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1 November 2024

Examination report No. 1 for your standard patent application

Catalyst Intellectual Property
PO Box 25520
Wellington 5012
New Zealand

Application number:	2024219856
Applicant name:	KORU BIOTECH SOLUTIONS LIMITED
Earliest priority date:	10 May 2023
Your reference:	KDL1008/AU2

Final date for acceptance:	**1 November 2025**
Date of this report:	1 November 2024
Examination request date:	18 September 2024

Dear Applicant,

Your application has been examined under *section 45 of the Patents Act 1990*. I consider that the application does not meet the requirements of the Act for the reasons indicated below.

What you need to do now

1. **Understand this examination report** – read through this report carefully to understand the issues identified.
2. **Overcome the issues** – you have until **1 November 2025** (12 months from the date of this report) to overcome all of the objections identified by the examiner in this examination report. If your response to this examination report does not overcome all of the examiner's objections, further adverse report(s) will be issued. If all objections in this (and any subsequent further reports) are not resolved by **1 November 2025**, your application will lapse and you will lose the opportunity to progress this application further.
3. **File your response promptly** – if you believe you can overcome the objections raised by the examiner in this (and any subsequent) examination report(s), please respond as soon as you are able. For more information on how to respond, see Responding to an examination report on our website. Please ensure that during the examination process you file your response(s) to allow sufficient time for IP Australia to consider it before the final date for acceptance. IP Australia will endeavour to either write another report, or accept your application, within 20 working days of receiving a response.

Your progress

- **Filed** – Application is filed
- **Examination** – Application is being examined
- **Acceptance** – Application is accepted (enters an opposition period lasting 3 months)
- **Grant** – Patent is granted (patent is now enforceable)
- **Continuation/Renewal** – Fees required to maintain application/patent (fees are due annually – please refer to the 'paid to' date in AusPat for your next due date)

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Did you know? *A prompt response will provide you more time to resolve the issues*

Things to be aware of

- NOTE: There is a current postponement of acceptance in place. If you overcome all other objections before the expiration of that postponement, the Commissioner will only accept the application at that time if you have filed a clear and unambiguous statement requesting the withdrawal of that postponement. Otherwise, a further adverse report will be issued.
- **Monitor and pay your continuation fees** – fees are due annually. Your next continuation fee is due on **10 May 2028**. Information about fees may be obtained by visiting time and costs page on our website.
- **If you need to file a divisional application** – the divisional must be filed while the present application is in force (i.e. it is not lapsed, withdrawn or refused). If the present application is in force and has also been accepted, you must file your divisional application no later than 3 months from the date we advertised the acceptance of the present application. For more information on divisional applications, please see Divisional applications on our website.

You may like to know

- You may submit your response using online services or post.

Details of your patent application can be viewed on Australian Patent Search.

Yours sincerely,

Zammam Areeb
Section: CHEM 3 - BIOTHERAPEUTICS
Phone: +61 2 6210 8440

Alternate contact: Andrew Achilleos
Phone: +61 2 6283 2280

Report details

Basis of the report

In examining this application I have considered:

- the PCT pamphlet as originally filed.

Summary of novelty, inventive step and patentable subject matter

	Satisfy requirements?	*Claim numbers*
Novelty/inventive step	**Yes**	NONE
	No	1-50
Patentable subject matter	**Yes**	1-50
	No	NONE

Detailed objections on issues that have been identified

Section 40 (support, disclosure, clarity, lack of unity)

1 Independent claims 2, 4, 8, 33, 41, 43 and 44, and dependent claims 5-6, 9-12, 16-17, 21-22, 24-29, 35-39, 45-46 and 49-50 are broader than the technical contribution to the art and lack support; therefore, the claims do not comply with Section 40(3).

The specification supports the administration of concanavalin A (ConA) or immunoglobulins from colostrum for the treatment of bacterial infections. However, many of the claims define methods administering, or compositions comprising of, agents that are broader than what is supported. Multimerising agents and antibody-binding agents are both a broad class and contain many agents that may not necessarily elicit the same effect as those agents that have support.

Therefore, independent claims 2, 4, 8, 33, 41, 43 and 44 lack support. Dependent claims 5-6, 9-12, 16-17, 21-22, 24-29, 35-39, 45-46 and 49-50 also lack support.

2 Claim 48 is broader than the technical contribution to the art and lacks support; therefore, the claim does not comply with Section 40(3).

Claim 48 lacks support because it defines the administration of ConA or an analogue, derivative or synthetic form thereof. These are all considered to be variants of ConA. However, it is unpredictable whether these variants will possess the same effect as ConA in terms of treating bacterial infections.

Therefore, claim 48 lacks support.

3 Many of the dependent claims lack clarity because they are not appended to the appropriate preceding claim:

Claim 10 is not clear because not all preceding claims are to gram-negative bacteria. Claim 13-14 are not clear because not all preceding claims are to immunoglobulins. Claims 16-19 and 21 are not clear because not all preceding claims are to the multimerising agent. Claim 22 is not clear because not all preceding claims are to glycoproteins. Claim 24 is not clear because not all preceding claims are to a capture agent. Claim 29 is not clear because not all claims define ex vivo administration.

Documents cited or considered relevant

D1: Kuo CF, Wang YH, Lei HY, Wang CH, Tsao N. Concanavalin A protects mice from a lethal inoculation of intragastric Klebsiella pneumoniae and reduces the induced liver damage. Antimicrob Agents Chemother. 2007 Sep;51(9):3122-30. doi: 10.1128/AAC.01379-06. Epub 2007 Jul 2. PMID: 17606678; PMCID: PMC2043212 [1]

Category: X Claims: 2, 4-6, 8-12, 16-29, 33-39, 41, 43-50

D2: Baltierra-Uribe, S.L., Montañez-Barragán, A., Romero-Ramírez, H., Klimov-Kravtchenko, K., Martínez-Pedro, K.I., Sánchez-Salguero, E., Camorlinga-Ponce, M., Torres, J. and Santos-Argumedo, L. (2021), Colostrum IgA1 antibodies recognize antigens from Helicobacter pylori and prevent cytoskeletal changes in human epithelial cells. Eur. J. Immunol., 51: 2641-2650. https://doi.org/10.1002/eji.202049117 [2]

Category: X Claims: 1-17, 21-22, 24-33, 35-43, 49-50

D3: Saad K, Abo-Elela MGM, El-Baseer KAA, Ahmed AE, Ahmad FA, Tawfeek MSK, El-Houfey AA, Aboul Khair MD, Abdel-Salam AM, Abo-Elgheit A, Qubaisy H, Ali AM, Abdel-Mawgoud E. Effects of bovine colostrum on recurrent respiratory tract infections and diarrhea in children. Medicine (Baltimore). 2016 Sep;95(37):e4560. doi: 10.1097/MD.0000000000004560. PMID: 27631207; PMCID: PMC5402550. [2]

Category: X Claims: 1-17, 21-22, 24-33, 35-43, 49-50

D4: Playford, R.J.; Choudhry, N.; Kelly, P.; Marchbank, T. Effects of Bovine Colostrum with or without Egg on In Vitro Bacterial-Induced Intestinal Damage with Relevance for SIBO and Infectious Diarrhea. Nutrients 2021, 13, 1024. https://doi.org/10.3390/nu13031024 [2]

Category: X Claims: 1-17, 21-22, 24-33, 35-43, 49-50

D5: Funatogawa K, Ide T, Kirikae F, Saruta K, Nakano M, Kirikae T. Use of immunoglobulin enriched bovine colostrum against oral challenge with enterohaemorrhagic Escherichia coli O157:H7 in mice. Microbiol Immunol. 2002;46(11):761-6. doi: 10.1111/j.1348-0421.2002.tb02761.x. PMID: 12516772. [2]

Category: X Claims: 1-17, 21-22, 24-33, 35-43, 49-50

D6: Sugiharto S, Poulsen AS, Canibe N, Lauridsen C. Effect of bovine colostrum feeding in comparison with milk replacer and natural feeding on the immune responses and colonisation of enterotoxigenic Escherichia coli in the intestinal tissue of piglets. Br J Nutr. 2015 Mar 28;113(6):923-34. doi: 10.1017/S0007114514003201. Epub 2015 Mar 6. PMID: 25743486; PMCID: PMC4392705. [2]

Category: X Claims: 1-17, 21-22, 24-33, 35-43, 49-50

D7: Steele J, Sponseller J, Schmidt D, Cohen O, Tzipori S. Hyperimmune bovine colostrum for treatment of GI infections: a review and update on Clostridium difficile. Hum Vaccin Immunother. 2013 Jul;9(7):1565-8. doi: 10.4161/hv.24078. Epub 2013 Feb 22. PMID: 23435084. [2]

Category: X Claims: 1-17, 21-22, 24-33, 35-43, 49-50

D8: Cross AS, Opal SM, Palardy JE, Shridhar S, Baliban SM, Scott AJ, Chahin AB, Ernst RK. A pilot study of an anti-endotoxin Ig-enriched bovine colostrum to prevent experimental sepsis. Innate Immun. 2021 Apr;27(3):266-274. doi: 10.1177/17534259211007538. PMID: 33858243; PMCID: PMC8054147. [2]

Category: X Claims: 1-17, 21-22, 24-33, 35-43, 49-50

D9: Isobe N, Kurose T, Suzuki N, Koshiishi T, Ueno K, Hisaeda K. Effect of oral administration of colostrum on inflammation in the udders of dairy cows suffering from mastitis. J Vet Med Sci. 2022 Jan 7;84(1):59-63. doi: 10.1292/jvms.21-0505. Epub 2021 Nov 12. PMID: 34776468; PMCID: PMC8810319. [2]

Category: X Claims: 1-17, 21-22, 24-33, 35-43, 49-50

D10: Jahani S, Shakiba A, Jahani L. The Antimicrobial Effect of Lactoferrin on Gram-Negative and Gram-Positive Bacteria. Int J Infect. 2015;2(3):e27954. https://doi.org/10.17795/iji27594 [2]

Category: A

D11: Davin JC, Senterre J, Mahieu PR. The high lectin-binding capacity of human secretory IgA protects nonspecifically mucosae against environmental antigens. Biol Neonate. 1991;59(3):121-5. doi: 10.1159/000243333. PMID: 2054423. [2]
Category: A

D12: WO 2012/071346 A1 (PANTHERYX INC et al.) 31 May 2012 [2]
Category: X Claims: 1-17, 21-22, 24-33, 35-43, 49-50

D13: Jandú JJB, Moraes Neto RN, Zagmignan A, de Sousa EM, Brelaz-de-Castro MCA, Dos Santos Correia MT, da Silva LCN. Targeting the Immune System with Plant Lectins to Combat Microbial Infections. Front Pharmacol. 2017 Oct 4;8:671. doi: 10.3389/fphar.2017.00671. PMID: 29046636; PMCID: PMC5632806.n"Benefits of Prophylactic and Therapeutic Treatments with Concanavalin A in Klebsiella pneumoniae Infection"
[2]
Category: X Claims: 2, 4-6, 8-12, 16-29, 33-39, 41, 43-50

[1] As cited in the WO FER for PCT/NZ2024/050051
[2] As cited in the WO FER for PCT/NZ2024/050051

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Please provide the citation details and associated patent application number with your request. Note that because of copyright restrictions we can only provide copies of hard copy books, journals and newspapers (see the Australian Patent Office Manual of Practice and Procedure at part 5.6.4.6 Identifying and Raising Citations). However, copies of any remaining documents should be readily obtainable from known electronic database sources.

Special categories of cited documents:

X: The claimed invention cannot be considered novel under *subsection 7(1)* in light of the document and/or cannot be considered to involve an inventive step under *subsection 7(2)* of the Act in light of the common general knowledge considered together with the document.
A: Document defining the general state of the art which is not considered to be of particular relevance.

Novelty and inventive step

4 Claims 2, 4-6, 8-12, 16-29, 33-39, 41, 43-50 are either not novel (and not inventive) or not inventive in light of D1 or D13. Claims 1-17, 21-22, 24-33, 35-43 and 49-50 are either not novel (and not inventive) or not inventive in light of any one of D2-D9 and D12.

D1 discloses the effect of Concanavalin A (ConA) tested on Klebsiella pneumoniae (see Abstract). Intravenous pretreatment with ConA was able to protect mice from Klebsiella pneumoniae infection in an intragastric model. Klebsiella pneumoniae is gram-negative and ConA was able to bind the Klebsiella pneumoniae cells directly and further agglutinate them. ConA treatment was capable of inhibiting liver damage caused by Klebsiella pneumoniae and Klebsiella pneumoniae-induced death (see Results). D1 discloses a formulation comprising ConA (see Methods). Such a formulation will inherently comprise of some of the ConA in dimeric form. ConA inherently is an antibody-binding protein. Additionally, ConA has an inherent property of binding IgA (see D11).

Therefore, D1 discloses all the features of independent claims 2, 4, 33, 41, 43, 44 and 48. All the features of dependent claims 5-6, 10-12, 16-19, 25, 34, 39 and 45-47 have been disclosed by D1.

In summary, claims 2, 4-6, 10-12, 16-19, 25, 33-34, 39, 41 and 43-48 are not novel in light of D1. D13 is a review article which cites D1. A similar objection can be made with D13.

The use of colostrum for the treatment of bacterial infections is well-known in the art. A number of documents can be used as relevant citations against the claims pertaining to the use of immunoglobulins for the treatment of bacterial infections.

D2 discloses that the protective effect of breastfeeding against H. pylori, a gram-negative bacterium, is well-known in the art. D2 discloses that colostrum-IgA reduces H. pylori infection of epithelial gastric cells (see Abstract). D2 discloses that human colostrum reduced the hummingbird phenotype of AGS cells infected with H.pylori (see Figures 4 and 5).

D3 studied the effects of bovine colostrum on diarrhea and gastrointestinal infections caused by gram-negative bacteria, such as E.coli (see Abstract and Table 3). D3 discloses that the bovine colostrum has direct antimicrobial and endotoxin-neutralising effects (see Abstract: Background). D3 discloses that bovine colostrum is homologous to human colostrum although immune factors are present in greater concentrations. D3 discloses that bovine colostrum is rich in IgG (see Introduction). D3 discloses that bovine colostrum therapy reduced bacterial infection-caused diarrhea in children (see Table 2).

D4 discloses that bovine colostrum strengthens mucosal integrity against a battery of bacteria relevant for small intestinal bacterial overgrowth, such as (Streptococcus, Escherichia coli, Staphylococcus, Bacteroides, Klebsiella, Enterococcus, and Proteus), and for infectious diarrhea. D4 discloses that small intestinal bacterial overgrowth is associated with inflammation (see Introduction).

D5 discloses the use of immunoglobulin enriched bovine colostrum against mice orally challenged with enterohemorrhagic E.coli. D5 discloses that oral administration of colostrum reduced bacteria numbers. D5 concludes that oral administration of bovine colostrum effectively protects mice against food-borne infections by inhibiting bacterial attachment to the intestinal mucous membrane, colonization and growth in the intestinal tract (see Abstract).

D6 discloses that feeding bovine colostrum to piglets reduced the colonisation of intestine by enterotoxigenic Escherichia coli (see Abstract). D6 notes that of bioactive components which the bovine colostrum is comprised of, IgG is the most important for immunity (see Introduction and Table 1).

D7 discloses that hyperimmune bovine colostrum, or purified derivative products, have been used successfully for treatment or prevention of cryptosporidiosis, shigellosis, rotavirus, enterotoxigenic E. coli, and C. difficile infection (CDI) (see Abstract).

D8 discloses bovine colostrum, which is anti-endotoxin Ig-enriched (see Title and Abstract), is an effective treatment to improve the outcome of lethal gut-derived disseminated infection and may reduce transmission of Gram-negative bacilli from the gastrointestinal tract (see Abstract). D8 discloses that when hyperimmune bovine colostrum enriched in antibodies were given orally to neutropenic rats challenged orally with Pseudomonas aeruginosa, administration of hyperimmune bovine colostrum improved survival compared to non-immune rats, while both bovine colostrum preparations improved survival compared to PBS controls (see Abstract).

D9 discloses the effect of oral administration of colostrum on inflammation in the udders of dairy cows suffering from mastitis. D9 discloses that oral administration of colostrum attenuates inflammation of the mammary gland (see Abstract).

D12 discloses a composition comprising bovine colostrum in powderised form. The composition is to work towards activating passive immunity (see [00249]). Subjects were administered the composition orally (see [00227]). The composition can be used for the treatment of gram-negative bacteria, such as H.pylori or Klebsiella (see [00220] and claim 6).

Any one of these documents can be used to destroy the novelty of claims directed to immunoglobulins - claims 1, 3, 13, 30, 40 and 42. Dependent claims 5-6 are also not novel in light of these documents. The gram-negative bacteria defined by claim 10 is disclosed by D3-D7, D9 and D12. Colostrum, whether

human or bovine, inherently comprises IgG and IgA; therefore, all the features of claims 14 and 31 are disclosed by any one of these documents.

D3-D9 and D12 destroy the novelty of claims 15 and 32 because they disclose the use of bovine colostrum. D2 discloses the use of human colostrum.

Therefore, claims 1, 3, 5-6, 10, 13-15, 30-32, 40 and 42 are not novel in light of D3-D9.

Claim 21 defines a method of administering a multimerising agent, which includes immunoglobulins, together with a glycoprotein. A glycoprotein will include lactoferrin within its scope. Colostrum will inherently be comprised of both immunoglobulins and lactoferrin. Therefore, the administration of colostrum will mean the administration of both immunoglobulins and lactoferrin. Therefore, claim 21 is not novel in light of D2-D9 and D12. A similar objection applies to claims 22.

Immunoglobulins can be considered as multimerising agents. Therefore, the novelty of independent claims 2, 4, 33, 41 and 43 are destroyed by any one of D2-D9 and D12. Given that D2-D9 and D12 discloses a colostrum composition, and given that colostrum comprises lactoferrin, dependent claim 35 is not novel in light of any one of D2-D9 and D12, while dependent claim 36 is not novel in light of D3-D9 and D12.

Lactoferrin can be considered a capture agent; therefore, claim 37 is also not novel in light of D2-D9 or D12. Lactoferrin can also bind lipopolysaccharides; therefore, claim 38 is not novel in light of D2-D9 or D12.

Therefore, claims 21-22 and 35-38 are not novel in light of any one of D3-D9 and D12. Note that claim 39 is dependent on claims 30 or 33, wherein the composition only needs to be suitable for treating gram-negative bacterial infections. Therefore, claim 39 is not novel in light of D2-D9 and D12.

All documents, except D9, do not disclose the administration of colostrum immunoglobulins for the treatment of mastitis. Furthermore, immunoglobulins can be considered to be multimerising agents. Therefore, independent claims 7-8 and dependent claim 9 are not novel in light of D9.

Claims 25-29 define the mode of administering the colostrum comprising immunoglobulins. D2 discloses the in vitro administration of human colostrum while D9 discloses the oral administration of colostrum to piglets; therefore, claim 26 is not novel.

In summary, claims 2, 4-6, 10-12, 16-19, 25, 33-34, 39, 41, 43-48 are not novel in light of D1. Claims 1-10, 13-15, 21-22, 26, 30-33, 35-39 and 40-43 are not novel in light of D9.

Please note that although D2-D9 and D12 were mainly employed for the discussion regarding claims directed to immunoglobulins or colostrum, the claims directed to multimerising agents, wherein "multimerising agents" is broadly defined (i.e. not restricted to ConA), will not be novel in light of any one of D2-D9 and D12. This is because immunoglobulins are multimerising agents.

Therefore, claims 1-19, 21-22, 25-26, 30-48 are not novel (and not inventive).

Although claims 20, 23-24, 27-29 and 49-50 are novel in light of the prior art, these claims are not inventive.

D1 does not disclose the use of ConA for the treatment of mastitis. Mastitis can be caused by bacterial infection, especially gram-negative bacteria. Therefore, the PSA would find it obvious to use ConA to treat mastitis in light of D1. Therefore, claims 8-9 can be considered not inventive in light of D1.

D1 does not disclose wherein the ConA is maintained at or below a pH of 5.4. However, such an additional feature does not contribute to an inventive step as the PSA will find the pH required to maintain ConA as a matter of routine. Therefore, claim 20 is not inventive in light of D1.

Claims 21-23 defines a method wherein the ConA is administered together with an additional agent, such as lactoferrin. Lactoferrin is well-known in the art for its anti-bacterial properties, particularly gram-negative bacteria (see D10) and for its LPS binding ability (see D3: Page 2 LHS). The administration

of both agents together for the treatment bacterial infections would be considered routine to the PSA and its effect will have no surprising benefits. Therefore, claim 23 is not inventive in light of D1. A similar objection applies to claim 24 because there is no surprising benefit in administering the defined capture reagents.

Therefore, claims 21-23 are not inventive in light of D1, while claim 24 is not inventive in light of any one of D1-D9 and D12.

The various modes of administration defined by claims 26-29 are not inventive because they are routine in the art and obvious to the PSA. Therefore, claims 26-29 are not inventive in light of D1 and claims 27-29 are not inventive in light of D2-D9 and D12.

Claims 35-38 are not inventive in light of D1 for similar reasons. The use of lactorferrin or the additional agents defined by claims 37-38 have no surprising benefit.

Claims 49 further defines a method wherein the method comprises the administration of an additional agent. An additional agent does not contribute to an inventive step and has no surprising benefit. Therefore, claims 49-50 are not inventive in light of any one of D1-D9 and D12.

Broadly speaking, claims 1-17, 21-22, 24-33, 35-43 and 49-50 are not inventive in light of any of D2-D9 and D12.

In summary, claims 1-50 are not novel (and not inventive) or not inventive.

END OF REPORT