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Clarification of recent analyst report regarding patent protection for iPPS

KEY HIGHLIGHTS

- Paradigm's primary and foundation patent in BME granted in the US and multiple other jurisdictions and supports ongoing programs.
- Key miscommunication in recent research note regarding Paradigm's patent portfolio. A "final rejection" is NOT final and subsequent clarification will be planned with the USPTO for the patent in question, which is an add-on patent to broaden Paradigm's IP portfolio.
- Paradigm has a broad patent portfolio covering multiple indications in all key jurisdictions. An update on Paradigm's granted patent portfolio will be provided to the market early in Q2 CY2022.
- Exclusive access to PPS API through bene Pharma provides access and protection consistent with composition of matter protection

Paradigm Biopharmaceuticals Ltd (ASX: PAR) ("Paradigm" or "the Company"), a clinical stage biopharmaceutical company focussed on repurposing existing molecules for new indications with unmet clinical needs, is providing a clarification response to a recent research note from Morgans titled "Non-intellectual Property".

The recent research note by Morgans contains an error and a flawed assumption about a pending patent application from the US Patent and Trademark Office (USPTO) regarding the rejection of the patent application "Treatment of Bone Marrow Pathologies with Polysulfated Polysaccharides" (US application number 16/636,545). The note incorrectly assumes a "final rejection" is final and fails to reflect the accurate patent process which allows for continued interaction with the USPTO over the coming months.

Clarification on this patent process has been provided **by Paul Whenman, Consulting Partner at FB Rice,** who has over 30 years of experience in the filing of patents in relation to pentosan polysulfate sodium. "*Once a final rejection issues, an applicant has a number of possible avenues to continue the prosecution of an application. Paradigm intends to request continued examination for this patent which is considered additive to their IP portfolio.*"

Paradigm's primary and foundational patents (US10,610,542, US9,861,657, 9,101,650) are for the use of PPS to treat BME regardless of associated disease, **these patents have been granted in the US and many other jurisdictions**.

Paradigm Chairman, Mr Paul Rennie commented "*Obtaining a final rejection is a frequent occurrence in US patent prosecution, which lead to further strategies to amend claims and continue the prosecution. Paradigm has previously received final rejections for other patents including our heart failure application which received a final rejection but subsequently obtained the grant of two US patents.*

We therefore do not view the rejection of this patent as material to our overall IP strategy. It is important however, to address the incorrect claims in the recent research note from Morgans, who made no attempt to verify their information with Paradigm or a patent expert prior to publication. IP and patent filings are complex matters and Paradigm has always provided feedback to questions on its IP and where relevant, provided interested parties a meeting with our patent attorney to assist in these matters.

The Morgan's report states that US application number 16/636,545 is Paradigm's core patent. This is incorrect. Paradigm's core patents are ***three granted patents*** *as per the table below. The three foundational patents are ALL GRANTED. As we have previously discussed, a third party seeking to treat osteoarthritis in the presence of BME will infringe these patents. This is not dependant on this patent application 16/636,545 being granted*."

Paradigm's BME Patents

	PAT. NO.		Title
1	10,610,542	T	Treatment of bone marrow edema (oedema) with polysulfated polysaccharides
2	9,861,657	T	Treatment of bone marrow edema (oedema) with polysulfated polysaccharides
3	9,101,650	T	Treatment of bone marrow edema (oedema) with polysulfated polysaccharides

Exclusive Supply Agreement with bene pharmaChem

The Morgans report has also dismissed the importance of the exclusive supply agreement between Paradigm and bene pharmaChem. To reach this conclusion, the analyst apparently believes that PPS could be readily sourced and authorised for human use. Paradigm has previously discussed the difficulty generic API manufacturers face to recreate the complex PPS molecule with an identical fingerprint to bene PPS registered with the FDA.

There is only one FDA approved manufacturer of PPS, bene pharmaChem GmBH (bene). Paradigm has exclusive, global supply agreements for iPPS for multiple indications extending for 25 years post first marketing approval. In addition, Paradigm has an ongoing collaboration agreement with bene for product related development support for meeting regulatory milestones and development of PPS for new indications and second-generation molecules.

PPS is a highly complex molecular platform technology; a semi-synthetic heparin-like macromolecular carbohydrate derivative that structurally resembles glycosaminoglycans which is derived from beechwood hemicellulose. The manufacture and composition of PPS is a trade secret tightly held by bene for over 60 years.

A generic manufacturer would be required to develop an identical molecular fingerprint of PPS. The complex molecular structure of PPS means generic manufacturers face a task of similar difficulty to that of developing a copy of a biosimilar. Potential generic entrants must provide GPC (gas permeable chromatography) data demonstrating identical structure and purity for each of the multiple moieties.

As a generic copy is highly unlikely to be identical, therefore a full clinical development program to demonstrate equivalent pharmacokinetic, pharmacodynamic, clinical safety and efficacy profiles will be required.

About Paradigm Biopharmaceuticals

Paradigm Biopharmaceuticals Ltd (ASX: PAR) is a late-stage drug development company with the mission to develop and commercialise pentosan polysulfate sodium for the treatment of pain associated with musculoskeletal disorders driven by injury, inflammation, ageing, degenerative disease, infection, or genetic predisposition. Paradigm is also exploring proof-of-concept studies for the use of PPS in respiratory and heart failure indications.

Authorised for release by Paul Rennie, Paradigm Chairman.

To learn more please visit: www.paradigmbiopharma.com

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