By March 2019, Apotex reached a market share of approximately 32.2% in the 250 mg abiraterone market;

C. Apotex experienced a steep decline in its US market share in the months immediately preceding August 8, 2019, such that by June 2019 Apotex only had a 2.7% market share; and

D. Apotex's market share recovered in subsequent months, but it never achieved the same level of market share.

[30] Janssen asserts that Apotex was the only market participant that experienced this drop in market share, leading to its theory that Apotex suffered a supply disruption beginning in and around March 2019. Janssen also relies on what it describes as public documentation surrounding US labelling, which it submits confirms that Apotex manufactures its abiraterone acetate product for the US market at the Signet plant. I understand that [redacted].

(2) Apotex's position

[31] In opposing both Janssen's motion to compel before the Case Management Judge and its present Rule 51 appeal, Apotex relies significantly on evidence it has produced in this litigation, through documentary discovery, its representative's testimony during examination for discovery by Janssen's counsel, and subsequent answers to discovery undertakings.

[32] The documentary evidence includes a chart setting out the annual production capacities of Apotex's Signet plant, and another alternative plant in Etobicoke, from 2017 to 2021, which Apotex submits includes both plants' theoretical maximum capacities and actual output. Apotex argues that this evidence establishes that its Signet facility had more than sufficient excess capacity to satisfy the entire Canadian market for abiraterone acetate. Apotex also produced a spreadsheet setting out its actual billings, which it argues support its position that it entered the market immediately after it received its NOC and made sales of abiraterone acetate continuously through to the day the spreadsheet was generated in July 2021.

[33] The oral discovery evidence upon which Apotex relies includes confirmation that [redacted]. Apotex also confirmed that it manufactured its Canadian abiraterone acetate product in the real world at its [redacted] facility but that it could also have used its [redacted] facility if needed. It further confirmed that it experienced no delays or difficulties in obtaining any of the excipients or non-active pharmaceutical ingredients for its product, and it provided supplier invoices and an inventory log for the supply of product for its abiraterone

tablets. Apotex submits that this evidence shows that it had [redacted] of available active pharmaceutical ingredients in the relevant period.

[34] Finally, Apotex notes that, in the course of Janssen's motion to compel, Apotex agreed to provide additional information regarding its Canadian manufacturing capabilities, which Apotex argues will further speak to Apotex's ability to supply the Canadian market at the relevant time period.

[35] Against the backdrop of this evidence, Apotex argues that Janssen already has the information it requires in relation to Apotex's manufacturing capacity for the Canadian abiraterone acetate market. It submits that the Case Management Judge understood this and on that basis concluded that the information Janssen was seeking in response to the Disputed Questions was irrelevant.

(3) Evidentiary arguments

[36] At this point in the analysis, it is also necessary to identify arguments advanced by each of the parties surrounding deficiencies in the other's evidence.

[37] Apotex takes the position that Janssen is unable to rely on the US Data Document as evidence in support of its Rule 51 motion, because it has not proven either the document or its contents. The document forms part of the record on this motion as an exhibit to an affidavit of a law clerk in Janssen's counsel's law firm, who swears only that he is attaching "U.S. IMS sales data, produced as Confidential Janssen Production 103." While Apotex's evidentiary argument

focuses upon the US Data Document, I understand it to take the same position in relation to the US labelling document that Janssen relies upon to establish that Apotex manufactures abiraterone acetate for the US market at the Signet plant.

[38] In response to this position, Janssen identifies what it considers to be deficiencies in Apotex's evidence in this motion. Janssen refers the Court to *South Yukon Forest Corporation v Canada*, 2004 FC 1645 [*South Yukon*], which addressed a motion seeking leave to amend a statement of claim and upheld the defendant's objection to the plaintiff's efforts to rely upon extracts from the discovery examination of the plaintiff's representative. The Court explained that the Rules allow use of discovery evidence by an adverse party but do not contemplate such use by the party whose representative gave that evidence on discovery (at paras 11-13).

[39] Janssen argues that, if Apotex is unable to rely on its own discovery evidence, the only other evidence in support of its position is documentary evidence attached to an affidavit sworn by a law clerk in the office of Apotex's counsel. Janssen submits that this is no different from the manner in which Janssen introduced the US Data Document.

[40] Apotex responds that the concern identified in *South Yukon* does not apply in the circumstances in which it has relied on its representative's discovery evidence. It submits that Janssen has relied on portions of the discovery examination of Apotex's representative, including in support of its position that nearly all Janssen's questions on its US supply disruption theory were refused, and that Apotex is therefore entitled to complete the record by providing the evidence as to which questions were answered.

(4) Analysis

[41] My decision to allow this Rule 51 appeal turns significantly on the principle that relevance for the purposes of discovery is defined by reference to the pleadings. This principle is captured expressly in Rule 240(a) and has been acknowledged in applicable jurisprudence (*e.g.*, *Apotex Inc v Pfizer Canada Inc*, 2006 FC 262 at para 9; *Proctor & Gamble Co v Kimberly-Clark of Canada Ltd* (1990), 35 CPR (3d) 321 (FCTD) at para 14). As I understand this principle, the Court's task is to assess relevance by reference to the facts pleaded by the parties, not by reference to the evidence that has previously been produced in the litigation.

[42] That said, there is potentially a role for evidence in informing an assessment of relevance. As noted earlier in these Reasons, the Court may decline to compel answers to questions that it considers to represent a fishing expedition. While this principle is often described as related to the Court's residual discretion (*e.g.*, *Lehigh* at para 35), it has also been treated as a component of the relevance analysis (*Grand River Enterprises Six Nations Ltd v Canada*, 2011 FCA 121).

[43] However, I agree with the submission advanced by Janssen's counsel at the hearing of this motion that it is not the Court's role, in assessing relevance for purposes of a motion to compel, to engage in any substantial assessment of the evidence that the parties offer on the issues in the litigation. In my view, an appreciation of this role informs both the appropriate analysis of the parties' evidentiary objections and the overall disposition of this Rule 51 appeal.

[44] First, on the subject of Janssen's evidence, I disagree with Apotex's position that Janssen is unable to rely upon the documents that it has included in its record without establishing the authenticity of these documents and/or proving their contents. Janssen takes the position that it would be entitled to ask the Disputed Questions, even without the benefit of the evidence that lays the foundation for the questions, because the Disputed Questions are relevant to the facts it has pleaded. However, it relies on this evidence to provide the Court with context for its line of questioning and to address any concern that it is engaged in a fishing expedition. I find merit to these arguments. As relevance is primarily defined by the pleadings, to the extent that evidence is offered to provide a foundation and explain why questions represent more than fishing, I would not consider it necessary to prove that evidence in the manner that would be required if it was offered to establish facts at trial.

[45] In my view, this conclusion flows from the fact that the purpose of discovery is to enable a party to obtain evidence that it does not yet have. This purpose is served by the general rule that the scope of discovery is principally defined by the facts pleaded, not by reference to evidence already obtained. It would unduly restrict the scope of discovery if the Court were to impose too high an evidentiary standard upon a party seeking to explain why it considers that particular questions may represent a fruitful train of inquiry. For instance, a party may come into possession of a document or other information related to an opponent's business, but have little ability to verify or support its provenance. Depending on the particular circumstances, it would not necessarily be untoward for that party to seek to ask discovery questions about the document or information, supported just by the fact that the document or information exists.

[46] I consider this conclusion to be particularly sound in a case where the opposing party is not expressly arguing that the information in question is incorrect or adducing evidence to support such a position. In the case at hand, Apotex's evidentiary argument focuses principally upon the US Data Document. While Apotex has not expressly acknowledged the accuracy of the data therein, I do not understand it to be arguing the data is incorrect. Indeed, Apotex explained in its written representations in this motion that, when it opposed the motion to compel before the Case Management Judge, it argued an alternative explanation for the reduction in its sales demonstrated by the data, namely that during that period Janssen was offering aggressive discounts to its own generic product.

[47] Similarly, in relation to the US labelling document that Janssen says confirms that Apotex manufactures its abiraterone product for the US market at the Signet plant, I do not understand Apotex to be disputing that assertion.

[48] Turning to Janssen's objections to Apotex's reliance upon its discovery evidence, again my conclusion is that the evidence is properly before the Court. I accept Apotex's argument that, given Janssen's reliance on Apotex's representative's discovery evidence in support of this motion, Apotex is entitled to complete the record before the Court by reference to other portions of that same evidence that is responsive to the evidence and arguments upon which Janssen relies.

[49] However, I do not find Apotex's arguments based on that evidence to represent a particularly compelling response to Janssen's motion. As previously noted, Apotex's arguments

amount to an assertion that it has already provided Janssen with the evidence it needs to understand the manufacturing capacity relevant to Janssen's pleading. Of course, it could be that the evidence Apotex has already provided represents a complete picture of its manufacturing capacity. It may be that Apotex's possible explanation, that the 2019 dip in its sales is attributable to Janssen's efforts in the market, is also correct. However, at the discovery stage of this proceeding, in my view Janssen is not required to accept this evidence and assertion without further exploration. Returning to the test for determining relevance, I find logic in Janssen's argument that the Disputed Questions may fairly lead to a train of inquiry that could assist it in responding to Apotex's claim.

[50] I am conscious that I am not deciding the motion to compel at first instance but rather considering an appeal of the Case Management Judge's Order, to which the palpable and overriding error standard applies. The Order does not set out any reasons for the Case Management Judge's conclusion that the Disputed Questions are irrelevant, nor do I consider the record in this Rule 51 motion to assist in that regard. I emphasize that, in making that observation, I am not in any way criticizing the work of the Case Management Judge. Consistent with the principles animating the reasoning in *Hutton*, case managers have a lot on their plate and are often required to quickly make detailed decisions in the interests of keeping litigation moving forward. Such circumstances do not always afford an opportunity to provide reasoning for every aspect of a case management order.

[51] However, in the absence of reasons from the Case Management Judge underlying her relevance finding, and applying the relevance analysis set out above, I find that the Order

demonstrates a palpable and overriding error. That is, the error is obvious and apparent, in that the Disputed Questions satisfy the test for relevance as informed by Janssen's pleading, and the error is overriding in that it changes the result of the motion to compel.

B. *Whether, in any event, the Disputed Questions are relevant and proportional and Apotex ought to be compelled to answer the questions*

[52] The second issue in this motion asks that, if the impugned portion of the Order is to be set aside, the Court consider whether the Disputed Questions are both relevant and proportional. As explained above, I find that they are relevant. Therefore, the remaining consideration is proportionality.

[53] On this point, I agree with Janssen's position that there is no compelling evidence before the Court that the Disputed Questions are overbroad or that answering them would be unduly burdensome for Apotex. The questions are pointed and direct, they relate to what appears to be one of Janssen's central defence positions, the answers should be within Apotex's control, and Apotex has not adduced evidence or particularly argued that it would be a significant burden for it to provide those answers.

VI. **Conclusion**

[54] In conclusion, I find that Janssen is entitled to the relief sought in this motion. My order will allow the appeal, set aside the Order of the Case Management Judge as it relates to the Disputed Questions, and require Apotex to answer the Disputed Questions and related follow-up interrogatories.

VII. **Costs**

[55] Each party proposed that the successful party in this motion be awarded $3000.00 in costs. My order will grant costs in that amount to Janssen.

PUBLIC ORDER IN T-607-21

THIS COURT ORDERS that:

1. The Defendants' motion is granted, their appeal is allowed, and the Order dated June 14, 2022, is set aside as it relates to the Disputed Questions.

2. The Plaintiff shall answer the Disputed Questions and related follow-up interrogatories.

3. The Defendants are awarded costs of this motion in the amount of $3000.00.

"Richard F. Southcott"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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